



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-07-ALL

DATE: December 20, 2019

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Burden Reduction and Discharge Planning Final Rules Guidance and Process

Memorandum Summary

- On September 30, 2019, the Centers for Medicare & Medicaid Services (CMS) published the *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction* Final Rule, as well as the *Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies* Final Rule.
- This policy memorandum provides guidance to the CMS Regional Offices (ROs), the State Survey Agencies (SAs) and the Accrediting Organizations (AOs) regarding the changes to the regulations and our approach for updating the State Operations Manual (SOM) and applicable surveyor systems.

Background

On September 30, 2019, CMS published two final rules which revised regulatory requirements for the various certified provider and supplier types.

The two final rules are as follows:

1. Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS 3346-F)

<https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and>

These are the final rule requirements for Religious Nonmedical Healthcare Institutions (RNHCIs) at §403, Ambulatory Surgical Centers (ASCs) at §416; Hospices at §418; Hospitals and Transplant at §482; Home Health Agencies (HHAs) at §484; Critical Access Hospitals (CAHs) and Comprehensive Outpatient Rehabilitation Facilities (CORFs) at §485; Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) at §491; Portable X-ray (PXR) at §486 End Stage Renal Disease (ESRD) Facilities at §494 and Emergency Preparedness.

2. Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies (CMS 3317-F)

<https://www.federalregister.gov/documents/2019/09/30/2019-20732/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals>

This final rule revised requirements for Hospitals, HHA and CAHs.

Guidance & SOM Updates

CMS has updated the SOM to reflect the regulatory changes as a result of these two final rules. The regulation changes are effective on November 29, 2019, with the exception of the following:

- The regulations at §482.42(b) and §485.640(b) regarding antibiotic stewardship programs for hospitals and CAHs, respectively, will be effective on March 30, 2020.
- The regulations at §485.641 regarding Quality Assessment and Performance Improvement Programs (QAPI) for CAHs will be effective on March 30, 2021.

The requirements that have delayed effective dates have been indicated accordingly within the attached updated SOM. CMS is aiming to subsequently release the SOM after this first release to provide the Interpretive Guidelines for these regulations in the Spring of 2020. Additional guidance will be forthcoming, and crosswalks will be available for some provider/supplier types accessible via the specific websites at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/index>.

Other changes to this SOM release include the below, which is also reflected in the summary of changes within the SOM package:

- **CAH-** Revisions to Appendix W also include renumbering the C-Tags; inserting regulations §485.601, §485.603, §485.604, and §485.606; and inserting the CAH Distinct Part Unit and Emergency Medical Treatment and Labor Act (EMTALA) C-Tags for reference. The changes also include updates to the Life Safety Code (LSC).
- **Hospital/CAH/RHC/FQHC-** Detailed requirements of United States Pharmacopeia (USP) have been removed from Appendices A, G, and W accordingly, as CMS requires compliance with applicable Federal and State law and adherence to accepted general standards of practice or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations.
- **Psych Hospitals-** The Special Conditions of Participation (CoPs) for the regulations §482.60 through §482.62(g)(2) psychiatric hospitals have been moved from the SOM Appendix AA to the SOM Appendix A. Appendix AA is being deleted as surveyors will now refer to Appendix A.
- **Transplant Programs** – Requirements at §482.82 that state that transplant centers must meet all data submission, clinical experience, and outcome requirements for Medicare re-approval have been removed. In addition, the special procedures for re-approval at §488.61 (f) through (h) is revised to remove the requirements with respect to the re-approval process for transplant centers. The change corresponds to the remove of the provisions at §482.82.

- **ESRD Facilities:** Appendix H updates the regulatory text based on requirements set forth in the 2008 Conditions for Coverage for ESRD Facilities and also includes revisions based on recent Federal regulation changes set forth in “Fire Safety Requirements for Certain Dialysis Facilities (CMS–3334–P).
- **RHC/FQHC** – Revisions to Appendix G include updates to regulatory text and interpretative guidance for both §491.9(b)(4) and §491.11(a) changing the requirement for an annual review to a biennial review.

Survey System Updates

CMS has updated the citation tags in the ASPEN (the national data system) and CASPER systems to ensure the revised regulations and minor revisions to guidance are current, available, and match the SOM. We expect providers and suppliers to meet the CoPs according to effective date. If there are system delays in updating ASPEN and CASPER, we would not expect survey citations to be issued until the ASPEN system aligns with the SOM regulatory changes. Please note providers-specific citation tag releases may be staggered within the ASPEN and CASPER systems. CMS will provide a notice to the CMS ROs and SAs if this occurs.

Training Updates

CMS is developing an online overview course for these revised regulatory requirements. This overview course will provide surveyors with information and intent behind the two final rules and provide an overview of the changes for each provider and supplier type. We will provide an email notification to the ROs and SAs with the release of training in January 2020, when the course will be available.

CMS is also developing a training course for the Special Psychiatric CoPs which will be available for all surveyors no later than the end of December 2019. This course will provide specific instructions on surveying for the psychiatric hospital CoPs. The Special Psychiatric training will ensure State surveyors who survey hospitals (i.e. acute, children’s, cancer, long term care hospitals) will be prepared to survey psychiatric hospitals. The State surveyors will assume the responsibility for surveying the psychiatric hospital CoPs in March 2020.

Additionally, CMS will be updating all basic surveyor training courses impacted by these regulatory changes. We will provide more information on the release of these basic course updates in the Spring of 2020.

Deemed Providers and Suppliers

CMS is in the process of reviewing the requested AO standards revisions. In accordance with the requirements at §488.8(b), AOs must revise their accreditation standards and survey process when applicable, to ensure they continue to meet or exceed the Medicare CoPs, Conditions for Coverage, and Conditions for Certification. We acknowledge that there may be instances during validation surveys in which the SA or AO citations may conflict due to these regulatory changes. CMS expects to have the revisions to the AO standards approved by February 2020. Therefore, CMS has determined that for provisions which have changed, until our systems align, will not be citing disparate findings.

Contact: Comments and questions should be submitted to the individual program type mailboxes listed below:

1. ASCs: QSOG_ASC@cms.hhs.gov
2. CAHs: QSOG_CAH@cms.hhs.gov
3. CMHCs: CMHC@cms.hhs.gov
4. CORF: QSOG_CORF@cms.hhs.gov
5. ESRDs: ESRDQuestions@cms.hhs.gov
6. Emergency Preparedness (EP): QSOG_EmergencyPrep@cms.hhs.gov
7. Hospital: QSOG_Hospital@cms.hhs.gov
8. Portable X-Ray: QSOG_PXR@cms.hhs.gov
9. Psych Hospitals: QSOG_PsychiatricHospital@cms.hhs.gov
10. Hospices: QSOG_Hospice@cms.hhs.gov
11. HHAs: hhasurveyprotocols@cms.hhs.gov
12. PRTFs: PRTF@cms.hhs.gov
13. RHCs/FQHCs: QSOG_RHC-FQHC@cms.hhs.gov
14. OPTs: QSOG_OPT@cms.hhs.gov
15. Transplant Programs: QSOG_Transplantteam@cms.hhs.gov
16. Life Safety Code (LSC): QSOG_LifeSafetyCode@cms.hhs.gov
17. For Long-term Care changes, please email the EP and LSC mailboxes.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David Wright
Director

Attachment: Advanced Copy SOM- All Providers and Suppliers

cc: Survey & Operations Group Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

**Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)**

Transmittal- Advanced Copy

Date:

SUBJECT: Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities, Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X - Organ Transplant Program and Appendix Z - Emergency Preparedness.

I. SUMMARY OF CHANGES: This transmittal includes regulatory revisions based on recent federal regulation changes via (CMS–3346–F; CMS–3334–F; CMS–3295–F; CMS–3277–CN). In addition, several updates to the appendices have been made for technical correction and clarify. The psychiatric hospital tags have moved from Appendix AA to Appendix A. Appendix AA is being deleted as surveyors will now refer to Appendix A for tags and guidance. Specific references to the United States Pharmacopeia (USP) have been removed from Appendices A, G, and W accordingly, as CMS requires compliance with applicable Federal and State law and adherence to accepted general standards of practice or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations. Appendix H updates the regulatory text based on requirements set forth in the 2008 Conditions for Coverage for ESRD Facilities and also includes revisions based on recent Federal regulation changes set forth in “Fire Safety Requirements for Certain Dialysis Facilities (CMS–3334–P).” Revisions to Appendix W also include renumbering the C-Tags; inserting regulations §485.601, §485.603, §485.604, and §485.606; and inserting the CAH Distinct Part Unit and Emergency Medical Treatment and Labor Act (EMTALA) C-Tags for reference. This transmittal will assure each of the appendices are updated to reflect the current regulatory language within the Medicare conditions. Interpretive guidance in several sections is pending and will be updated with a future release.

NEW/REVISED MATERIAL -

EFFECTIVE DATE: Upon Issuance

IMPLEMENTATION DATE: Upon Issuance

State Operations Manual

Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

(Rev.)

A-0148

(Rev.)

§482.13(d)(2) - The patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form or format requested by the individual. If it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or if not, in a readable hard copy form or such other form or format as agreed by the facility and the individual, and within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

Interpretive Guidelines §482.13(d)(2)

Guidance is pending and will be updated in future release.

A-0168

(Rev.)

§482.13(e)(5) - The use of restraint or seclusion must be in accordance with the order of a physician or other licensed practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law.

Interpretive Guidelines §482.13(e)(5)

Hospitals must have policies and procedures for the initiation of restraint or seclusion that identify the categories of *licensed practitioners (LPs)* that are permitted to order restraint or seclusion in that hospital, consistent with State law.

The regulation requires that a physician or other *LP* responsible for the care of the patient to order restraint or seclusion prior to the application of restraint or seclusion. In some situations, however, the need for a restraint or seclusion intervention may occur so quickly that an order cannot be obtained prior to the application of restraint or seclusion. In these **emergency application situations**, the order must be obtained either during the emergency application of the restraint or seclusion, or immediately (within a few minutes) after the restraint or seclusion has been applied. The failure to immediately obtain an order is viewed as the application of restraint or seclusion without an order.

The hospital should address this process in its restraint and seclusion policies and procedures. The policies and procedures should specify who can initiate the emergency application of restraint or seclusion prior to obtaining an order from a physician or other *LP*.

Licensed Practitioner (*LP*)

For the purpose of ordering restraint or seclusion, an *LP* is any practitioner permitted by State law and hospital policy as having the authority to order restraints or seclusion for patients.

A resident who is authorized by State law and the hospital's residency program to practice as a physician can carry out functions reserved for a physician or *LP* by the regulation. A medical school student holds no license, and his/her work is reviewed and must be countersigned by the attending physician; therefore, he or she is not licensed or independent. A medical school student is not a *LP*.

Protocols

A protocol cannot serve as a substitute for obtaining a physician's or other *LP*'s order prior to initiating each episode of restraint or seclusion use. If a hospital uses protocols that include the use of restraint or seclusion, a specific physician or *LP* order is still required for each episode of restraint or seclusion use. The philosophy that serves as a foundation for the regulation is that restraint or seclusion use is an exceptional event, not a routine response to a certain patient condition or behavior. Each patient must be assessed, and interventions should be tailored to meet the individual patient's needs. The creation of a protocol can run counter to this philosophy if it sets up the expectation that restraint or seclusion will be used as a routine part of care. The use of restraint or seclusion is a last resort when less restrictive measures have been determined ineffective to ensure the safety of the patient, staff or others, should not be a standard response to a behavior or patient need.

Survey Procedures §482.13(e)(5)

- Review hospital policies and medical staff by-laws to ascertain clinical practice guidelines that describe the responsibilities of medical staff and clinicians who are privileged to order restraint and seclusion.
- Do the hospital's written policies identify what categories of practitioners the State recognizes as an *LP* or as having the authority to order restraint and seclusion?
- Does the hospital have written policies indicating which practitioners are permitted to order restraint or seclusion in the facility?
- Do the hospital's written policies conform to State law?

- Does the hospital have established policies for who can initiate restraint or seclusion?
- Does the hospital utilize protocols for the use of restraint or seclusion? If so, is the use of protocols consistent with the requirements of the regulation?
- Do the medical records reviewed identify the physician or *LP* who ordered each use of restraint or seclusion?
- During the medical record review, verify that a physician or *LP* order was obtained prior to the initiation of restraint or seclusion. When emergency application of restraint or seclusion was necessary, verify that a physician or *LP* order was obtained immediately (within a few minutes) after application of the restraint or seclusion.

A-0172

(Rev.)

[Unless superseded by State law that is more restrictive --]

§482.13(e)(8)(ii) - After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient..

Interpretive Guidelines §482.13(e)(8)(ii)

At a minimum, if a patient remains in restraint or seclusion for the management of violent or self-destructive behavior 24 hours after the original order, the physician or other *LP* must see the patient and conduct a face-to-face re-evaluation before writing a new order for the continued use of restraint or seclusion. Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior is an extreme measure with the potential for serious harm to the patient.

State laws may be more restrictive and require the physician or other *LP* to conduct a face-to-face re-evaluation within a shorter timeframe.

When the physician or other *LP* renews an order or writes a new order authorizing the continued use of restraint or seclusion, there must be documentation in the patient's medical record that describes the findings of the physician's or other *LPs* re-evaluation supporting the continued use of restraint or seclusion.

EXCEPTION: Repetitive self-mutilating behaviors – see interpretive guidance for [§482.13\(e\)\(6\)](#).

Survey Procedures §482.13(e)(8)(ii)

- If restraint or seclusion is used to manage violent or self-destructive behavior for longer than 24 hours, is there documentation of a new written order, patient assessments, and a re-evaluation by a physician or other *LP* in the medical record? Does the documentation provide sufficient evidence to support the need to continue the use of restraint or seclusion? Is there evidence in the medical record that the symptoms necessitating the continued use of restraint or seclusion have persisted?
- Does the patient's plan of care or treatment plan address the use of restraint or seclusion?
- What is the patient's documented clinical response to the continued need for restraint and seclusion?

A-0175

(Rev.)

§482.13(e)(10) - The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

Interpretive Guidelines §482.13(e)(10)

Ongoing assessment and monitoring of the patient's condition by a physician, other *LP* or trained staff is crucial for prevention of patient injury or death, as well as ensuring that the use of restraint or seclusion is discontinued at the earliest possible time. Hospital policies are expected to guide staff in determining appropriate intervals for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint or seclusion used. The selection of an intervention and determination of the necessary frequency of assessment and monitoring should be individualized, taking into consideration variables such as the patient's condition, cognitive status, risks associated with the use of the chosen intervention, and other relevant factors. In some cases, checks every 15 minutes or vital signs taken every 2 hours may not be sufficient to ensure the patient's safety. In others, it may be excessive or disruptive to patient care (e.g., it may be unnecessary to mandate that a patient with wrist restraints, and who is asleep, be checked every 15 minutes and awakened every 2 hours to take the patient's vital signs). Similarly, depending on the patient's needs and situational factors, the use of restraint or seclusion may require either periodic (e.g., every 15 minutes, every 30 minutes, etc.) or continual (i.e., moment to moment) monitoring and assessment.

Hospital policies should address: frequencies of monitoring and assessment; assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity, etc.); providing for nutritional needs, range of motion exercises, and elimination needs; and mental status and

neurological evaluations.

With the exception of the simultaneous use of restraint and seclusion, one-to-one observation with a staff member in constant attendance is not required by this regulation unless deemed necessary based on a practitioner's clinical judgment. For example, placing staff at the bedside of a patient with wrist restraints may be unnecessary. However, for a more restrictive or risky intervention and/or a patient who is suicidal, self injurious, or combative, staff may determine that continual face-to-face monitoring is needed. The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety.

Hospitals have flexibility in determining which staff performs the patient assessment and monitoring. This determination must be in accordance with the practitioner's scope of clinical practice and State law. For example, assessment and monitoring are activities within a registered nurse's scope of practice. However, some trained, unlicensed staff may perform components of monitoring (e.g., checking the patient's vital signs, hydration and circulation; the patient's level of distress and agitation; or skin integrity), and may also provide for general care needs (e.g., eating, hydration, toileting, and range of motion exercises). Section [482.13\(f\)](#) requires that before applying restraints, implementing seclusion, or performing associated monitoring and care tasks, staff must be trained and able to demonstrate competency in the performance of these actions.

Survey Procedures §482.13(e)(10)

- Review hospital policies regarding assessment and monitoring of a patient in restraint or seclusion.
 - What evidence do you find that the hospital's monitoring policies are put into practice for all restrained or secluded patients?
 - Do hospital policies identify which categories of staff are responsible for assessing and monitoring the patient?
 - Do hospital policies include time frames for offering fluids and nourishment, toileting/elimination, range of motion, exercise of limbs and systematic release of restrained limbs? Is this documented in the patient's medical record?
- Review patient medical records:
 - Was there a valid rationale for the decision regarding the frequency of patient assessment and monitoring documented in the medical record?
 - Was documentation consistent, relevant, and reflective of the patient's condition?

- Are time frames described for how often a patient is monitored for vital signs, respiratory and cardiac status, and skin integrity checks?
- Is there documentation of ongoing patient monitoring and assessment (e.g., skin integrity, circulation, respiration, intake and output, hygiene, injury, etc)?
- Is the patient's mental status assessed? Is this documented in the medical record?
- Is the patient assessed regarding continued need for the use of seclusion or restraint?
- Is there adequate justification for continued use and is this documented?
- Is the level of supervision appropriate to meet the safety needs of the patient who is at a higher risk for injury (e.g., self-injurious, suicidal)?

A-0176

(Rev.)

§482.13(e)(11) - Physician and other licensed practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

Interpretive Guidelines §482.13(e)(11)

At a minimum, physicians and other *LPs* authorized to order restraint and seclusion must have a working knowledge of hospital policy regarding the use of restraint and seclusion.

Hospitals have the flexibility to identify training requirements above this minimum requirement based on the competency level of their physicians and other *LPs*, and the needs of the patient population(s) that they serve. Physicians receive training in the assessment, monitoring, and evaluation of a patient's condition as part of their medical school education. However, physicians generally do not receive training regarding application of restraint or implementation of seclusion as part of their basic education. Depending on the level and frequency of involvement that a physician or other *LP* has in the performance of these activities, additional training may or may not be necessary to ensure the competency of these individuals in this area. The hospital is in the best position to determine if additional physician or other *LP* training is necessary based on the model of care, level of physician competency, and the needs of the patient population(s) that the hospital serves.

Survey Procedures §482.13(e)(11)

- Review the hospital policy regarding restraint and seclusion training requirements

for physicians and other *LPs*. Are the minimum training requirements addressed?

- Review medical staff credentialing and privileging files to determine if physicians or other *LPs* involved in restraint and seclusion activities have completed the required training.

A-0178

(Rev.)

§482.13(e)(12) - When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention --

(i) By a –

(A) Physician or other licensed practitioner; or

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (f) of this section.

Interpretive Guidelines §482.13(e)(12)(i)

When restraint or seclusion is used to manage violent or self-destructive behavior, a physician or other *LP*, or a registered nurse (RN) trained in accordance with the requirements specified under §482.13(f), must see the patient face-to-face within 1-hour after the initiation of the intervention. This requirement also applies when a drug or medication is used as a restraint to manage violent or self-destructive behavior.

The 1-hour face-to-face patient evaluation must be conducted in person by a physician or other *LP*, or trained RN. A telephone call or telemedicine methodology is not permitted.

If a patient's violent or self-destructive behavior resolves and the restraint or seclusion intervention is discontinued before the practitioner arrives to perform the 1-hour face-to-face evaluation, the practitioner is still required to see the patient face-to-face and conduct the evaluation within 1 hour after the initiation of this intervention. The fact that the patient's behavior warranted the use of a restraint or seclusion indicates a serious medical or psychological need for prompt evaluation of the patient behavior that led to the intervention. The evaluation would also determine whether there is a continued need for the intervention, factors that may have contributed to the violent or self-destructive behavior, and whether the intervention was appropriate to address the violent or self-destructive behavior.

EXCEPTION: Repetitive self-mutilating behaviors – see interpretive guidance for §482.13(e)(6).

Survey Procedures §482.13(e)(12)(i)

- Review the hospital policy regarding the 1-hour face-to-face evaluation.
- What categories of practitioners does the hospital policy authorize to conduct the 1-hour face-to-face evaluation?
- Interview staff to determine if practice is consistent with hospital policy.

A-0182

(Rev.)

§482.13(e)(14) - - If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse, the trained registered nurse must consult the attending physician or other licensed practitioner who is responsible for the care of the patient soon as possible after the completion of the 1 hour face-to-face evaluation.

Interpretive Guidelines §482.13(e)(14)

When a trained RN conducts the required face-to-face evaluation, he or she must consult the attending physician or other *LP* responsible for the patient’s care as soon as possible after the completion of the evaluation. Hospital policy should address the expected time frame for and the components of the consultation with the attending physician or other *LP* consistent with “as soon as possible.” This consultation should include, at a minimum, a discussion of the findings of the 1-hour face-to-face evaluation, the need for other interventions or treatments, and the need to continue or discontinue the use of restraint or seclusion. A consultation that is not conducted prior to a renewal of the order would not be consistent with the requirement, “as soon as possible.”

Survey Procedures §482.13(e)(14):

- Review the relevant hospital restraint and seclusion policy.
- Does the hospital policy clarify expectations regarding the requirement, “as soon as possible”?
- Does documentation in the patient’s medical record indicate consultation with the attending physician or other *LP* when the 1-hour face-to-face evaluation was conducted by a trained RN?
- Is practice consistent with hospital policy?

A-0214

(Rev.)

l§482.13(g) Standard: Death Reporting Requirements: [- Hospitals must report deaths associated with the use of seclusion or restraint.]

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

Interpretive Guidelines §482.13(g)(2), (3)(ii), & (4)

Hospitals must maintain an internal log or other type of tracking system for recording information on each death that occurs:

- While a patient is in only 2-point soft, cloth-like non-rigid wrist restraints and there is no use of seclusion; and
- Within 24 hours of the patient being removed from 2-point soft, cloth-like non-rigid wrist restraints where there was no use of any other type of restraint or seclusion.

Use of the log or tracking system is limited only to patient deaths meeting one of these two criteria. Examples of patient deaths associated with restraints that must still be reported to CMS include:

- Deaths occurring during or within 24 hours of discontinuation of 2-point soft, cloth-like non-rigid wrist restraints used in combination with any other restraint device or with seclusion; or

- Deaths associated with the use of other types of wrist restraints, such as 2-point rigid or leather wrist restraints.

These cases would not be included in this internal log or tracking system and would require reporting the death to CMS using telephone, fax, or electronically.

The two-point soft wrist restraint death report must be entered into the internal log or tracking system within 7 days of the patient's death.

The death report log or tracking system entry must include:

- The patient's name;
- Patient's date of birth;
- Patient's date of death;
- Name of the attending physician or other licensed practitioner who is responsible for the care or the patient;
- Patient's medical record number; and
- Primary diagnosis(es).

Depending on the size and nature of the patient population the hospital serves and the types of services it provides, there will likely be variations in the frequency of restraint use as well as in the incidence of patient deaths. Surveyors should adjust their expectations for the volume of log or tracking system entries accordingly. For example, hospitals with intensive care units might be more likely to use both soft, 2-point wrist restraints and to have seriously ill patients who die as a result of their disease while such restraints are being used or within 24 hours after their discontinuance. On the other hand, a rehabilitation hospital would be expected to use such restraints less frequently, and to have patients who die less frequently while hospitalized.

The log or tracking system must be available in written, i.e., hard copy, or electronic form immediately upon CMS's request. CMS will specify the form in which the information is to be provided. Generally CMS would request access to the log or tracking system during an on-site survey by CMS staff or State surveyors acting on CMS's behalf when assessing compliance with restraint/seclusion requirements. However, CMS may also request that a copy of portions or the entire log or tracking system be provided, even though no survey is in progress. Accreditation organizations conducting hospital inspections in accordance with a CMS-approved Medicare hospital accreditation program are also entitled to immediate access to the log or tracking system.

The hospital is not required to make the contents of the log or tracking system available to any other outside parties, unless required to do so under other Federal or State law.

The hospital must document in the patient's medical record the date and time the death report entry was made into the log or tracking system.

Survey Procedures §482.13(g)(2), (3)(ii), & (4)

- Does the hospital have restraint/seclusion death reporting policies and procedures that address responsibilities and systems for identifying restraint/seclusion-associated deaths that must be recorded in an internal hospital log/tracking system, and for implementing the reporting and recordkeeping requirements?
- Ask the hospital how it ensures that each death that must be captured in the log/tracking system is identified and entered.
- Interview inpatient unit staff to determine whether they have had patients who die while 2-point soft wrist restraints are being used without seclusion or within 24 hours of their discontinuance. If yes, ask the hospital to demonstrate that it has recorded such deaths.
- If the hospital's log or tracking system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint/seclusion-associated death.
- Review the log/tracking system for patient deaths associated with use of only 2-point soft wrist restraints to determine if:
 - Each entry was made within 7 days of the patient's death; and
 - Each entry contains all the information required under the regulation.
- Is the hospital able to make the log or tracking system available immediately on request?
- Review a sample of medical records of patients whose deaths were entered in the log or tracking system.
 - Does the medical record indicate that only soft, 2-point wrist restraints were used?
- Is there documentation in the medical record of the entry into the log or tracking system?

A-0273

(Rev.)

Data Collection & Analysis

§§482.21(a), 482.21(b)(1), 482.21(b)(2)(i), & 482.21(b)(3)

§482.21(a) Standard: Program Scope

(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes....

(2) The hospital must measure, analyze, and track quality indicators...and other aspects of performance that assess processes of care, hospital service and operations.

§482.21(b) Standard: Program Data.

(1) The program must incorporate quality indicator data including patient care data, and other relevant data *such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions.*

(2) The hospital must use the data collected to--
(i) Monitor the effectiveness and safety of services and quality of care; and...

(3) The frequency and detail of data collection must be specified by the hospital's governing body.

A-0320
(Rev.)

§482.21(f) Standard: Unified and integrated QAPI program for multi-hospital systems. If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

Interpretive Guidelines §482.21(f)
Guidance is pending and will be updated in future release.

A-0321
(Rev.)

§482.21(f)(1) The unified and integrated QAPI program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and

Interpretive Guidelines §482.21(f)(1)

Guidance is pending and will be updated in future release.

A-0322

(Rev.)

§482.21(f)(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

Interpretive Guidelines §482.21(f)(2)

Guidance is pending and will be updated in future release.

A-0358

(Rev.)

[The bylaws must:]

§482.22(c)(5) Include a requirement that --

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, *and except as provided under paragraph (c)(5)(iii) of this section.* The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an *oral and* maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy

Interpretive Guidelines §482.22(c)(5)(i)

The purpose of a medical history and physical examination (H&P) is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient.

The Medical Staff bylaws must include a requirement that an H&P be completed and documented for each patient no more than 30 days prior to or 24 hours after hospital admission or registration, but prior to surgery or a procedure requiring anesthesia services *except when the patient is receiving an outpatient surgical or procedural services and when the medical staff has developed and maintained a policy (in accordance with §482.22(c)(5)(v)) that identifies specific patients that do not require a comprehensive medical H&P, or any update to it, prior to the specific outpatient surgery or procedure.*

The H&P may be handwritten or transcribed, but always must be placed within the patient's medical record within 24 hours of admission or registration, or prior to surgery

or a procedure requiring anesthesia services, whichever comes first.

An H&P is required prior to surgery and prior to procedures requiring anesthesia services, regardless of whether care is being provided on an inpatient or outpatient basis. (71 FR 68676) An H&P that is completed within 24 hours of the patient's admission or registration, but after the surgical procedure, procedure requiring anesthesia, or other procedure requiring an H&P would not be in compliance with this requirement.

The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), *oral and* maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Section 1861(r) defines a physician as a:

- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry; or a
- Chiropractor.

In all cases the practitioners included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act attaches further limitations as to the type of hospital services for which a practitioner is considered to be a "physician." For example, a chiropractor is considered a physician only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation).

Other qualified licensed individuals are those licensed practitioners who are authorized in accordance with their State scope of practice laws or regulations to perform an H&P and who are also formally authorized by the hospital to conduct an H&P. Other qualified licensed practitioners could include nurse practitioners and physician assistants.

More than one qualified practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents. (71 FR 68675)

A hospital may adopt a policy allowing submission of an H&P prior to the patient's hospital admission or registration by a physician who may not be a member of the hospital's medical staff or who does not have admitting privileges at that hospital, or by a qualified licensed individual who does not practice at that hospital but is acting within his/her scope of practice under State law or regulations. Generally, this occurs where the H&P is completed in advance by the patient's primary care practitioner. (71 FR 68675)

When the H&P is conducted within 30 days before admission or registration, an update must be completed and documented by a licensed practitioner who is credentialed and

privileged by the hospital's medical staff to perform an H&P. (71 FR 68675) (See discussion of H&P update requirements at 42 CFR 482.22(c)(5)(ii).)

Surveyors should cite noncompliance with the requirements of 42 CFR 482.22(c)(5) for failure by the hospital to comply with any of this standard's components.

Survey Procedures §482.22(c)(5)(i)

- Review the medical staff bylaws to determine whether they require that a physical examination and medical history be done for each patient no more than 30 days before or 24 hours after admission or registration by a physician (as defined in section 1861(r) of the Act), an *oral and* maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. Verify whether the bylaws require the H&P be completed prior to surgery or a procedure requiring anesthesia services.
- Review the hospital's policy, if any, to determine whether other qualified licensed individuals are permitted to conduct H&Ps to ensure that it is consistent with the State's scope of practice law or regulations.
- Verify that non-physicians who perform H&Ps within the hospital are qualified and have been credentialed and privileged in accordance with the hospital's policy.
- Review a sample of inpatient and outpatient medical records that include a variety of patient populations undergoing both surgical and non-surgical procedures to verify that:
 - There is an H&P that was completed no more than 30 days before or 24 hours after admission or registration, but, in all cases, prior to surgery or a procedure requiring anesthesia services, *except when an assessment is completed and documented pursuant to §482.22(c)(5)(iii);* and
 - The H&P was performed by a physician, an *oral and* maxillofacial surgeon, or other qualified licensed individual authorized in accordance with State law and hospital policy.

A-0359

(Rev.)

[The bylaws must:]

§482.22(c)(5) - Include a requirement that --

- (ii) **An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring**

anesthesia services, when the medical history and physical examination are completed within 30 days before admission or *registration, and except as provided under paragraph (c)(5)(iii) of this section*. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an *oral and* maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Interpretive Guidelines §482.22(c)(5)(ii)

The Medical Staff bylaws must include a requirement that when a medical history and physical examination has been completed within 30 days before admission or registration, an updated medical record entry must be completed and documented in the patient's medical record within 24 hours after admission or registration, *except when the patient is receiving an outpatient surgical or procedural services and when the medical staff has developed and maintained a policy (in accordance with §482.22(c)(5)(v)) that identifies specific patients that do not require a comprehensive medical H&P, or any update to it, prior to the outpatient surgery or procedure.*

The examination must be conducted by a licensed practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P. In all cases, the update must take place prior to surgery or a procedure requiring anesthesia services. The update note must document an examination for any changes in the patient's condition since the patient's H&P was performed that might be significant for the planned course of treatment. The physician or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record.

If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed (71 FR 68676). Any changes in the patient's condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services. Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

Survey Procedures §482.22(c)(5)(ii)

- Review the medical staff bylaws to determine whether they include provisions

requiring that, when the medical history and physical examination was completed within 30 days before admission or registration, an updated medical record entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration.

- Determine whether the bylaws require that, in all cases involving surgery or a procedure requiring anesthesia services, the update to the H&P must be completed and documented prior to the surgery or procedure.
- In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within 30 days before admission or registration. Verify that an updated medical record entry documenting an examination for any changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration. Verify that in all cases involving surgery or a procedure requiring anesthesia services, the update was completed and documented prior to the surgery or procedure.

A-0360
(Rev.)

[The bylaws must:]

§482.22(c)(5) - Include a requirement that --

(iii) An assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii) of this section) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v) of this section, specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The assessment must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

Interpretive Guidelines §482.22(c)(5)(iii)
Guidance is pending and will be updated in future release.

A-0361
(Rev.)

[The bylaws must:]

§482.22(c)(5) - Include a requirement that --

- (iv) The medical staff develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) of this section would apply. The provisions of paragraphs (c)(5)(iii), (iv), and (v) of this section do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs of (c)(5)(i) and (ii) of this section for all patients.*

Interpretive Guidelines §482.22(c)(5)(iv)

Guidance is pending and will be updated in future release.

A-0362

(Rev.)

[The bylaws must:]

§482.22(c)(5) - Include a requirement that --

- (v) The medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) of this section would apply, must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on:
 - (A) Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure.*
 - (B) Nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures.*
 - (C) Applicable state and local health and safety laws.**

Interpretive Guidelines §482.22(c)(5)(v)

Guidance is pending and will be updated in future release.

A-0392

(Rev.)

§482.23(b) Standard: Staffing and Delivery of Care

The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care

to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for care of any patient.

Interpretive Guidelines §482.23(b)

The nursing service must ensure that patient needs are met by ongoing assessments of patients' needs and provides nursing staff to meet those needs. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit.

There must be a RN physically present on the premises and on duty at all times. Every inpatient unit/department/location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the immediate availability of a RN for the care of any patient.

A RN would not be considered immediately available if the RN were working on more than one unit, building, floor in a building, or provider (distinct part SNF, RHC, excluded unit, etc.) at the same time.

Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.

Survey Procedures §482.23(b)

- Determine that there are written staffing schedules which correlate to the number and acuity of patients. Verify that there is supervision of personnel performance and nursing care for each department or nursing unit. To determine if there are adequate numbers of nurses to provide nursing care to all patients as needed, take into consideration:
 - Physical layout and size of the hospital;
 - Number of patients;
 - Intensity of illness and nursing needs;
 - Availability of nurses' aides and orderlies and other resources for nurses, e.g., housekeeping services, ward clerks etc.;
 - Training and experience of personnel;
- Review medical records to determine if patient care that is to be provided by nurses is being provided as ordered.

(Rev.)

§482.23(b)(4) - The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient *that reflects the patient's goals and the nursing care to be provided to meet the patient's needs*. The nursing care plan may be part of an interdisciplinary care plan.

Interpretive Guidelines §482.23(b)(4)

Nursing care planning starts upon admission. It includes planning the patient's *nursing care to meet the patient's needs and interventions toward meeting patient treatment goals* while in the hospital as well as planning for discharge to meet post-hospital needs. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs. The nursing care plan is kept current by ongoing assessments of the patient's needs and of the patient's response to interventions, *assessment of patient treatment goals*, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's medical record and must comply with the medical records requirements at §482.24.

Hospitals have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient's care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient's health care team.

The required documentation for the nursing component of an interdisciplinary care plan remains the same. For other components, the hospital should follow the current documentation policies that it uses to document services provided by other disciplines, such as services provided by physical therapists, occupational therapists, speech-language pathologists, and others. Documentation should follow the standards of practice for those disciplines in addition to any specific requirements that the hospital might want to establish. The documentation must also comply with the requirements of the medical records requirement at §482.24. (77 FR 29049, May 16, 2012)

Survey Procedures §482.23(b)(4)

Select a sample of nursing or interdisciplinary care plans. Approximately 6-12 plans should be reviewed. For each plan reviewed, with respect to the nursing care component:

- Was the plan initiated as soon as possible after admission for each patient?
- Does the plan describe *and reflect* patient goals as part of the patient's nursing care assessment and, as appropriate, physiological and psychosocial factors and

patient discharge planning?

- Is the plan consistent with the plan for medical care of the practitioner responsible for the care of the patient?
- Is there evidence of reassessment of the patient's nursing care needs and response to nursing interventions and, as applicable, revisions to the plan?
- Was the plan implemented in a timely manner?

A-0398

(Rev.)

§482.23(b)(6) - *All licensed nurses who provide services* in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of *all nursing personnel which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).*

Interpretive Guidelines §482.23(b)(6)

The hospital must ensure that there are adequate numbers of clinical nursing personnel to meet its patients nursing care needs. In order to meet their patient's needs the hospital may supplement their hospital employed licensed nurses with volunteer and or contract licensed nurses.

The hospital and the director of the nursing service are responsible for the clinical activities of all nursing personnel *regardless of whether they are hospital employees, contracted staff, or volunteers.*

All licensed nurses who are working at the hospital must adhere to the policies and procedures of the hospital. The hospital and the director of the nursing service are responsible for ensuring that *licensed* nursing personnel know the hospital's policies and procedures in order to adhere to those policies and procedures.

The hospital and the director of the nursing service ensure that nursing care staff person is adequately supervised and that their clinical activities are evaluated. This supervision and evaluation of the clinical activities of each non-employee nursing staff person must be conducted by an appropriately qualified hospital-employed RN.

Survey Procedures §482.23(b)(6)

- Review the method for orienting *all* licensed nurses to hospital policies and procedures. The orientation should include at least the following:
 - The hospital and the unit;

- Emergency procedures;
- Nursing services policies and procedures; and
- Safety policies and procedures.
- Determine if *all* nursing personnel are appropriately oriented prior to providing care.
- Confirm with the director of nurses that *all* nurses performance *are* evaluated by the hospital at least once a year. If the performance evaluation is not considered confidential, review two evaluations.

A-0399
(Rev.)

§482.23(b)(7) - The hospital must have policies and procedures in place establishing which outpatient departments, if any, are not required under hospital policy to have a registered nurse present. The policies and procedures must:

- (i) Establish the criteria such outpatient departments must meet, taking into account the types of services delivered, the general level of acuity of patients served by the department, and the established standards of practice for the services delivered;*
- (ii) Establish alternative staffing plans;*
- (iii) Be approved by the director of nursing;*
- (iv) Be reviewed at least once every 3 years*

Interpretive Guidelines §482.23(b)(7)
Guidance is pending and will be updated in future release.

A-0405
(Rev.)

§482.23(c) Standard: Preparation and Administration of Drugs.

- (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care, and accepted standards of practice.**
- (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations....**

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

Interpretive Guidelines §§482.23(c)(1), (c)(1)(i) and (c)(2)

According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.¹ It has been estimated that drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7 percent of all stays), and 838,000 treat-and-release ED visits (0.8 percent of all visits).² Although technological advances in electronic order entry, medication administration, and electronic medical records hold a great deal of promise for decreasing medication errors, there are a multitude of human and environmental factors that will impact their success. The increasing complexity of medical care and patient acuity present significant challenges that require an approach to medication administration that takes advantage of available technology while recognizing that it must be integrated into the medication administration work processes in a manner that meets the needs of patients and promotes their safety.

The regulations at §482.23(c) and §482.23(c)(1) promote safety in the preparation and administration of drugs and biologicals to hospital patients by requiring preparation and administration in accordance with:

- Federal and State law;
- Accepted standards of practice;
- Orders of the practitioner(s) responsible for the patient's care, as permitted under State law, hospital policy and medical staff bylaws, rules and regulations; and
- Medical staff-approved policies and procedures.

Federal and State Law

Federal law regulates the approval and classification of drugs and biologicals. Individual States establish laws and regulations which specify the scope of practice for various types of licensed healthcare professionals, including which medications they may prescribe and administer, including controlled substances.

Accepted Standards of Practice

¹Institute of Medicine. Preventing Medication Errors. Washington DC: The National Academies Press, 2007.

²Lucado, Jennifer, et al, *Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments*. Statistical Brief #109, April, 2011. Healthcare Cost and Utilization Project, Agency For Healthcare Research and Quality, Rockville, MD.

Hospital policies and procedures for the preparation and administration of all drugs and biologicals must not only comply with all applicable Federal and State laws, but also must be consistent with accepted standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in medication preparation and administration. Examples of such organizations include, but are not limited to:

- American Society of Health-System Pharmacists (<http://www.ashp.org/default.aspx>)
- Infusion Nurses Society (<http://www.ins1.org>)
- Institute for Safe Medication Practices (www.ismp.org)
- National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org)
- U.S Pharmacopeia (www.usp.org)

Orders of an authorized practitioner

Drugs must be administered in response to an order from a practitioner, or on the basis of a standing order which is appropriately authenticated subsequently by a practitioner. (See §482.23(c)(1) (ii) concerning standing orders.) Generally, the ordering practitioner is the practitioner(s) responsible for the care of the patient. However, other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations. This includes practitioners ordering outpatient services who do not have privileges in the hospital but who are permitted under their State scope of practice and authorized by hospital and medical staff policy to order outpatient services.

In accordance with standard practice, all practitioner orders for the administration of drugs and biologicals must include at least the following:

- Name of the patient;
- Age and weight of the patient, to facilitate dose calculation when applicable. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the hospital's policies. (Note that dose calculations are based on metric weight (kg, or g for newborns). If a hospital permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, hospitals must specify a uniform approach to be used by prescribing practitioners. For example, a hospital could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric);
- Date and time of the order;

- Drug name;
- Dose, frequency, and route;
- Dose calculation requirements, when applicable;
- Exact strength or concentration, when applicable;
- Quantity and/or duration, when applicable;
- Specific instructions for use, when applicable; and;
- Name of the prescriber.

Medical Staff Approved Policies and Procedures

The hospital's medical staff must approve policies and procedures for medication administration, consistent with the requirements of Federal and State law and accepted standards of practice. It is recommended that the medical staff consult with nurses, pharmacists, Quality Assessment and Performance Improvement program staff, and others in developing these policies and procedures. The adopted policies and procedures must address key issues related to medication administration, which include but are not limited to:

Personnel authorized to administer medication

§482.23(c)(2) requires that all drugs and biologicals are administered by, or under the supervision of, nursing or other personnel, in accordance with Federal or State law and approved medical staff policies and procedures. State law requirements include licensure requirements. Policies and procedures must identify categories of licensed personnel and the types of medications they are permitted to administer, in accordance with state laws. The policies and procedures must also address education and training for all personnel administering drugs and biologicals.

Medication administration education and training is typically included in hospital orientation or other continuing education for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication administration may include but are not limited to the following:

- Safe handling and preparation of authorized medications;
- Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications;
- Equipment, devices, special procedures, and/or techniques required for medication administration;

Policies and procedures must address the required components of the training and if the training provided during hospital orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

Basic safe practices for medication administration

The hospital's policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (often referred to as the "five rights" of medication administration practice):

- **Right patient:** the patient's identity— acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the hospital; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.
- **Right medication:** the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;
- **Right dose:** the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);
- **Right route:** the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and
- **Right time:** the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

NOTE: the "5 rights" focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the "5 rights" of medication administration, for example when there has been a prescribing or a dispensing error. Hospitals are also expected to comply with requirements under the Pharmaceutical Services CoP at §482.25 and the patient safety requirements under the Quality Assessment and Performance Improvement CoP at §482.21, using a comprehensive systems approach to all components of the medication process.

For Information – Not Required/Not to be Cited

Recent literature* identifies up to nine “rights” of medication administration including:

- Right patient
- Right drug
- Right route
- Right time
- Right dose
- Right documentation
- Right action (appropriate reason)
- Right form
- Right response

However, other sources refer to 8 or 10 “rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 “rights.”

*Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.

Hospitals are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly, whether they arise prior to the preparation, dispensing, or administration of the medication.

Hospitals must also ensure staff adherence to accepted standards of practice required to prevent healthcare-associated infections related to medication preparation and/or administration, *including compounded sterile preparations (CSPs)*. Adherence to these standards is assessed under the infection control CoP at 42 CFR 482.42.

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the U.S. Food and Drug Administration’s (FDA) approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer’s approved labeling.

A drug or biological is also outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later. The BUD is the date and time after which the medication must not be used, stored or transported. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available. The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer.

Timing of Medication Administration

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them. The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration. Consequently, the application of a uniform required window of time before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately. This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, hospital policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration. The policies and procedures must address at least the following:

- Medications **not eligible** for scheduled dosing times;
- Medications **eligible for** scheduled dosing times;
- Administration of eligible medications outside of their scheduled dosing times and windows; and
- Evaluation of medication administration timing policies, including adherence to them.

Medications or categories of medication not eligible for scheduled dosing times

The policies and procedures must identify medications or categories of medication which are not eligible for scheduled dosing times, either in general or in specific clinical applications. These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors. Examples of medications that hospitals may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

- Stat doses (immediate);
- First time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);
- One-time doses; doses specifically timed for procedures;
- Time-sequenced doses; doses timed for serum drug levels;
- Investigational drugs; or
- Drugs prescribed on an as needed basis (prn doses).

The policies and procedures must ensure timely administration of such medications. In addition they must specify if the policy for the administration of these medications will be applied hospital-wide or only for specific diagnosis types, hospital units or clinical situations.

Medications eligible for scheduled dosing times

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc. The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time. Medication administration policies and procedures typically establish standardized dosing times for the administration of all ‘scheduled’ medications. For example, medications prescribed for BID (twice a day) administration might, under a given hospital’s policies and procedures, be scheduled to be administered at 8am and 8pm. Another hospital might choose to schedule BID medications at 7:30 am and 7:30 pm. Use of these standardized times facilitates the medication administration process, e.g., by providing to the hospital’s pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration. For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address: first dose medications, including parameters within which nursing staff are allowed to use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times; retiming of missed or omitted doses; medications that will not follow scheduled dosing times; and patient units that are not subject to following the scheduled dosing times.

Time-critical scheduled medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. Accordingly, scheduled medications identified under the hospital's policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of 1 hour.

It is possible for a given medication to be time-critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients. Therefore, hospital policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical. Examples of time-critical scheduled medications/medication types may include, but are not limited to:

- Antibiotics;
- Anticoagulants;
- Insulin;
- Anticonvulsants;
- Immunosuppressive agents;
- Pain medication (non-IV);
- Medications prescribed for administration within a specified period of time of the medication order;
- Medications that must be administered apart from other medications for optimal therapeutic effect; or
- Medications prescribed more frequently than every 4 hours.

Non-time-critical scheduled medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm. For such medications greater flexibility in the timing of their administration is permissible. Specifically:

- Medications prescribed for daily, weekly or monthly administration may be within 2 hours before or after the scheduled dosing time, for a total window that does not exceed 4 hours.

- Medications prescribed more frequently than daily but no more frequently than every 4 hours may be administered within 1 hour before or after the scheduled dosing time, for a total window that does not exceed 2 hours.

Missed or late administration of medications

The hospital's policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time. This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration. Likewise, policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff are allowed to use their own judgment regarding the rescheduling of missed or late doses and when notification of the physician or other practitioner responsible for the care of the patient is required prior doing so. In either case, the reporting of medication errors that are the result of missed or late dose administration must be reported to the attending physician in accordance with requirements at §482.25(b)(6). See interpretive guidance at §482.25(b)(6) for more details on internal reporting requirements

Evaluation of medication administration timing policies

Hospitals must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration. Consistent with the QAPI requirements at 42 CFR 482.21(c)(2), medication errors related to the timing of medication administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the medical staff must consider whether there is a need to revise the policies and procedures governing medication administration timing.

Assessment/Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications,

including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;

- Physical signs and clinical symptoms relevant to the patient’s medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.

Certain types of medications are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. (See also the discussion of high-risk medications (typically referred to as “high-alert” medications) in the guidance for §482.25(a)(1))

For Information – Not Required/Not to be Cited

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. The current list may be found at:

<http://www.ismp.org/Tools/highAlertMedicationLists.asp>

In addition, certain factors place some patients at greater risk for adverse effects of medication. Factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea, patient weight (obesity may increase apnea or smaller patients may be more sensitive to dose levels of medications), asthma, history of smoking, drug-drug interactions, and first-time medication use may contribute to increased risk.

Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients’ medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are transferred internally from one unit to another, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established hospital protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. (See the guidance for §482.23(c)(5) and §482.25(b)(6), concerning reporting of adverse medication-related events.)

An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient

who is receiving pain medication via a patient controlled analgesia (PCA) pump. Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all hospital settings in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. (See also the discussion of the requirements for intravenous medications at §482.23(c)(4)).

As part of the monitoring process, staff are expected to include the patient's reports of his/her experience of the medication's effects. Further, when monitoring requires awakening the patient in order to assess effects of the medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

Hospital policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the hospital's requirements for the method(s) of communication.

Documentation

Note that documentation of medication administration is addressed in the Medical Records CoP, at §482.24(c), which specifies the required content of the medical record. Within this regulation §482.24(c)(vi) requires that the record contain: "All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition." Documentation is expected to occur after actual administration of the medication to the patient; advance documentation is not only inappropriate, but may result in medication errors. Proper documentation of medication administration actions taken and their outcomes is essential for planning and delivering future care of the patient. See the guidance for the various parts of §482.24(c) concerning documentation in the medical record. Deficiencies in documentation would be cited under the applicable Medical Records regulation.

Survey Procedures §§482.23(c)(1), (c)(1)(i), and (c)(2)

Verify that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:

- Verify that there are policies and procedures approved by the medical staff and governing body concerning ordering of drugs and biologicals by practitioners.

- Verify that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.
 - Verify nursing staff authorized to administer drugs and biologicals are practicing within their State-permitted scope of practice.
 - Are personnel other than nursing personnel administering drugs or biologicals? If yes, determine if those personnel are administering drugs or biologicals in accordance with Federal and State laws and regulations, including scope of practice laws, hospital policy, and medical staff by-laws, rules and regulations. Use the above procedures to determine compliance.
- Verify that there are policies and procedures approved by medical staff addressing the timing of medication administration.
- Verify that the hospital has, consistent with its policies, identified medications: which are:
 - not eligible for scheduled dosing times;
 - Eligible for scheduled dosing times and are time-critical; and
 - Eligible for scheduled dosing times and are not time-critical.
- Verify the hospital has established total windows of time that do not exceed the following:
 - 1 hour for time-critical scheduled medications;
 - 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours; and
 - 4 hours for medications prescribed for daily or longer administration intervals.
- Verify that the hospital's policy describes requirements for the administration of identified time-critical medications. Is it clear whether time-critical medications or medication types are identified as such for the entire hospital or are unit-, patient diagnosis-, or clinical situation- specific?
- Review a sample of medical records to determine whether medication administration conformed to an authorized practitioner's order, i.e., that there is an order from an authorized practitioner, or an applicable standing order, and that the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and

procedures. Check that the practitioner's order was still in force at the time the drug was administered.

- Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed
 - Is the patient's identity confirmed prior to medication administration?
 - Are procedures to assure the correct medication, dose, and route followed?
 - Are drugs administered in accordance with the hospital's established policies and procedures for safe and timely medication administration?
 - Does the nurse remain with the patient until oral medication is taken?
 - Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?
 - Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?
 - Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?
- Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.
 - Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?
 - Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?

A-0409

(Rev.)

§482.23(c)(3)(iii) - Orders for drugs and biologicals may be documented and signed by other practitioners, only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

Interpretive Guidelines §482.23(c)(3)(iii)

All orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, must be documented and signed by a practitioner who is responsible for the

care of the patient or who is another practitioner who is authorized by hospital policy and medical staff bylaws, rules and regulations, and who is acting in accordance with State law, including scope of practice laws.

Flu and pneumonia vaccines

Influenza and pneumococcal vaccines may be administered per physician-approved hospital policy, i.e., hospital policy approved by the physician members of the medical staff. There must be an assessment of contraindications prior to administration of the vaccine(s). There is no requirement for authentication by a practitioner when influenza and pneumococcal vaccines are administered to a patient in accordance with hospital policy and State law.

Standing orders

Nurses or other personnel authorized by hospital policy and in accordance with State law may administer drugs and biologicals in accordance with pre-printed and electronic standing orders, order sets, and protocols for patient orders, collectively referred to in this guidance as “standing orders,” to address well- defined clinical scenarios involving medication administration. The requirements governing the hospital’s development and use of standing orders are found at the Medical Records CoP, under §482.24(c)(3). For the nursing services requirement under §482.23(c)(1) (ii), compliance assessment focuses on whether nurses comply with the hospital’s established standing orders policies and procedures when administering drugs or biological in accordance with a standing order.

Survey Procedures §482.23(c)(1) (ii), (c)(3) and (c)(3)(iii)

- Review the hospital’s policy for drug and biological orders. Does it require that all administration of drugs or biologicals be based on either an applicable standing order or the order of a practitioner who is responsible for the care of the patient or otherwise authorized by hospital and medical staff policy and in accordance with State law to write orders?
- Interview nursing staff to determine whether they initiate medications in accordance with standing orders. Are they familiar with the hospital’s policies and procedures for using standing orders? Are they following the policies and procedures? Ask to see the protocol for a standing order used by nursing staff, and ask nursing staff to explain how their practice conforms to the protocol.
- Review a sample of open and closed patient medical records. Although the regulation applies to both inpatient and outpatient medical records, the sample should be weighted to include more inpatient records.
- Determine whether all orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, are included in the patient’s medical record and authenticated by a practitioner who is authorized to write orders by hospital

and medical staff policy and in accordance with State law and who is responsible for the care of the patient.

- Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner.
- Determine whether all orders for drugs and biologicals contain the required elements.

A-0410

(Rev.)

§482.23(c)(4) - Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

Interpretive Guidelines §482.23(c)(4)

Intravenous (IV) medications and blood transfusions must be administered in accordance with State law and approved medical staff policies and procedures. Further, many of the medications included in the high-alert categories are administered intravenously. (See also the discussion of high-risk/high-alert medications in the guidance for §482.25(b).) Hospital policies and procedures for blood transfusions and IV medications must be based on accepted standards of practice, and must address at least the following:

Vascular Access Route

Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan. Safe administration of blood transfusions and IV medications includes the correct choice of vascular access. IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication's chemical properties or safety concerns. Hospital policies and procedures must address which medications can be given intravenously via what type of access.

Other Patient Safety Practices

In addition to the basic safe practices that apply to all medication administration (See the discussion of safe medication administration practices, and medication administration in general, at §482.23(c)), there are additional safe practices specific to IV medication administration that require consideration, including but not limited to, the following:

- Tracing invasive lines and tubes prior to administration to ensure the medication is to be administered via the proper route (for example, peripheral catheter versus epidural catheter connections);

- Avoiding forcing connections when the equipment offers clear resistance;
- Verifying proper programming of infusion devices (concentrations, flow rate, dose rate).

Patient Monitoring

As discussed in the medication administration guidance for §§482.23(c)(1), (c)(1)(i) and (c)(2), patients must be monitored for the effects of medications. To the extent that IV medications have a more rapid effect on the body, it is important that staff administering medications understand each medication and its monitoring requirements. Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements, including assessment of patients for risk factors that would influence the type and frequency of monitoring.

For example: a 50 year old patient with a history of renal failure is receiving IV vancomycin to treat a wound infection. The hospital policy for IV antibiotics, including vancomycin, requires the patient's kidney function to be monitored daily with blood draws. Based on review of the lab results, a practitioner responsible for the care of the patient would be expected to determine on a timely basis whether or not the antibiotic dose needs to be adjusted to protect kidney function or prevent drug toxicity while achieving the desired therapeutic effects. Staff administering the medication would be expected to review the lab results as well, and to raise with a practitioner responsible for the care of the patient any concerns they might have about whether an adjustment in the medication is needed.

Hospital policies and procedures related to monitoring patients receiving IV medications are expected to address, but are not limited to, the following:

- **Monitoring for Fluid & Electrolyte Balance**

Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance. Hospital policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications.

- **Monitoring Patients Receiving High-alert Medications, Including IV Opioids**

Policies and procedures related to IV medication administration must address those medications the hospital has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously.

At a minimum, hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients

Opioids are a class of medication used frequently in hospitals to treat pain. The

sedating effects of opioids make it difficult at times to properly assess the patient's level of sedation. It can be erroneously assumed that patients are asleep when they are actually exhibiting progressive symptoms of respiratory compromise - somnolence, decreased respiratory rate, and decrease in oxygen levels. These symptoms, if unrecognized, can progress to respiratory depression and even death.

Certain characteristics, in addition to those discussed in the medication administration guidance for §§482.23(c)(1), (c)(1)(i) and (c)(2), place patients receiving opioids at higher risk for oversedation and respiratory depression. These additional factors include, but are not limited to³:

- Snoring or history of sleep apnea
- No recent opioid use or first-time use of IV opioids
- Increased opioid dose requirement or opioid habituation
- Longer length of time receiving general anesthesia during surgery
- Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other central nervous system depressants
- Preexisting pulmonary or cardiac disease
- Thoracic or other surgical incisions that may impair breathing

Of particular concern are patients receiving IV opioids post-operatively. The effects of IV opioids in post-operative patients must be monitored vigilantly via serial assessments of pain, respiratory status, and sedation levels.

Hospitals must have policies and procedures related to the use of high-alert medications, including IV opioids for post-operative patients. Policies and procedures must address, at a minimum, the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods. The policies and procedures must also address whether and under what circumstances practitioners prescribing IV opioids are allowed to establish protocols for IV opioid administration and monitoring that differ from the hospital-wide policies and procedures.

The frequency of the serial assessments and duration of the monitoring timeframe for post-operative patients receiving IV opioids must be determined based on at least the following considerations:

- Patient risk for adverse events;
- Opioid dosing frequency and IV delivery method. (push or patient-controlled analgesia (PCA));
- Duration of IV opioid therapy.

3 Jarzyna D., Junquist C., Pasero C., et al. American Society for Pain Management Nursing - Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression. Pain Management Nursing, Vol 12, No. 3 (September), 2011: pp 118-145

Regardless of the above factors, at a minimum monitoring must include the following:

- Vital signs (blood pressure, temperature, pulse, respiratory rate)
- Pain level;
- Respiratory status;
- Sedation level; sedation levels are important indicators for the clinical effects of opioids. Sedation is a useful assessment parameter to observe the effects of opioids since sedation typically precedes respiratory depression⁴. See the blue box below for information on sedation assessment methods.

For Information – Not Required/Not to be Cited

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

In addition to vigilant nursing assessment at appropriate intervals, hospitals may choose to use technology to support effective monitoring of patients' respiratory rate and oxygen levels.

For additional information regarding recommendations of expert organizations on post-operative opioid monitoring, including technology-supported monitoring, see blue boxes below. The practices described in the blue boxes below are not required under the regulations.

The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient in order to assess effects of the medications. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

For Information – Not Required/Not to be Cited

Institute for Safe Medication Practices Guidelines for PCA Monitoring

⁴ Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

Assessment of Opioid Tolerance	Vital Signs	Pain	Sedation	Respiratory		
				Rate	Quality	SPO ₂ * &/or ETCO ₂ **
Baseline Assessment before PCA	X	X	X	X	X	X
PCA Initiation or Change in Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
PCA Dose Change or Bolus Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Adverse Event or Patient Deterioration (e.g., adverse change in sedation score) Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Hand-offs/Shift Change	X	X	X	X	X	X
Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council * SPO ₂ : Saturation of peripheral oxygen via pulse oximetry ** ETCO ₂ : End-tidal carbon dioxide via capnography						

For Information – Not Required/Not to be Cited
Anesthesia Patient Safety Foundation

- APSF calls for every patient receiving postoperative opioid analgesics to be managed based on the following clinical considerations*:
 - Individualize the dose and infusion rate of opioid while considering the unique aspects of each patient’s history and physical status.
 - Make continuous monitoring of oxygenation (pulse oximetry) the routine rather than the exception.
 - Assess the need for supplemental oxygen, especially if pulse oximetry or intermittent nurse assessment are the only methods of identifying progressive hypoventilation.
 - When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.

APSF also has issued a video on opioid induced ventilatory impairment:
http://apsf.org/resources_video4.php

*Stoelting, RK., Weinger MB. Dangers of postoperative opioids: Is there a Cure? APSF Newsletter 2009;24:2.

For Information – Not Required/Not to be Cited
The Patient Safety Movement Foundation

PSMF recommends all patients receiving IV opioids have continuous measure-through motion and low perfusion pulse oximetry, and that patients on supplemental oxygen also have continuous respiration rate monitoring. It also calls for the monitoring system to be linked with a notification system to clinical staff who can respond immediately. It calls for an escalation protocol so that if a staff person does not acknowledge the alert in 60 seconds a second person will be notified.

The Patient Safety Movement Foundation - Actionable Patient Safety Solution (APSS) #1: Failure to Rescue: Post-Operative Respiratory Depression. January 13, 2013

Adverse patient reactions require timely and appropriate intervention, per established protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. (See the guidance for §482.23(c)(5) and §482.25(b)(6), concerning

reporting of adverse medication-related events.)

Blood Components and Blood Administration Procedures

According to the U.S. Department of Health and Human Services, 13,785,000 units of whole blood and red blood cells were transfused in the United States in 2011⁵. The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. However, administration of blood products via transfusion is governed by §482.23(c)(4). Blood transfusions can be life-saving. However, like IV medications, blood transfusions are not without risk of harm to patients. Transfusion reactions and/or errors can be fatal.

In addition to the safe practices and other safety considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

- Confirming the following prior to each blood transfusion:
 - the patient's identity
 - verification of the right blood product for the right patient

The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.

- Requirements for patient monitoring, including frequency and documentation of monitoring
- How to identify, treat, and report any adverse reactions the patient may experience during or related to transfusion.

Staff Training and Competencies

Intravenous (IV) medications and blood transfusions must be administered by qualified personnel, regardless of whether they are practitioners or non-practitioners. Generally IV medications and blood transfusions are administered to patients by registered nurses (RNs), consistent with State law governing scope of practice, and approved medical staff policies and procedures.

Among other things, personnel must be able to demonstrate competency in venipuncture, in accordance with State law and hospital policy. If other types of vascular access are utilized, staff must have demonstrated competency in appropriate usage, care, and maintenance. Staff must also be trained in early detection of and timely intervention for

⁵ The 2011 National Blood Collection and Utilization Survey Report. Retrieved September 27, 2013 from <http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf>

IV opioid-induced over-sedation and respiratory depression.

Education and training regarding these procedures are typically included in the nurse's hospital orientation. Nursing staff who receive training for intravenous medication administration and/or blood transfusion administration during hospital orientation or during other continuing education programs would meet the requirements of this regulation. Content of the training must address each required component of the approved medical staff policies and procedures.

Other non-practitioners, for example, licensed practical nurses or licensed vocational nurses, with demonstrated competence may also administer IV medications and blood transfusions if they are acting in accordance with State law, including scope of practice law, and the hospital's approved medical staff policies and procedures. (77 FR 29050, May 16, 2012)

For non-practitioners, the appropriate competencies must be documented in the qualified staff person's employee record.

All State law and scope of practice requirements must be met regarding the administration of intravenous medications and blood transfusions, as applicable.

Survey Procedures §482.23(c)(4)

- Interview nursing staff on different units who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:
 - Venipuncture techniques;
 - Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps;
 - Maintaining fluid and electrolyte balance;
 - Patient assessment for risk related to IV medications and appropriate monitoring;
 - Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients;
 - With respect to blood transfusions:
 - Blood components;
 - Process for verification of the right blood product for the right patient; and

- Transfusion reactions: identification, treatment, and reporting requirements.
- Review the files for a sample of staff who administer blood products and IV medications, for evidence that competency was assessed and training was provided as appropriate.
- If able, observe blood transfusion and IV medication administration to assess staff adherence to accepted standards of practice.
 - Were safe medication administration practices used?
 - Was the transfused patient correctly identified and matched to the correct blood product prior to administration?
 - Was the appropriate access used for IV medications?
 - Were appropriate steps taken with regard to IV tubing and infusion pumps?
 - Are patients being monitored post-infusion for adverse reactions?
- If staff appear to not be following accepted standards of practice for patient risk assessment related to IV medications, particularly opioids, and appropriate monitoring of patients receiving IV medications and/or blood transfusions, review policies and procedures for IV medication administration and blood transfusion to determine if they address safe practices considerations.
- Review a sample of medical records.
 - Are blood transfusions and IV medications administered in accordance with State law and approved medical staff policies and procedures?
 - Are blood transfusions and IV medications administered by personnel who are working within their scope of practice in accordance with State law and approved medical staff policies?

A-0411
(Rev.)

§482.23(c)(5) - There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

Interpretive Guidelines §482.23(c)(5)
Adverse drug reactions and drug administration errors

There is a similar but more detailed and prescriptive requirement concerning internal hospital reporting of adverse drug reactions, drug administration errors and incompatibilities under the Pharmaceutical Services CoP at §482.25(b)(6). Therefore, it

is not necessary for hospitals to establish a different procedure in the case of adverse drug reactions and drug administration errors for such events when nurses administer drugs or transfusions. Consult the guidance for §482.25(b)(6) to see what must be reported, to whom, and in what timeframe. Failure to make required reports concerning adverse drug reactions and errors in administration of drugs should be cited under §482.23(c)(5) when the drug was administered by a nurse, as well as under §482.25(b)(6).

Transfusion reactions

Transfusion reactions can occur during or after a blood transfusion. A patient's immune system recognizes the foreign blood product and attempts to destroy the transfused cells. Incompatible blood products are typically the cause of transfusion reactions. Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death.

Transfusion reactions are serious and can be life-threatening. The hospital must have policies and procedures in place for the internal reporting of transfusion reactions. The policies must include procedures for reporting transfusion reactions immediately to the practitioner responsible for the care of the patient. The transfusion reaction must also be reported to the hospital-wide quality assessment performance improvement program as an adverse event, in accordance with the QAPI CoP at 42 CFR 482.21(c)(2). The transfusion reaction must be documented in the patient's medical record, including the prompt notification of the responsible practitioner.

Survey Procedures §482.23(c)(5)

- For adverse drug events and medication administration errors, follow the survey procedures for §482.25(b)(6). Deficiencies are to be cited under both §482.23(c)(5) and §482.25(b)(6) when the drug or transfusion related to an adverse drug reaction, transfusion reaction or medication administration error relates to a drug or transfusion administered by a nurse.
- Request the hospital policy and procedure for internal reporting of transfusion reactions.
- Interview nursing staff responsible for administering blood transfusions to determine whether they are familiar with and comply with the hospital's policies.
- Ask to see if there are any transfusion-related incident reports. Is there evidence that the transfusion reaction was reported immediately to the practitioner responsible for the patient's care? Was it reported to the hospital's QAPI program?

A-0458

(Rev.)

§482.24(c)(4) - All records must document the following, as appropriate:

(i) Evidence of--

(A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, *and except as provided under paragraph (c)(4)(i)(C) of this section*. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.24(c)(4)(i)(A)

Guidance is pending and will be updated in future release.

A-0461

(Rev.)

§482.24(c)(4) - [All records must document the following, as appropriate:

(i) Evidence of --]

(B) An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration, *and except as provided under paragraph (c)(4)(i)(C) of this section*. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

Interpretive Guidelines §482.24(c)(4)(i)(B)

Guidance is pending and will be updated in future release.

A-0462

(Rev.)

§482.24(c)(4) - All records must document the following, as appropriate:

(i) Evidence of --

(C) An assessment of the patient (in lieu of the requirements of paragraphs (c)(4)(i)(A) and (B) of this section) completed and documented after registration, but prior to surgery or a procedure requiring anesthesia

services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

Interpretive Guidelines §482.23(c)(4)(i)(C)

Guidance is pending and will be updated in future release.

A-0500

(Rev.)

§482.25(b) Standard: Delivery of Services

In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

Interpretive Guidelines §482.25(b)

Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines. The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Other sources of additional guidelines could include, but are not limited to: American Society of Health-System Pharmacists, American College of Clinical Pharmacy, American Pharmacists Association, United States Pharmacopeia, etc.

The hospital must have a process in place for medication orders to be received in the pharmacy and dispensed in a safe and timely manner. Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to, the following:

- Implementing systems such as dose limits, pre-printed orders, special labeling, or double checks to minimize adverse drug events, especially for high alert medications;
- Reviewing all medication orders (except in emergency situations) for appropriateness by a pharmacist before the first dose is dispensed. A process is established for resolving questions with the prescribing practitioner and the discussion and outcome are documented in the patient's medical record or pharmacy copy of the prescriber's order;

This review should include:

- Therapeutic appropriateness of a patient's medication regimen;
 - Therapeutic duplication in the patient's medication regimen;
 - Appropriateness of the drug, dose, frequency, and route of administration;
 - Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
 - Real or potential allergies or sensitivities; and
 - Other contraindications.
- Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons;
 - Policies and procedures that address the use of medications brought into the hospital by patients or their families when self-administration of medications is permitted by hospital policy; and
 - Having a system in place to reconcile medications that are not administered (e.g., left in the patient's medication drawer) when the pharmacy inventories patient medications or restocks patient medications. For example, did the patient refuse the medication, was there a clinical or treatment reason the medication was not used, or was the medication not used due to an error?

Monitoring the Effects of Medications

The pharmaceutical service may be responsible for monitoring the effects of medication(s) specified per hospital policy to assure medication therapy is appropriate and minimizes the occurrence of adverse events. Typically this occurs with anticoagulant therapy and antibiotics prescribed for the pharmacy to establish or adjust the dosage (i.e.; "pharmacy to dose" order). In such cases, the pharmacy's monitoring process includes:

- Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;
- Physical signs and clinical symptoms relevant to the patient's medication therapy;
- Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy.

(See also the Nursing CoP discussion regarding monitoring of patients at §482.23(c)(4)).

Survey Procedures §482.25(b)

- Are medication orders routinely reviewed by the pharmacy before the first dose? What evidence can the hospital present that such reviews take place?
- Are questions regarding medication orders resolved with the prescriber and a written notation of these discussions documented in the patient's medical record or pharmacy copy of the prescriber's order?
- Does the hospital pharmacy have a system for monitoring the effects of medication therapies for cases specified per hospital policy?
- Does the hospital retrieve and remove medications available for patient use when the hospital has been informed of a drug recall?

A-0501

(Rev.)

§482.25(b)(1) - All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

Interpretive Guidelines §482.25(b)(1)

All pharmaceutical services involving compounding, packaging, or dispensing of drugs and biologicals, must be conducted by or under the supervision of a pharmacist and performed consistent with State and Federal laws. The hospital must adopt and implement written policies and procedures to ensure all medications are prepared by authorized personnel.

Compounded Preparations

Hospitals use many medications that need to be reconstituted, mixed or which otherwise may be considered "compounded" preparations. Some may be compounded in the hospital pharmacy and/or the hospital may obtain some or all from external sources. The external sources could include:

- (1) Manufacturers;
- (2) registered outsourcing facilities, and/or
- (3) compounding pharmacies.

Regardless of the source, if accepted standards for safe compounding are not met, compounded medications may contain less or more than the intended dose and/or may

be chemically or microbiologically contaminated, with potentially devastating or even lethal consequences for the patients who receive them.

Use of Registered Outsourcing Facilities

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an “outsourcing facility.” The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities, per section 503B:

- Must comply with the FDA’s Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA’s publishes the most current versions of its draft and final regulations and guidance related to compounding on its website:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>;
- Will be inspected by FDA according to a risk-based schedule; and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

In a January 2014 letter to purchasers of compounded medications (available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm>), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that, “[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling.”

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at:

<http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm>

Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.”

Use of Compounding Pharmacies

Compounding pharmacies, not registered as an outsourcing facility with the FDA, are popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board. If a hospital obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the hospital must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- Ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current *standards of practice for compounding medications* and can the hospital document that it obtains and reviews such data?
- Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

**For Information – Not Required/Not to be Cited
ASHP Research and Education Foundation™ “Outsourcing Sterile
Products Preparation: Contractor Assessment Tool”**

The ASHP Research and Education Foundation™ offers a tool that hospitals may find useful for assessing vendors that provide compounded sterile preparations. The tool can be found at:

<http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx> and click on "Start using Sterile Products Outsourcing Tool now."

Medications Compounded by the Hospital’s Pharmacy

Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when there is a need for emergency or immediate patient administration of a compounded sterile preparation). In addition, all compounding of medications used or dispensed by the hospital must be performed consistent with standards of safe practice applicable to both sterile and non-sterile compounding.

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

Packaging and Labeling of Medications

Safe medication use includes proper packaging and labeling to reduce the risk of error. For individual drug containers: each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a beyond-use date (BUD). In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

For Information Only

Certain provisions of the FDCA address the labeling of prescription drugs generally (e.g., section 503(b)(2) of the FDCA). Section 503B of the FDCA includes labeling requirements for drugs compounded by registered outsourcing facilities (see section 503B(a)(10)). Although hospitals are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other Federal laws.

Dispensing of Medications

Medications must be dispensed by the hospital in a manner that is safe and meets the needs of the patient:

- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;
- Medications are dispensed in a timely manner. The hospital must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly;
- Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy;

- The hospital consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system;
- All concerns, issues or questions are clarified with the individual prescriber before dispensing; and
- Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.

Medications must be available for administration to patients when needed, including when the pharmacy is not open. Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following: automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.

- Automated Dispensing Cabinets (ADCs) for medications are a secure option for medication storage since they ensure locked storage of medications and allow for electronic tracking of controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification so that they can only be accessed by authorized personnel.
- Policies and procedures must address who can access medications during after-hours.

Survey Procedures §482.25(b)(1)

- Determine that only pharmacists or pharmacist-supervised personnel compound, package and dispense drugs or biologicals in accordance with State and Federal laws and regulations and accepted standards of practice by:
 - Interviewing pharmacy and hospital staff to determine who prepares and dispenses drugs and biologicals;
 - Observing on site preparation and dispensing operations;
 - Inspecting drug storage areas.
- Can the hospital demonstrate that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices? Can the pharmacy director provide evidence that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices?

- If the hospital obtains compounded products from external compounding sources, are the external source(s) registered with the FDA as outsourcing facilities? If not, can the hospital demonstrate that it systematically evaluates and monitors whether the outside compounding pharmacy adheres to accepted standards for safe compounding?
- Can the pharmacy director explain the risk level(s) of the CSPs being produced in-house and/or obtained from external sources?
- If any CSPs are produced in the hospital:
 - Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the hospital and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the hospital's policies and procedures?
 - Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices?
 - Ask the pharmacy director to demonstrate how the following are accomplished to ensure that sterile compounding practices are consistent with standards for the risk level(s) of CSPs being produced for/dispensed to hospital patients:
 - Verification of compounding accuracy and sterility;
 - Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;
 - Personnel training and competency assessment, including but not limited to accuracy/precision in identifying and measuring ingredients; cleansing and garbing; aseptic manipulation skills; environmental quality and disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and post-production quality checks.
- Review the hospital's procedures for maintaining the quality of CSPs during storage, transport and dispensing. Are CSPs packaged in a manner to protect package integrity and sterility? How are CSP-specific requirements with respect to motion, light exposure, temperature and potentially hazardous contents addressed? How does the hospital ensure that such information is

effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable?

- Can the hospital document that it is systematically monitoring and tracking adherence to all of the quality assurance and personnel training and competency standards described above? Have any problems or risks been identified? If so, did the hospital take effective action to protect patients, if relevant, and to effectively remedy the problem/risk?

A-0505

(Rev.)

§482.25(b)(3) - Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

Interpretive Guidelines §482.25(b)(3)

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use. This would include drugs that are the subject of a manufacturer's recall.

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.

A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available. The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer. The policies and procedures must be based on accepted professional principles.

For individual drug containers: each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

Survey Procedures §482.25(b)(3)

- Spot-check the labels of individual drug containers to verify that they conform to Federal and State laws, and/or contain the following minimal information:
 - Each patient's individual drug container bears his/her full name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD;
 - Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date;
- If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD;
- Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.

A-0592

(Rev.)

§482.27(b) Standard: - Potentially Infectious Blood and Blood Components

- (1) **Potentially human immunodeficiency virus (HIV) infectious blood and blood components. Potentially HIV infectious blood and blood components are prior collections from a donor –**
 - (i) **Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation;**
 - (ii) **Who tests positive on the supplemental (additional, more specific) test or other follow-up testing required by FDA; and**
 - (iii) **For whom the timing of seroconversion cannot be precisely estimated.**
- (2) **Potentially hepatitis C virus (HCV) infectious blood and blood components. Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.**
- (3) **Services furnished by an outside blood collecting establishment. If a hospital**

regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital --

- (i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;
 - (ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA;
 - (iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).
- (4) Quarantine of blood and blood components pending completion of testing. If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood component and quarantine all blood and blood components from previous donations in inventory.
 - (i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.
 - (ii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must –
 - (A) Dispose of the blood and blood components; and
 - (B) Notify the transfusion recipients as set forth in paragraph (b)(6) of this section.
 - (iii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine

as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).

- (5) **Recordkeeping by the hospital. The hospital must maintain --**
- (i) **Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and**
 - (ii) **A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.**
- (6) **Patient notification. If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or appropriate individual, the hospital must take the following actions:**
- (i) **Make reasonable attempts to notify the patient, or to notify the attending physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.**
 - (ii) **If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian or relative.**
 - (iii) **Document in the patient's medical record the notification or attempts to give the required notification.**
- (7) **Time frame for notification. For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 21 CFR 610.47 the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless--**
- (i) **The patient is located and notified; or**
 - (ii) **The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to *exceed 12 weeks.***
- (8) **Content of notification. The notification must include the following**

information:

- (i) A basic explanation of the need for HIV or HCV testing and counseling.
- (ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling.
- (iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

Interpretive Guidelines §482.27(b)

This regulation requires the hospital to have a system in place to take appropriate action when notified that blood or blood components it received are at increased risk of transmitting HIV or HCV.

A-0710

(Rev.)

§482.41(b)

(1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

(ii) Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(2) *In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a hospital, but only if the waiver will not adversely affect the health and safety of the patients.*

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

Interpretive Guidelines §482.41(b)(1) –(3)

Guidance is pending and will be updated in future release.

A-0713

(Rev.)

§482.41(b)(4) - The hospital must have procedures for the proper routine storage and prompt disposal of trash.

Interpretive Guidelines §482.41(b)(4)

Guidance is pending and will be updated in future release.

A-0714

(Rev.)

§482.41(b)(5) - The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

Survey Procedures §482.41(b)(5)

Guidance is pending and will be updated in future release.

A-0715

(Rev.)

§482.41(b)(6) - The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

Interpretive Guidelines §482.41(b)(6)

Guidance is pending and will be updated in future release.

A-0716

(Rev.)

§482.41(b)(7) - *A hospital may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.*

Interpretive Guidelines, 482.41(b)(7):

Guidance is pending and will be updated in future release.

A-0717

(Rev.)

§482.41(b)(8) *When a sprinkler system is shut down for more than 10 hours, the hospital must:*

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

Interpretive Guidelines §482.41(b)(8):

Guidance is pending and will be updated in future release.

A-0718

(Rev.)

§482.41(b)(9) *Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.*

(i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.

(ii) The sill height in special nursing care areas of new occupancies must not exceed 60 inches.

Interpretive Guidelines §482.41(b)(9):

Guidance is pending and will be updated in future release.

A-0720

(Rev.)

§482.41(c) Standard: Building Safety

Except as otherwise provided in this section, the hospital must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a hospital.

(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the hospital, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

*Interpretive Guidelines §482.41(c)(1) and (2):
Guidance is pending and will be updated in future release.*

A-0722

(Rev.)

§482.41(d) Standard: Facilities

The hospital must maintain adequate facilities for its services.

Interpretive Guidelines §482.41(d)

Adequate facilities means the hospital has facilities that are:

- Designed and maintained in accordance with Federal, State and local laws, regulations and guidelines; and
- Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.

Survey Procedures §482.41(d)

- Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.
- Review the facility's water supply and distribution system to ensure that the water quality is acceptable for its intended use (drinking water, irrigation water, lab water, etc.). Review the facility water quality monitoring and, as appropriate, treatment system.

A-0723

(Rev.)

§482.41(d)(1) - Diagnostic and therapeutic facilities must be located for the safety of

patients.

Interpretive Guidelines §482.41(d)(1)

Guidance is pending and will be updated in future release.

A-0724

(Rev.)

§482.41(d)(2) - Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

Interpretive Guidelines §482.41(d)(2)

Guidance is pending and will be updated in future release.

A-0725

(Rev.)

§482.41(d)(3) - The extent and complexity of facilities must be determined by the services offered.

Interpretive Guidelines §482.41(d)(3)

Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services offered in accordance with Federal and State laws, regulations and guidelines and accepted standards of practice for that location or service.

Survey Procedures §482.41(d)(3)

Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

A-0726

(Rev.)

§482.41(d)(4) - There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

Interpretive Guidelines §482.41(d)(4)

Guidance is pending and will be updated in future release.

A-0730

(Rev.)

§482.41(e)

The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

*http://www.archives.gov/federal_register/code_of_federalregulations/ibr_locations.htm
l. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.*

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

A-0747

(Rev.)

§482.42 Condition of Participation: Infection *Prevention and Control* and Antibiotic Stewardship Programs

The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.

Interpretive Guidelines §482.42

Guidance is pending and will be updated in future release.

A-0748

(Rev.)

§482.42(a) Standard: *Infection prevention and control program organization and policies. The hospital must demonstrate that:*

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

Interpretive Guidelines §482.42(a)(1)

Guidance is pending and will be updated in future release.

A-0749

(Rev.)

§482.42(a)(2) *The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings;*

Interpretive Guidelines §482.42(a)(2)

Guidance is pending and will be updated in future release.

A-0750

(Rev.)

§482.42(a)(3) *The infection prevention and control program includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and addresses any infection control issues identified by public health authorities; and*

Interpretive Guidelines §482.42(a)(3)

Guidance is pending and will be updated in future release.

A-0751

(Rev.)

§482.42(a)(4) *The infection prevention and control program reflects the scope and complexity of the hospital services provided.*

Interpretive Guidelines §482.42(a)(4)

Guidance is pending and will be updated in future release.

A-0760

(Rev. Implementation by 03/30/2020)

§482.42(b)(1) Standard: Antibiotic stewardship program organization and policies. The hospital must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership,

Interpretive Guidelines §482.42(b)(1)

Guidance is pending and will be updated in future release.

A-0761

(Rev. Implementation by 03/30/2020)

§482.42(b)(2) The hospital-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

Interpretive Guidelines §482.42(b)(2)

Guidance is pending and will be updated in future release.

A-0762

(Rev. Implementation by 03/30/2020)

[§482.42(b)(2) The hospital-wide antibiotic stewardship program:]

(ii) Documents the evidence-based use of antibiotics in all departments and services of the hospital; and

Interpretive Guidelines §482.42(b)(2)

Guidance is pending and will be updated in future release.

A-0763

(Rev. Implementation by 03/30/2020)

[§482.42(b)(2) The hospital-wide antibiotic stewardship program:]

(iii) Documents improvements, including sustained improvements, in proper antibiotic use, such as through reductions in CDI and antibiotic resistance in all departments and services of the hospital;

Interpretive Guidelines §482.42(b)(2)

Guidance is pending and will be updated in future release.

A-0764

(Rev. Implementation by 03/30/2020)

§482.42(b)(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

Interpretive Guidelines §482.42(b)(3)

Guidance is pending and will be updated in future release.

A-0765

(Rev. Implementation by 03/30/2020)

§482.42(b)(4) The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.

Interpretive Guidelines §482.42(b)(4)

Guidance is pending and will be updated in future release.

A-0770

(Rev.)

§482.42(c)(1) Standard: Leadership responsibilities

(1) The governing body must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

Interpretive Guidelines §482.42(c)(1)(i)

Guidance is pending and will be updated in future release.

A-0771

(Rev.)

[§482.42(c)(1) The governing body must ensure all of the following:]

(ii) All HAIs and other infectious diseases identified by the infection prevention

and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with hospital QAPI leadership.

Interpretive Guidelines §482.42(c)(1)(ii)

Guidance is pending and will be updated in future release.

A-0772

(Rev.)

§482.42(c)(2) Standard: Leadership responsibilities

(2) The infection preventionist(s)/infection control professional(s) is responsible for:

(i) The development and implementation of hospital-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

Interpretive Guidelines §482.42(c)(2)(i)

Guidance is pending and will be updated in future release.

A-0773

(Rev.)

[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

Interpretive Guidelines §482.42(c)(2)(ii)

Guidance is pending and will be updated in future release.

A-0774

(Rev.)

[§482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]

(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.

Interpretive Guidelines §482.42(c)(2)(iii)

Guidance is pending and will be updated in future release.

A-0775

(Rev.)

[\$482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies, and procedures.

Interpretive Guidelines §482.42(c)(2)(iv)

Guidance is pending and will be updated in future release.

A-0776

(Rev.)

[\$482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by hospital personnel.

Interpretive Guidelines §482.42(c)(2)(v)

Guidance is pending and will be updated in future release.

A-0777

(Rev.)

[\$482.42(c)(2) The infection preventionist(s)/infection control professional(s) is responsible for:]

(vi) Communication and collaboration with the antibiotic stewardship program.

Interpretive Guidelines §482.42(c)(2)(vi)

Guidance is pending and will be updated in future release.

A-0778

(Rev.)

§482.42(c)(3) Standard: Leadership responsibilities

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a hospital-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

Interpretive Guidelines §482.42(c)(3)(i)

Guidance is pending and will be updated in future release.

A-0779

(Rev.)

[\$482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

Interpretive Guidelines §482.42(c)(3)(ii)

Guidance is pending and will be updated in future release.

A-0780

(Rev.)

[\$482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as with the hospital's infection prevention and control and QAPI programs, on antibiotic use issues.

Interpretive Guidelines §482.42(c)(3)(iii)

Guidance is pending and will be updated in future release.

A-0781

(Rev.)

[\$482.42(c)(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

Interpretive Guidelines §482.42(c)(3)(iv)

Guidance is pending and will be updated in future release.

A-0785

(Rev.)

§482.42(d) Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.

If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

Interpretive Guidelines §482.42(d)

Guidance is pending and will be updated in future release.

A-0786

(Rev.)

§482.42(d)(1) Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-hospital systems.

(1) The unified and integrated infection prevention and control and antibiotic stewardship program sare established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital;

Interpretive Guidelines §482.42(d)(1)

Guidance is pending and will be updated in future release.

A-0787

(Rev.)

§482.42(d)(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;

Interpretive Guidelines §482.42(d)(2)

Guidance is pending and will be updated in future release.

A-0788

(Rev.)

§482.42(d)(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and

Interpretive Guidelines §482.42(d)(3)

Guidance is pending and will be updated in future release.

A-0789

(Rev.)

§482.42(d)(4) A qualified individual (or individuals) with expertise in infection prevention and control has been designated at the hospital as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to hospital staff.

Interpretive Guidelines §482.42(d)(4)

Guidance is pending and will be updated in future release.

A-0799

(Rev.)

§482.43 Condition of Participation: Discharge Planning

The hospital must have in effect a discharge planning process that focuses on the patient goals and treatment preferences and includes the patient and his or her caregivers support person(s) in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to a preventable hospital readmissions.

Interpretive Guidelines §482.43

Guidance is pending and will be updated in future release.

A-0800

(Rev.)

§482.43(a) Standard: Discharge Planning Process

(a) The hospital's discharge planning process must identify at an early stage of hospitalization those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's

physician.

Interpretive Guidelines §482.43(a)

Guidance is pending and will be updated in future release.

A-0801

(Rev.)

§482.43(a)(4) Standard: Discharge Planning Process

(4) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

Interpretive Guidelines §482.43(a)(4)

Guidance is pending and will be updated in future release.

A-0802

(Rev.)

§482.43(a)(6) Standard: Discharge Planning Process

(6) The hospital's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

Interpretive Guidelines §482.43(a)(6)

Guidance is pending and will be updated in future release.

A-0803

(Rev.)

§482.43(a)(7) Standard: Discharge Planning Process

(7) The hospital must assess its discharge planning process on a regular basis. The assessment must include ongoing, periodic review of a representative sample of discharge plans, including those patients who were admitted within 30 days of a previous admission, to ensure that the plans are responsive to the patient post-discharge needs.

Interpretive Guidelines §482.43(a)(7)

Guidance is pending and will be updated in future release.

A-0804

(Rev.)

§482.43(a)(8) Standard: Discharge Planning Process

(8) The hospital must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use on measures. The hospital must ensure that the post-acute care data on quality measures and data on resource measures is relevant and applicable to the patient's goals and treatment preferences.

Interpretive Guidelines §482.43(a)(8)

Guidance is pending and will be updated in future release.

A-0805

(Rev.)

§482.43(a)(1) Standard: Discharge Planning Evaluation

(1) Any discharge planning evaluation must be made in a timely basis to ensure the appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

Interpretive Guidelines §482.43(a)(1)

Guidance is pending and will be updated in future release.

A-0807

(Rev.)

§482.43(a)(2) Standard: Discharge Planning Evaluation

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to hospice care services, post-hospital extended care services, home health services, and non-health care services and community based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

Interpretive Guidelines §482.43(a)(2)

Guidance is pending and will be updated in future release.

A-0808

(Rev.)

§482.43(a)(3) Standard: Discharge Planning Evaluation

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

Interpretive Guidelines §482.43(a)(3)

Guidance is pending and will be updated in future release.

A-0809

(Rev.)

§482.43(a)(5) – Any discharge planning evaluation or discharge plan under this paragraph must be developed by or under the supervision of a registered nurse, social worker, or other appropriately qualified personnel.

Interpretive Guidelines §482.43(a)(5)

Guidance is pending and will be updated in future release.

A-0813

(Rev.)

§482.43(b) Standard: Discharge of the patient and the provision and transmission of the patient's necessary medical information. The hospital must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

Interpretive Guidelines §482.43(b)

Guidance is pending and will be updated in future release.

A-0814

(Rev.)

§482.43(c) Standard: Requirements related to post-acute care services.

For those patients discharged to home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, the following requirements apply, in addition to those set out at paragraphs (a) and (b) of this section:

Interpretive Guidelines §482.43(c)

Guidance is pending and will be updated in future release.

A-0815
(Rev.)

§482.43(c)(1) –The hospital must include the discharge planning a list of HHA’s, SNF’s, IRF’s, or LTCH’s that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) The list must only be presented to patients for whom home health care post hospital extended care services, SNF, IRF, or LTCH services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must make the patient aware of the need to verify with their managed care organization which practitioners, providers or certified suppliers are in the network of the patient’s managed care organization, it must share this with the patient or the patient’s representative.

(iii) [The hospital must] document in the patient’s medical record that the list was presented to the patient or to the patient’s representative.....

Interpretive Guidelines §482.43(c)(1)(i)-(iii)
Guidance is pending and will be updated in future release.

A-0816
(Rev.)

§482.43(c)(2) The hospital , as part of the discharge planning process, msut inform the patient or the patient’s representative of their freedom to choose among participating Medicare providers and suppliers of the post-discharge services and must, when possible, respect the patient’s or the patient’s representative goals of care and treatment preferences, as well as other preferences they express. The hospital must not specify or otherwise limit the qualified providers or suppliers that are available to the patients.

Interpretive Guidelines §482.43(c)(2)
Guidance is pending and will be updated in future release.

A-0817
(Rev.)

§482.43(c)(3) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital

under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of part 420, subpart C, of this chapter.

Interpretive Guidelines §482.43(c)(3)

Guidance is pending and will be updated in future release.

A-0952

(Rev.)

§482.51(b)(1) - Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration, *and except as provided under paragraph (b)(1)(iii) of this section.*

Interpretive Guidelines §482.43(b)(1)(i)

There must be a complete history and physical examination (H & P), and an update, if applicable, in the medical record of every patient prior to surgery, or a procedure requiring anesthesia services, except in emergencies *and, under §482.51(b)(1)(iii), for those specific patients that are not required to have a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services as determined by medical staff policy.*

- The H&P must be conducted in accordance with the requirements of 42 CFR 482.22(c)(5).
- The H&P must be completed and documented no more than 30 days before or 24 hours after admission or registration. In all cases *when it is determined that an H&P is required*, except for emergencies, the H&P must be completed and documented **before** the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.
- If the H&P was completed within 30 days before admission or registration, then an updated examination must be completed and documented within 24 hours after admission or registration. In all cases *when it is determined that an H&P is required*, except for emergencies, the update must be completed and documented **before** the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.

Survey Procedures §482.51(b)(1)(i)

Review a sample of open and closed medical records of patients (both inpatient and outpatient) who have had surgery or a procedure requiring anesthesia.

- Determine whether an H&P, *if required* was conducted and documented in a timely

manner.

- Determine whether the H&P, *if required*, was conducted in accordance with the requirements of 42 CFR 482.22(c)(5).
- Determine whether the records of patients *who are required to have an H&P*, did not have an H&P in a timely manner or update indicate that the surgery or procedure was conducted on an emergency basis.

A-0953

(Rev.)

§482.51(b)(1) - Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration, *and except as provided under paragraph (b)(1)(iii) of this section.*

Interpretive Guidelines §482.51(b)(1)(ii)

Guidance is pending and will be updated in future release.

A-0954

(Rev.)

§482.51(b)(1) - Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(iii) An assessment of the patient must be completed and documented after registration (in lieu of the requirements of paragraphs (b)(1)(i) and (ii) of this section) when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at § 482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

Interpretive Guidelines §482.51(b)(1)(iii)

Guidance is pending and will be updated in future release.

A-1562

(Rev.)

§482.58(b) Skilled nursing facility services. The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter

§482.58(b)(1) Resident rights (§483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2), *and* (4), (f)(4)(ii) *and* (iii), (h), (g)(8) *and* (17), and (g)(18) introductory text *of this chapter*).

§483.10(b)(7): In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf. The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law.

In the case of a resident representative whose decision-making authority is limited by State law or court appointment, the resident retains the right to make those decision outside the representative's authority.

(ii)The resident's wishes and preferences must be considered in the exercise of rights by the representative.

(iii)To the extent practicable, the resident must be provided with opportunities to participate in the care planning process.

§483.10(c)(1): The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.

§483.10(c)(2)(iii): The right to be informed, in advance, of changes to the plan of care.

§483.10(c)(6): The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.

§483.10(d): Choice of attending physician. The resident has the right to choose his or her attending physician.

The physician must be licensed to practice, and

If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in paragraphs (d)(4) and (5) of this section to assure provision of appropriate and adequate care and treatment.

The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.

The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.

(5) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

§483.10(e)(2): The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

§483.10(e)(4): The right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

§483.10(f)(4)(ii): The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time.

§483.10(f)(4)(iii): The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time.

§483.10(g)(8): The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:

Privacy of such communications consistent with this section; and

(ii) Access to stationery, postage, and writing implements at the resident's own expense.

§483.10(g)(17): The facility must—

Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and when the resident becomes eligible for Medicaid of—

The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in §483.10(g)(17)(i)(A) and (B) of this section.

§483.10(g)(18):[introductory text]: The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/Medicaid or by the facility's per diem rate.

§483.10(h): Privacy and confidentiality. The resident has a right to personal privacy and confidentiality of his or her personal and medical records.

Interpretive Guidelines §482.58(b)(1)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §482.58(b)(1)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

A-1567

(Rev.)

§482.58(b)(4) Social services (§483.40(d) *of this chapter*).

- **§483.40(d):** The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

Interpretive Guidelines §482.58(b)(4)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §482.58(b)(4)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

A-1569

(Rev.)

§482.58(b)(5) Discharge *summary* (§483.20(l))

[Note: The regulations at §483.20(l) setting forth the requirements for a nursing home resident discharge summary was revised and re-designated as §483.21(c)(2) in 2016 (81 FR 68858, Oct. 4, 2016) which provides, “When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to:

(i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.

(ii) A final summary of the resident's status to include items in paragraph (b)(2) of §483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative.

(iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).

(iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.”]

A-1573

(Rev.)

§482.58(b)(7) Dental services (§483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

- **§483.55 Dental services.** The facility must assist residents in obtaining routine and 24-hour emergency dental care.

(a) Skilled nursing facilities. A facility...

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

(3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

(4) Must if necessary or if requested, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dental services location; and

(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the

resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

(b) Nursing facilities. The facility-

- (1) Must provide or obtain from an outside resource, in accordance with §483.70(g), the following dental services to meet the needs of each resident:**
 - (i) Routine dental services (to the extent covered under the State plan); and**
 - (ii) Emergency dental services;**
- (2) Must, if necessary or if requested, assist the resident—**
 - (i) In making appointments; and**
 - (ii) By arranging for transportation to and from the dental services locations;**
- (3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;**
- (4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and**
- (5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.**

Interpretive Guidelines §482.58(b)(7)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §482.58(b)(7)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

Special Provisions Applying to Psychiatric Hospitals

Moved from Appendix AA to this Appendix

A-1600
(Rev.)

§482.60-Special Provisions Applying to Psychiatric Hospitals - Psychiatric hospitals must

Interpretive Guidelines §482.60
Guidance is pending and will be updated in future release

A-1601
(Rev.)

§482.60(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons.

Interpretive Guidelines §482.60
The hospital will be deemed to meet standard (a) if it meets standards (c) and (d).

A-1605
(Rev.)

§482.60(b) Meet the Conditions of Participation specified in §§482.1 through 482.23 and §§482.25 through 482.57;

Interpretive Guidelines §482.60(b)
Guidance is pending and will be updated in future release.

A-1610
(Rev.)

§482.60(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries as specified in §482.61; and

Interpretive Guidelines §482.60(c)
Guidance is pending and will be updated in future release.

A-1615
(Rev.)

§482.60(d) Meet the staffing requirements specified in §482.62.

Interpretive Guidelines §482.60(d)

Guidance is pending and will be updated in future release.

A-1620

(Rev.)

§482.61 Condition of Participation: Special Medical Record Requirements for Psychiatric Hospitals

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

Interpretive Guidelines §482.61

The clinical record should provide information that indicates need for admission and treatment, treatment goals, changes in status of treatment and discharge planning, and follow-up and the outcomes experienced by patients. The structure and content of the individual patient's record must be an accurate functional representation of the actual experience of the individual in the facility. It must contain enough information to indicate that the facility knows the status of the patient, has adequate plans to intervene, and provides sufficient evidence of the effects of the intervention, and how their interventions served as a function of the outcomes experienced. You must be able to identify this through interviews with staff, and when possible with individuals being served, as well as through observations.

A-1621

(Rev.)

§482.61(a) Standard: Development of Assessment/Diagnostic Data
Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

Interpretive Guidelines §482.61(a)

Guidance is pending and will be updated in future release.

A-1622

(Rev.)

§482.61(a)(1) The identification data must include the patient's legal status.

Interpretive Guidelines §482.61(a)(1)

Definition: Legal Status is defined in the State statutes and dictates the circumstances under which the patient was admitted and/or is being treated - i.e., voluntary, involuntary,

committed by court, evaluation and recertification are in accordance with state requirements.

Determine through interview with hospital staff the terminology they use in defining “legal status.” If evaluation and recertification is required by the State, determine that legal documentation supporting this status is present. Changes in legal status should also be recorded with the date of change.

A-1623
(Rev.)

§482.61(a)(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnosis of intercurrent diseases as well as the psychiatric diagnosis.

Interpretive Guidelines §482.61(a)(2)

There is an admission or working psychiatric diagnosis (including rule-out diagnoses) written in the most current edition of the American Psychiatric Association’s Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature. This diagnosis is made and entered into the chart of each patient at the time of the admission examination. The final diagnosis may differ from the initial diagnosis if subsequent evaluation and observation support a change.

If a diagnosis is absent, there must be justification for its absence. For example, if a patient was psychotic on admission and was not accompanied by family or significant others.

Intercurrent (other than psychiatric) diagnoses must be documented when they are made. Attention should be paid to physical examination notes, including known medical conditions, even allergies and recent exposure to infections, illness, or substance abuse, and to available laboratory or test reports which identify abnormal findings to see that these are reflected by appropriate diagnosis.

These diagnoses may be found in a variety of locations in the medical record, e.g., the identification/face sheet, the finding of admission physical examination, the psychiatric evaluation the “admission work up “ or the physician’s progress notes. Diagnostic categories should include physical illness when present.

Survey Procedures §482.61(a)(2)

Are abnormal physical examination findings and/or laboratory findings justified by further diagnostic testing and/or development of an intercurrent diagnosis, and, if so, was such done?

If an identified physical illness requires immediate treatment, is the treatment being given?

How will an identified physical illness be likely to impact on the patient’s eventual outcome? To what extent has this potential impact been addressed by the team?

A-1624
(Rev.)

§482.61(a)(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

Interpretive Guidelines §482.61(a)(3)

The purpose of this regulation is to provide an understanding of what caused the patient to come to the hospital, and the patient's response to admission.

The hospital records the statements and reason for admission given by family and by others, as well as the patient (preferably verbatim), with informant identified, in a variety of locations, e.g., in transfer and admission notes from the physician, nurses and social workers.

Records should not contain vague, ill-defined reports from unknown sources. Records should record "who," "what," "where," "when," and "why."

Survey Procedures §482.61(a)(3)

Can the patient describe problems, stresses, situations experienced prior to hospitalization or do they still exist?

Who is the informant?

Did the informant witness the patient's behavior? If not, on what basis has the informant come to know the patient's behavior?

Has staff elicited whether the patient has exhibited similar behavior previously? If so, what was different this time to make hospitalization necessary?

Were there other changes/events in the patient's environment (death, separations of significant others) which contributed to the need for hospitalization? If so, has staff explored how these will impact in the patient's treatment? Has this been addressed by the treatment team?

Has there been an interruption or change in the patient's medication which may have been a factor in the patient's hospitalization?

A-1625
(Rev.)

§482.61(a)(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

Interpretive Guidelines §482.61(a)(4)

The purpose of the social work assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans are to be formulated.

Patient length of stay is a key factor influencing hospital documentation policy, i.e., establishing timeframes for completion, documentation, and filing of the psychosocial assessment, and treatment planning in the medical record.

A psychosocial history/assessment must be completed on all patients. Three key components to be addressed:

A. Factual and Historical Information

1. Specific reasons for the patient's admission or readmission;
2. A description of the patient's past and present biopsychosocial functioning;
3. Family and marital history, dynamics, and patient's relationships with family and significant others;
4. Pertinent religious and cultural factors;
5. History of physical, sexual and emotional abuse;
6. Significant aspects of psychiatric, medical, and substance abuse history and treatment as presented by family members and significant others;
7. Educational, vocational, employment, and military service history;
8. Identification of community resources including previously used treatment sources;
9. Identification of present environmental and financial needs.

B. Social Evaluation

1. Patient strength and deficits;
2. High risk psychosocial issues requiring early treatment planning and intervention - i.e., unattended child(ren) in home; prior noncompliance to specific treatment and/ or discharge interventions; and potential obstacles to present treatment and discharge planning.

C. Conclusions and Recommendations

Assessment of Sections A and B shall result in the development of (C) recommendations related to the following areas:

1. Anticipated necessary steps for discharge to occur;
2. High risk patient and/or family psychosocial issues requiring early treatment planning and immediate intervention regardless of the patient's length of stay;
3. Specific community resources/ support systems for utilization in discharge planning - i.e., housing, living arrangements, financial aid, and aftercare treatment sources;
4. Anticipated social work role(s) in treatment and discharge planning.

Survey Procedures §482.61(a)(4)

Does the psychosocial history/assessment indicate:

1. Clear identification of the informants(s) and sources of information?
2. Whether information is considered reliable?
3. Patient participation to the extent possible in provision of data relative to treatment and discharge planning?
4. Integration of significant data including identified high risk psychosocial issues (problems) into the treatment plan?
5. How does the hospital insure the information is reliable?

A-1626
(Rev.)

§482.61(a)(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

Interpretive Guidelines §482.61(a)(5)

Upon admission the patient should receive a thorough history and physical examination with all indicated laboratory examinations. These investigations must be sufficient to discover all structural, functional, systemic and metabolic disorders. A thorough history of the patient's past physical disorders, head trauma, accidents, substance dependence/abuse, exposure to toxic agents, tumors, infections, seizures or temporary loss of consciousness, and headaches, will alert the physician to look for the presence of continuing pathology or possible sequelae any of which may turn out to be significant and pertinent to the present mental illness. Equally important is a thorough physical examination to look for signs of any current illness since psychotic symptoms may be due to a general medical condition or substance related disorder.

The screening neurological examination

As part of the physical examination, the physician will perform a "screening" neurological examination. While there is no precise definition of a screening neurological examination in medical practice such examination is expected to assess gross function of the various divisions of the central nervous system as opposite to detailed, fine testing of each division. Gross testing of Cranial Nerves II through XII should be included. Statements such as "Cranial Nerves II to XII intact" are not acceptable. These areas may be found in various parts of the physical examination and not just grouped specifically under the neurological. In any case where a system review indicate positive neurological symptomatology, a more detailed examination would be necessary, with neurological work-up or consultation ordered as appropriate after the screening neurological examination was completed.

Complete neurological examination.

A complete, comprehensive neurological examination includes a review of the patient's history, physical examination and for psychiatric patients, a review of the psychiatric evaluation. The neurologist/psychiatrist himself/herself also takes a history to obtain the necessary information not already available in the medical record or referral form. The neurological examination is a detailed, orderly survey of the various sections of the nervous system. As an example, whereas a simple reading of a printed page will be sufficient to assess grossly the patient's sight (cranial nerve II) in a complete neurological examination, the neurologist may test visual acuity with a snellen chart, perform a fundoscopic examination of both eyes (sometimes after dilating the pupils) and he/she will examine the patient's visual fields. In the examination of the motor system, the power of muscle groups of the extremities, the neck and trunk are tested. Where an indication of diminished strength is noted, testing of smaller muscle groups and even

individual muscles are tested. In a complete neurological examinations all the systems are examined, but the physician will emphasize even more the areas pertinent to the problem for which the examination was requested.

Survey Procedures §482.61(a)(5)

Did the presence of an abnormal physical finding or laboratory finding justify the need for further diagnostic testing, or for the development of an intercurrent diagnosis? If the finding justified further follow-up in either situation, was such follow-up done?

Is there evidence that a screening neurological examination was done and recorded at the time of the physical examination?

Was the screening neurological or history indicative of possible involvement (tremors, paralysis, motor weakness or muscle atrophy, severe headaches, seizures, head trauma)?

If indicated, was a complete, comprehensive neurological exam ordered, completed and recorded in the medical record in a timely manner?

***A-1630
(Rev.)***

§482.61(b) Standard: Psychiatric Evaluation. Each patient must receive a psychiatric evaluation that must—

Interpretive Guidelines §482.61(b)

The psychiatric evaluation is done for the purpose of determining the patient's diagnosis and treatment and, therefore, it must contain the necessary information to justify the diagnosis and planned treatment.

The psychiatric evaluation is a total appraisal or assessment of the patient's illness. It is the physician's assessment of the contributing factors and forces in the evolution of the patient's illness including the patient's perception of his or her illness. Through the psychiatric evaluation the physician seeks to secure a biographical-historical perspective of the patient's personality, with a clear psychological picture of the patient as a specific human being with his or her individual problems. While performing the psychiatric evaluation, the physician reaches an understanding of the patient's basic personality structure, of the patient's developmental period, of his or her value systems, of his or her past medical history including surgical procedures and other treatments, his or her past psychological traumatic experiences, his or her defense mechanisms, his or her supporting systems, any precipitating factors and how all these may have impacted and interplayed with each other to result in the present illness. In the psychiatric evaluation the patient should emerge as a dynamic human being with a past, a present and a potential future with a thread of logical continuity.

The psychiatric evaluation includes all the requirements described in this standard and the information necessary to justify the diagnosis and treatment. A physician's signature is necessary. In those cases where the mental status portion of the psychiatric evaluation is performed by a non-physician, there should be evidence that the person is credentialed by the hospital, legally authorized by the State to perform that function, and a physician review and countersignature is present, where required by hospital policy or State law.

In order to satisfy the requirements §482.61(b) (1-7) of this standard, and to meet the standards of medical practice, the psychiatric evaluation should include the following component parts:

Survey Procedures §482.61(b)

The patient's chief complaints and/or reaction to hospitalization, recorded in patient's own words where possible. Why is the patient in the hospital? Was it his/her idea? (Does he/she feel ill/disturbed/frightened?) Is the patient in the hospital against his/her will? Who decided to hospitalize/why?

Past history of any psychiatric problems and treatment, including prior precipitating factors, diagnosis, course and treatment. Has the patient been chronically ill? Continuously/repeatedly? How severely has the past illness/treatment interfered with the patient's development and/or adjustment? Are there persistent symptoms/signs/behaviors that must be addressed and treated in order to favorably impact on the future psychiatric course? What medications or supports helped him/her improve in the past? Are the same resources available to impact on the patient's treatment during this episode?

Past family, educational, vocational, occupational and social history. To what extent, if any, is there a presence or absence of familial predisposition? What is the patient's educational level? Was he/she a good student? Is he/she still interested in learning? What jobs has the patient held? For how long? Is he/she now employed/unemployed? For how long? Has he/she ever worked? How does the patient get along with people? As a child, did he/she have friends? Does he/she have friends now? Within the psychiatric evaluation does one find the specific signs and symptoms, and other factors, that justify the diagnosis?

A-1631
(Rev.)

§482.61(b)(1) Be completed within 60 hours of admission;

Interpretive Guidelines §482.61(b)(1)
Guidance is pending and will be updated in future release

A-1632
(Rev.)

§482.61(b)(2) Include a medical history

Interpretive Guidelines §482.61(b)(2)

The psychiatric evaluation must include the non-psychiatric medical history including physical disabilities, intellectual disabilities and treatment.

Survey Procedures §482.61(b)(2)

Does the evaluation include:

Relevant past surgery? Past medical conditions and disabilities especially those of a chronic nature?

Have these contributed to the patient's psychiatric condition? How?

Are any of these conditions still present to any significant degree? Are they likely to impact on the patient's recovery/remission? Should they be addressed immediately? Does the facility have the capability to intervene? If not, how is the need to be met?

A-1633

(Rev.)

§482.61(b)(3) Contain a record of mental status;

Interpretive Guidelines §482.61(b)(3)

The mental status must describe the appearance and behavior, emotional response, verbalization, thought content, and cognition of the patient as reported by the patient and observed by the examiner at the time of the examination. This description is appropriate to the patient's condition.

Explore the mental status for descriptions of the patient's presentation during the examination that are relevant to the diagnosis and treatment of the patient. An example of a portion of the patient interview: The patient periodically states the examiner's name correctly during this examination after hearing it once, accurately describes his past history in great detail, precisely characterizes his present situation, can list events in logical sequence that have led to his present illness, but believes that his pre-admission insomnia, anorexia, and 35 pound weight loss over the past four months are totally the result of his sexual promiscuity of ten years ago and have nothing to do with his concurrent use of 50 to 60 mg. of Amphetamine daily." From this information one can conclude that the patient is oriented, his memory is intact, but that he has poor judgment and no insight. It is not acceptable just to write "oriented, memory intact, judgment poor, and insight nil," without any supportive information.

A-1634

(Rev.)

§482.61(b)(4) Note the onset of illness and the circumstances leading to admission;

Interpretive Guidelines §482.61(b)(4)

In a hospitalized patient, the identified problem should be related to the patient's need for hospital admission. The psychiatric evaluation includes a history of present illness, including onset, precipitating factors and reason for the current admission, signs and symptoms, course, and the results of any treatment received.

Survey Procedures §482.61(b)(4)

How long has the patient been ill? Was it a gradual or sudden onset?

Is this a recurrence?

What were the precipitating factors? What happened?

What symptoms, signs, behaviors made this hospitalization necessary?

What treatment has the patient already received before coming to the hospital?

Is any medication he received listed?

A-1635

(Rev.)

§482.61(b)(5) Describe attitudes and behavior;

Interpretive Guidelines §482.61(b)(5)

The problem statement should describe behavior(s) which require change in order for the patient to function in a less restrictive setting. The identified problems may also include behavioral or relationship difficulties with significant others which require active treatment in order to facilitate a successful discharge.

A-1636

(Rev.)

§482.61(b)(6) Estimate intellectual functioning, memory functioning and orientation; and

Interpretive Guidelines §482.61(b)(6)

Refer to §482.61(b)(3)

A-1637

(Rev.)

§482.61(b)(7) Include an inventory of the patient's assets in descriptive, not interpretive fashion.

Interpretive Guidelines §482.61(b)(7)

Although the term strength is often used interchangeably with assets, only the assets that describe personal factors on which to base the treatment plan or which are useful in therapy represent personal strengths. Strengths are personal attributes i.e., knowledge, interests, skills, aptitudes, personal experiences, education, talents and employment status, which may be useful in developing a meaningful treatment plan. For purposes of

the regulation, words such as “youth,” “pretty,” “Social Security income,” and “has a car” do not represent assets. (See also §482.61(c)(1).)

A-1640
(Rev.)

§482.61 (c)(1) Standard Treatment Plan. Each patient must have an individualized, comprehensive treatment plan based on an inventory of the patient’s strengths and disabilities.

Interpretive Guidelines §482.61(c)(1)

The patient and treatment team collaboratively develop the patient’s treatment plan. The treatment plan is the outline of what the hospital has committed itself to do for the patient, based on an assessment of the patient’s needs. The facility selects its format for treatment plans and treatment plan updates.

Survey Procedure §482.61(c)(1)

Determination of compliance regarding treatment plans is accomplished by the surveyor using the following methods, and to the extent possible, the following order:

1. Observation of the patient and staff at planned therapies/meetings, in various settings both on and off the patient units, in formal and informal staff-patient interactions and in a variety of daily settings;
2. Interviews with patients, families, treatment staff and others involved directly or indirectly with active treatment;
3. Reviews of scheduled treatment programs (individual, group, family meetings, therapeutic activities, therapeutic procedures);
4. Attendance at multidisciplinary treatment planning meetings, if time permits; and
5. Medical record review.

Has the information gained from assessing/evaluating the patient been utilized to create an individualized treatment plan?

A disability is any psychiatric, biopsychosocial problem requiring treatment/intervention. The term disability and problem are used interchangeably. The treatment plan is derived from the information contained in the psychiatric evaluation and in the assessments/diagnostic data collected by the total treatment team. Based on the assessment summaries formulated by team members of various disciplines, the treatment team identifies which patient disabilities will be treated during hospitalization. Patient strengths that can be utilized in treatment must be identified. (See also §482.61(b)(7).) Treatment planning depends on several variables; whether the admission is limited to crisis intervention, short-term treatment or long-term treatment. The briefer the hospital stay, the fewer disciplines may be involved in the patient’s treatment.

There must be evidence of periodic review of the patient’s response and progress toward meeting planned goals. If the patient has made progress toward meeting goals, or if there is a lack of progress, the review must justify: (1) continuing with the current goals and

approaches; or (2) revising the treatment plan to increase the possibility of a successful treatment outcome.

Consideration must be given to the type of psychiatric program(s) under review to determine the timeframe for treatment plan review. The interval within which treatment plan reviews are conducted is determined by the hospital, however, the hospital's review system must be sufficiently responsive to ensure the treatment plan is reviewed: whenever a goal(s) has been accomplished; when a patient is regressing; when a patient is failing to progress; or when a patient requires a new treatment goal. The facility is expected to pursue aggressively the attendance of all relevant participants at the team meetings. Question any routine and regular absences of individuals who would be expected to attend.

Is the treatment plan individualized, i.e., patient-specific, or is there a predictable sameness from plan to plan?

When packaged plans or programs are used, do staff include needed individual adaptations in the plan?

Are the patient's observed behaviors consistent with the problems and strengths identified in the plan or update?

Have the views which the patient communicated to the surveyor regarding problems which require treatment during hospitalization and plans for discharge, been incorporated in the plan or update?

A-1641
(Rev.)

§482.61(c)(1)(i) The written plan must include—A substantiated diagnosis;

Interpretive Guidelines §482.61(c)(1)(i)

The substantiated diagnosis serves as the basis for treatment interventions. A substantiated diagnosis is the diagnosis identified by the treatment team to be the primary focus upon which treatment planning will be based. It evolves from the synthesis of data from various disciplines.

At the time of admission, the patient may have been given an initial diagnosis or a rule-out diagnosis. At the time of treatment planning, a substantiated diagnosis must be recorded. It may be the same as the initial diagnosis, or, based on new information and assessment, it may differ.

Rule-out diagnoses, by themselves are not acceptable as a substantiated diagnosis.

Data to substantiate the diagnosis may be found in, but is not limited to, the psychiatric evaluation, the medical history and physical examination, laboratory tests, medical and

other psychological consults, assessments done by disciplines involved in patient evaluations and information supplied from other sources such as community agencies and significant others.

Survey Procedures §482.61(c)(1)(i)

What specific problems will be treated during the patient's hospitalization?

Does the treatment plan identify and precisely describe problem behaviors rather than generalized statements i.e., "paranoid," "aggressive," "depressed?" or generic terminology i.e., "alteration in thought process," "ineffective coping," "alteration in mood?"

Are physical problems identified and included in the treatment plan if they require treatment, or interfere with treatment, during the patient's hospitalization?

A-1642

(Rev.)

§482.61(c)(1)(ii) Short-term and long range goals;

Interpretive Guidelines §482.61(c)(1)(ii)

Based on the problems identified for treatment, short-term and long-range goals are developed. Whether the use of short-term or a combination of short-term and long-range goals is appropriate is dependent on the length of hospital stay.

Short-term and long-range goals include specific dates for expected achievement. As goals are achieved, the treatment plan should be revised. When a goal is modified, changed or discontinued without achievement, the plan should be reviewed for relevancy, and updated as needed.

In crisis intervention and short-term treatment there may be only one timeframe for treatment goals. As the length of hospital stay increases (often because of the long-term chronic nature of the patient's illness), both long-range and short-term goals are needed.

The long-range goal is achieved through the development of a series of short-term goals, i.e., smaller, logical sequential steps which will result in reaching the long-range goal. Both the short-term and long-range goals must be stated as expected behavioral outcomes for the patient. Goals must be related to the problems identified for treatment. Goals must be written as observable, measurable patient behaviors to be achieved. Discharge criteria may be included as long-range goals.

Survey Procedures §482.61(c)(1)(ii)

How do treatment plan goals relate to the problems being treated?

Do goals indicate the outcomes to be achieved by the patient?

Are the goals written in a way that allow changes in the patient's behavior to be measured?

If not apparent, what criteria do staff use to measure success?

How relevant are the treatment plan goals to the patient's condition?

A-1643
(Rev.)

§482.61(c)(1)(iii) The specific treatment modalities utilized;

Interpretive Guidelines §482.61(c)(1)(iii)

This requirement refers to all of the planned treatment modalities used to treat the patient during hospitalization. Having identified the problems requiring treatment, and defining outcome goals to be achieved, appropriate treatment approaches must be identified.

Modalities include all of the active treatment measures provided to the patient. It describes the treatment that will be provided to the patient. It describes the treatment that will be provided by various staff.

A daily schedule of unit activities does not, in itself, constitute planned modalities of treatment. It is expected that when a patient attends various treatment modalities/activities, it is a part of individualized planning with a specific purpose and focus for that patient.

Simply "naming" modalities (i.e., individual therapy, group therapy, occupational therapy, medication education) is not acceptable. The focus of the treatment must be included.

Simply "stating" modality approaches (i.e., "set limits," "encourage socialization," "discharge planning as needed") is not acceptable. Modality approaches must be specifically described in order to assure consistency of approach.

Observation of staff implementing treatment, both in structured and non-structured settings, is a major criterion to determine whether active treatment is being provided in accordance with planned treatment.

It must be clear to you that the active treatment received by the patient is internally consistent and not simply a series of disconnected specific modalities delivered within certain scheduled intervals.

Survey Procedures §482.61(c)(1)(iii)

Are qualified staff observed following the methods, approaches and staff intervention as stated?

Can staff explain the focus of the modality they have provided?

Are observed treatment methods, approaches and interventions from all disciplines included in the plan?

Do the pieces of the treatment plan work together to achieve the greatest possible gain for the patient?

Does the hospital integrate its activities, therapies, treatments, and patient routines to work for the patient's therapeutic interest first, and its own convenience second?

Do the disciplines present at observed treatment planning meetings represent all of the patient's needs?

If the patient attends treatment planning, how do the staff prepare the patient to participate?

If the patient does not attend, what reasons do staff give to explain the absence?
Is there a process to enable staff to reach a consensus regarding how treatment will be carried out?

Is the patient included in the decision-making, whenever possible?

Are the final decisions regarding treatment approaches defined clearly by the end of the discussion?

How does the patient get to know his/her treatment regime?

How does the treatment team encourage the patient to accept responsibility for engaging in the treatment regime, rather than accepting it passively?

A-1644
(Rev.)

§482.61(c)(1)(iv) The responsibilities of each member of the treatment team; and

Interpretive Guidelines §482.61(c)(1)(iv)

There are no "correct" number of staff who comprise the treatment team. The disciplines involved in the patient's treatment depend upon the problems to be treated, the short-term and long-range goals and the treatment approaches and modalities used to achieve the goals.

The intent of the regulation is to insure that each individual on the treatment team who is primarily responsible for ensuring compliance with particular aspects of the patient's individualized treatment program is identified. Identification of the staff should be

recorded in a manner that includes the name and discipline of the individual. If other professionals or paraprofessionals provide care, the facility has the latitude to decide the manner with which it will identify them on the treatment plan.

The patient, as well as family/significant others, should be aware of the staff responsible for various aspects of treatment.

Survey Procedures §482.61(c)(1)(iv)

Are staff who are designated in the treatment plan observed carrying out treatment activities and therapies? Is the information in the plan consistent with surveyor observations?

Are the patients able to name the staff responsible for implementing their treatment? Is this information consistent with the treatment plan?

***A-1645
(Rev.)***

§482.61(c)(1)(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

Interpretive Guidelines §482.61(c)(1)(v)

When the progress and treatment notes are reviewed, the content of the notes must relate to the treatment plan. The notes must indicate what the hospital staff is doing to carry out the treatment plan and the patient's response to the interventions.

Survey Procedures §482.61(c)(1)(v)

Are the treatment notes relative to the identified problems?

Are the treatment notes indicative of the patient's response to treatment?

Do the progress notes relate to specific patient problems or progress?

***A-1650
(Rev.)***

§482.61(c)(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

Interpretive Guidelines §482.61(c)(2)

Active treatment is an essential requirement for inpatient psychiatric care. Active treatment is a clinical process involving ongoing assessment, diagnosis, intervention, evaluation of care and treatment, and planning for discharge and aftercare, under the direction of a psychiatrist. The patient is in the hospital because it has been determined that the patient requires intensive, 24 hour, specialized psychiatric intervention that

cannot be provided outside the psychiatric hospital. The medical record must indicate that the hospital adheres to the patient's right to be counseled about medication, its intended effects, and the potential side effects. If the patient requires, because of danger to self or others, a more restrictive environment, the hospital must indicate that the staff attempted to care for the patient in the least restrictive setting before progressing to a more restrictive setting.

Through observation, look for evidence that each patient is receiving all the aspects of treatment to which the hospital has committed itself based upon his/her assessment, evaluation and plan of care. It is the hospital's responsibility to provide those treatment modalities with sufficient frequency and intensity to assure that the patient achieves his/her optimal level of functioning.

Through observation and interviews, look for evidence that each patient's rights are being addressed and protected. There should be policies and procedures in place to address the following areas: informed consent, confidentiality, privacy, and security. Expect to see detailed policies and procedures regarding the therapeutic use of restrictions, such as visitors, mail, and phone calls. Seclusion and restraint policies and procedures must address patient protection and safety while in a restricted setting.

Clarification of the types of notes found in the medical record.

Treatment notes are recordings in the medical record that indicate provision of, and a patient's response to, a specific modality. This modality may be drug therapy, individual, family, marital, or group therapy, art therapy, recreational therapy, and any specialized therapy ordered by the physician or anyone credentialed by the facility, in accordance with the State law, to write orders in the medical record.

A combined treatment and progress note may be written.

Progress notes are recordings in the medical record that are written by persons directly responsible for the care and active treatment of the patient. Progress notes give a chronological picture of how the patient is progressing toward the accomplishment of the individual goals in the treatment plan. These are frequently shift notes, weekly notes, or monthly notes.

Survey Procedures §482.61(c)(2)

Does the patient know his/her diagnosis?

What did the patient contribute to the formulation of the treatment plan? Goals of treatment?

If the patient receives medication, does the patient understand the reason for the medication? The name of the medication? The dose prescribed? The time of administration? The desired effects? The potential side effects?

If medication is changed, is there a rationale for the change?

Are staff members recording their observations relative to the patient's response to the treatment modalities, including medication?

Is there evidence that the patient was afforded the opportunity to participate in his/her plan of care?

What progress has the patient made? Has the patient achieved his/her optimal level of functioning? If not, why? Are these reasons/barriers reflected in the current treatment plan? Do treatment and progress notes support these insights?

Does the observed status of the patient in the various treatment modalities correspond to the progress note reports of status?

Do all treatment team members document their observations and interventions so that the information is available to the entire team?

If a restrictive procedure is used (e.g., restraint and/or seclusion), is there evidence that attempts were made systematically to treat the patient in the least restrictive manner?

Is there evidence that the rights of the patient were protected while in the restrictive setting in accordance with Federal and State law and accepted standards of practice?

A-1655
(Rev.)

§482.61(d) – Standard: Recording Progress.

Progress notes must be recorded by the *physician(s), psychologists, or other licensed independent practitioner(s)* responsible for the care of the patient as specified in §482.12(c); nurse, social worker and, when appropriate, others significantly involved in active treatment modalities.

Interpretive Guidelines §482.61(d)

Refer to §482.61(c)(2) Interpretive Guidelines for clarification between treatment notes and progress notes. The recording of progress is evidence of individual patient performance. Specifically, the progress notes recorded by the professional staff, or others responsible for the patient's treatment, must give a chronological picture of the patient's progress or lack of progress towards attaining short and long-range goals outlined in the individual treatment plan. Progress notes should relate to the goals of the treatment plan. Notes that state, "patient slept well" or "no complaints" constitute observations and do not indicate how the patient is responding to treatment and progressing towards set goals. Frequency alone does not determine the adequacy of progress notes. Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind. Notes should be dated and signed (signature and title or discipline).

Survey Procedures §482.61(d)

Are the physicians who are significantly involved in active treatment modalities/interventions actually documenting progress?

Do the progress notes relate to the goals of the treatment plan? Do they include precise statements of progress?

Is there a correlation between what is observed by the surveyor and what is described in the notes?

Do the notes give a clear picture of the patient's progress or lack thereof, during the course of hospitalization?

In reviewing the patient's progress, are aftercare/discharge plans being evaluated?
Are the nurses who are significantly involved in active treatment modalities/interventions actually documenting progress?

Are the social workers that are significantly involved in active treatment modalities/interventions plan actually documenting progress?

Are staff from other disciplines, i.e., rehabilitative therapy and psychology, which are significantly involved in active treatment modalities/interventions actually documenting progress?

A-1660

(Rev.)

§482.61(d) . . .The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter . . .

Interpretive Guidelines §482.61(d)

Guidance is pending and will be updated in future release

Survey Procedures §482.61(d)

What is the frequency of progress notes in relation to the condition of the patient?

A-1661

(Rev.)

§482.61(d) . . .*and must contain* recommendations for revisions in the treatment plan as indicated . . .

Interpretive Guidelines §482.61(d)

Guidance is pending and will be updated in future release

Survey Procedures §482.61(d)

Do the progress notes contain documentation substantiating changes/revisions in the treatment plan and subsequent assessment of the patient's responses and progress?

A-1662

(Rev.)

§482.61(d) . . . as well as [must contain] a precise assessment of the patient's progress in accordance with the original or revised treatment plan.

Interpretive Guidelines §482.61(d)

Guidance is pending and will be updated in future release

Survey Procedures §482.61(d)

Do the notes give a clear picture of the patient's progress, or lack thereof, during the course of hospitalization?

Are the progress notes related to the goals of the treatment plan?

A-1670

(Rev.)

§482.61(e) Standard: Discharge planning and discharge summary. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and...

Interpretive Guidelines §482.61(e)

The record of each patient who has been discharged should indicate the extent to which goals established in the patient's treatment plan have been met.

As part of discharge planning, staff consider the discharge alternatives addressed in the psychosocial assessment and the extent to which the goals in the treatment plan have been met.

The surveyor should refer to hospital policy for discharge timeframes.

The discharge summary should contain a recapitulation of the patient's hospitalization, which is a summary of the circumstances and rationale for admission, and a synopsis of accomplishments achieved as reflected through the treatment plan. This summary includes the reasons for admission, treatment achieved during hospitalization, a baseline of the psychiatric, physical and social functioning of the patient at the time of discharge, and evidence of the patient/family response to the treatment interventions.

A-1671

(Rev.)

§482.61(e) [The record of each patient who has been discharged must have a discharge summary that includes] . . . recommendations from appropriate services concerning follow-up or aftercare as well as ...

Interpretive Guidelines §482.61(e)

The patient's discharge summary should describe the services and supports that are appropriate to the patient's needs and that will be effective on the day of discharge.

Examples include:

- A complete description of arrangements with treatment and other community resources for the provision of follow-up services. Reference should be made to prior verbal and written communication and exchange of information;
- A plan outlining psychiatric, medical/physical treatment and the medication regimen as applicable;
- Specific appointment date(s) and names and addresses of the service provider(s);
- Description of community housing/living arrangement;
- Economic/financial status or plan, i.e., supplemental security income benefits;
- Recreational and leisure resources; and A complete description of the involvement of family and significant others with the patient after discharge.

Survey Procedures §482.61(e)

How does the discharge planning process verify appointment source(s), dates and addresses?

How was the patient involved in the discharge and aftercare planning process?

Were discharge related documents made available to the patient, family, community treatment source and/or any other appropriate sources?

Is there indication that the discharge planning process included the participation of multidisciplinary staff and the patient? Have the results been communicated to the post-hospital treatment entity?

Is there evidence that contact with the post-hospital treatment entity included communication of treatment recommendations (including information regarding the patient's medications)?

Is a contact person named, and does the patient have a specific appointment date and time for the initial follow-up visit?

A-1672
(Rev.)

§482.61(e) [The record of each patient who has been discharged must have a discharge summary that includes] ... a brief summary of the patient's condition on discharge.

Interpretive Guidelines §482.61(e)

The patient's discharge planning process should address anticipated problems after discharge and suggested means for intervention, i.e., accessibility and availability of community resources and support systems including transportation, special problems related to the patient's functional ability to participate in aftercare planning.

The discharge summary and/or plan should contain information about the status of the patient on the day of discharge, including psychiatric, physical and functional condition.

A-1680
(Rev.)

§482.62 Condition of Participation: Special Staff Requirements for Psychiatric Hospitals

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.

Interpretive Guidelines §482.62

The purpose of this Condition of Participation is to ensure that the psychiatric hospital is adequately staffed with qualified mental health professionals and supportive staff to carry out an intensive and comprehensive active treatment program and to protect and promote the physical and mental health of the patients.

Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Review incident reports, medication error reports, patient and staff injury reports, for indications that staffing is an issue.

Adequate numbers are defined to mean the numbers, and deployment, of staff with qualifications to evaluate, plan, implement and document active treatment.

Do not look at numbers alone. The hospital is responsible for organizing its available staff and administrative duties along with patient appointments, treatment plan meetings, treatment sessions, activities, materials, equipment and patient assignments to wards and groups in such a way that results in patients achieving the maximum therapeutic benefit.

Survey Procedure §482.62

Assess the adequacy of the Special Staffing Condition by:

1. Observing sampled patients and others during structured sessions and in unstructured settings. You should be able to observe behavioral evidence of a rational organization of resources.
2. Next, interview patients and staff to determine whether or not necessary treatment modalities and other services are being provided in a timely manner.
3. Next review the medical records of patients in the sample to ascertain if necessary active treatment assessments, treatments, evaluations and activities have been conducted and documented.
4. Also, review other records such as restraint and seclusion records, incident reports, medication error reports, reports of patient/staff injuries, etc., to determine the extent to which staffing levels or deployment contributed to negative patient outcomes.
5. Evaluate all outcome data in light of the success or failure observed during the survey relevant to each patient receiving active treatment, and achieving desired outcomes of care. This is the primary basis for evaluating the adequacy of the hospital's staffing under this Special Condition.

A-1685
(Rev.)

§482.62(a)(1) Standard: Personnel. *The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:*
(1) Evaluate Patients.

Interpretive Guidelines §482.62(a)(1)
Guidance is pending and will be updated in future release

Survey Procedures §482.62(a)(1)

Is there adequate staff to assure that the admission work-ups (assessment, diagnostic data gathering) are completed in a timely manner?

Is there evidence that there is continuing evaluation of the patient's progress and response to treatment?

Are evaluations delayed or absent?

A-1686
(Rev.)

§482.62(a)(2) *[The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:]*

(2) Formulate written individualized, comprehensive treatment plans;

Interpretive Guidelines §482.62(a)(2)

Staffing must be sufficient so that members of the patient's treatment team and others responsible for evaluation and assessment can contribute their respective data for consideration in the formulation of the treatment plan.

Survey Procedures §482.62(a)(2)

Was there sufficient discipline participation at the treatment team meeting to assure formulation of a treatment plan that meets the patient's individualized needs?

What problems prevent staff members from attending treatment meetings? Do they relate to staffing?

Are the assessments/evaluations absent or delayed to the extent that they are not useful to the treatment team for the purpose of planning individualized treatment?

A-1687

(Rev.)

§482.62(a)(3) [The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:]

(3) Provide active treatment measures; and

Interpretive Guidelines §482.62(a)(3)

Active treatment occurs when the patient receives treatment interventions that are delivered under the direction of a physician, and which are specific to patient strengths, disabilities, and problems identified in the treatment plan. Treatment interventions and other services are furnished in accordance with accepted standards of professional practice. Although the active treatment process must be identifiable in documentation, it must be first and foremost observable and evident in daily practice.

Treatment interventions need to be individualized, in that the patient receives assistance with resolving or ameliorating the problems/circumstances that led to hospitalization. Expect to see treatment focused on the unique needs of individual patients. For example, several patients may be referred to "Anger Management Group," but the focus of discussion and therapeutic intervention may differ depending on the individual patient's particular issue regarding managing anger.

Whether structure must be imposed by staff or whether the patient can direct his or her own activities for periods of time (without staff supervision), is based on the patient's ability to engage in constructive, appropriate behavior (without engaging in harm to self or others). Be certain that the patient's time on the unit is maximized toward the further development of appropriate desired outcomes, including but not limited to leisure and recreation.

Survey Procedures §482.62(a)(3)

Through observation, interviews and record reviews, can you determine that patients receive active treatment?

Is the distribution of staff consistent with particular patient needs? Is appropriate staffing sufficient to carry out treatment plans?

Does the patient attend therapies that are relevant to the identified problems that brought the patient to the hospital?

Are staff absences and/or vacancies preventing the patient from receiving active treatment? Are patients not attending therapeutic activities off the unit because there is no staff to escort them? Are therapeutic groups not available on the unit for patients who are not able to go off the unit?

Are patients observed not engaged in activities while staff attend to administrative tasks?

Are active treatment sessions or activities carried out at discrete time intervals exclusively? Or is active treatment implemented as the patient's needs emerge during the course of the day, as well?

Does a review of quality assurance data reveal a pattern of serious incidents occurring on particular shifts and/or days of the week?

What do patients report to the surveyor are their treatment modalities?

Do patient interviews indicate that patients believe the treatment being provided is helpful?

Does the scheduling of activities and their content relate directly to the patient's treatment objectives or are the activities/content generalized, non-therapeutic "time-fillers"?

Can staff describe how their activities relate to the patient's treatment objectives?

At any point in time, in any of the patient's experiences in the hospital is the thrust of the patient's treatment plan observable during the staff and/or patient interactions?

Is there a consistent, observable pattern of evidence that hospital staff provide, reinforce and otherwise implement measures to achieve active treatment objectives?

A-1688

(Rev.)

§482.62(a)(4) [The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:]

(4) Engage in discharge planning.

Interpretive Guidelines §482.62(a)(4)

The patient together with all relevant professionals caring for the patient should be expected to participate in the discharge planning process. Staffing should be sufficient to facilitate this outcome, to the maximum extent possible.

Survey Procedures §482.62(a)(4)

Do patients participate in their discharge planning process? If not, why?

Do staff interviews elicit information that staff working with patients are aware of the discharge plans for those patients?

Do record review and interviews indicate that all relevant staff have participated in discharge planning?

A-1690

(Rev.)

§482.62(b) Standard: Director of inpatient psychiatric services; medical staff. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program...

Interpretive Guidelines §482.62(b)

Inpatient psychiatric services include the following functions: admission interviews, assessments and evaluations; psychiatric and medical work-ups; treatment team leadership; medication management; on-call provision of emergency psychiatric and medical treatment; provision of individual, group and family therapies; provision of clinical supervision to other professionals and paraprofessionals; provision of medical and psychiatric educational workshops and conferences for all staff; and provision of consultation to staff for clinical and/or administrative matters.

The clinical director is ultimately responsible for the medical and psychiatric care that is provided to patients. The clinical director should ascertain that quality improvement programs are in place to monitor all areas of patient care, and should implement educational programs for all levels of staff.

Survey Procedure §482.62(b)

Just prior to the end of the survey, schedule a meeting with the clinical director. By the time of this meeting, you should already have conducted required observation, interviews and record reviews for at least a majority of the patients in the sample. Collect any additional information that is necessary to consider in light of outcomes observed for patients, including: the qualifications of the clinical director; the leadership exhibited for the scope of psychiatric/medical treatment programs needed by patients; and the rationale for medical staffing coverage. If necessary, follow-up on letters of complaint previously reported serious problems, discrepancies with Data Collection Medical Staff Coverage (CMS-729).

A-1691
(Rev.)

§482.62(b) ...The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

Interpretive Guidelines §482.62(b)

The number of full-time, part-time and consulting staff, who are board certified within each category and their availability to the hospital must be adequate to provide psychiatric services, as described above. Adequacy is considered in light of the following:

1. Number of admissions, discharges and current patients by treatment units;
2. Size of the hospital;
3. Geographic proximity of the wards and units;
4. Organization and kinds of treatment services rendered to the patients;
5. Availability of the physician coverage on evening, nights and weekends;
6. Availability of physicians to participate in treatment planning;
7. Availability of psychiatrists to consult with non-psychiatric physicians about psychotropic medication regimens; and
8. Availability of physicians to consult with multi-disciplinary staff about treatment issues.

Survey Procedures §482.62(b)

How many staff are board certified? Fully trained? How many full-time/part-time specialties are represented?

How are medical staff deployed? To what programs/units are they assigned? Why?

How much time do physicians spend on the units? Based on observations, interviews, and medical record reviews is coverage adequate to meet the needs of sampled patients? To meet the needs of other patients observed during the survey?

A-1692
(Rev.)

§482.62(b)(1) The clinical director, service chief or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology, or the American Osteopathic Board of Neurology and Psychiatry.

Interpretive Guidelines §482.62(b)(1)

A physician is qualified to take the examinations for board certification upon successful completion of a psychiatric residency program approved by the American Board of Psychiatry and Neurology and/or the American Osteopathic Board of Psychiatry and Neurology.

Survey Procedures §482.62(b)(1)

Review the clinical director's personnel folder or ask the clinical director if he/she has one of the following:

- a. Certification of the American Board of Psychiatry and Neurology and/or certification of the American Osteopathic Board of Neurology and Psychiatry.
- b. If no certification, evidence that the person took the Boards would satisfy that the person had the training and equivalency to be admitted to the board examination.
- c. If indicated, medical school and residency training
- d. Length of time he has been employed at the facility; length of time he has been at his position

To be admitted to the American Board Examinations the following conditions must be met:

1. License without restrictions
2. Graduation from a medical school approved by either the Medical Osteopathic Association or the American Medical Association.
3. A successful completion of an approved residency-training program for at least 3 years before 1988 that the American Council on Graduate Medical Education (ACGME) approves. After 1988, it has to be a four year accredited program.

A-1693

(Rev.)

§482.62(b)(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

Interpretive Guidelines §482.62(b)(2)

Services and treatment prescribed to patients must be in accordance with appropriate and acceptable standards of practice.

In states that allow psychologists to have admitting privileges, it is still the responsibility of the clinical director to oversee the quality of the patient's treatment.

Survey Procedures §482.62 (b)(2)

What mechanisms does the director use to monitor and evaluate the work of the medical staff (personal interviews? Quality Improvement reports? incident reports?)?

When problems are discovered by the clinical director, how are they corrected?

Are services, notes, and reports timely?

Are medications used appropriately for the patient's diagnosis?

A-1695
(Rev.)

§482.62(c) Standard: Availability of medical personnel. Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic services and treatment are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

Interpretive Guidelines §482.62(c)

Contracts or other arrangements with individuals and/or providers assure that medical and surgical services are available to meet the needs of the patients. Review the medical and surgical services provided by the hospital during the interview with the clinical director.

Discuss contract or arrangements with the clinical director for services provided off grounds.

Survey Procedures §482.62(c)

How did the hospital meet the medical/surgical/diagnostic needs represented by each patient in the sample? Were these done timely? Appropriately?

If contracts are not current or available, how are these services provided for the patient, if needed? Is there evidence of negative outcomes as a result of these arrangements?

Are reports from other services such as pharmacy, radiology, and clinical laboratory timely? Appropriate?

A-1700
(Rev.)

§482.62(d) Standard: Nursing services. The hospital or unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

Interpretive Guidelines §482.62(d)

Psychiatric nursing functions may include the following: supervision of paraprofessional staff; assessment, planning, provision, and evaluation of psychiatric nursing care to patients; medication teaching; management of the therapeutic milieu; provision of mandatory and voluntary in-service training to all staff; and provision of specialized

treatments and therapies, such as individual, group and family therapies, that require the clinical expertise of a professional psychiatric nurse.

Expect to see evidence of orientation programs as well as ongoing continuing education programs for Licensed Practical Nurses and mental health workers that stress individualized treatment interventions.

Determine that there is a qualified Director of Nursing (DON) providing the required leadership and supervision for the psychiatric nursing department.

A-1701
(Rev.)

§482.62(d)(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill . . .

Interpretive Guidelines §482.62(d)(1)

During the interview with the DON, assess his/her educational background and psychiatric nursing and leadership skills. If the DON has less than a Master's Degree in Psychiatric Nursing, expect to see evidence of experience and on-going training in psychiatric nursing. Documented consultation from a nurse with a Master's in Psychiatric Nursing constitutes on-going training.

Survey Procedures §482.62(d)(1)

Are nursing assessments completed on all patients?

Do the multidisciplinary treatment plans reflect nursing input which include specific nursing interventions for nursing problems (e.g. violence toward self/others, physical/medical crises)?

Is nursing care evaluated by an R.N., with changes in the care based on the patient's progress or lack thereof?

Are intrusive techniques (e.g. seclusion, restraint, electroconvulsive therapy (ECT), and/or medical procedures) and patient incidents (e.g. medication errors, patient falls, patient-to-patient and patient-to-staff injuries) monitored in accordance with hospital policy, State statutes and safe nursing practice?

Are nursing personnel observed relating to patients in a therapeutic manner?

A-1702
(Rev.)

§482.62(d)(1) . . . The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

Interpretive Guidelines §482.62(d)(1)

Based on structured observations of the patients in the sample and other patients in the hospital, patient and staff interviews and medical record review, ascertain that nursing services are provided in accordance with safe, acceptable standards of nursing practice.

Information obtained from the DON should include: implementation of continuous quality improvement programs; provision of orientation, in-service and continuing education programs for nursing personnel especially in the areas of psychiatric nursing, nursing process, prevention and management of violence, CPR and Universal Precautions.

A-1703

(Rev.)

§482.62(d)(2) The staffing pattern must ensure the availability of a registered nurse 24 hours each day. . . .

Interpretive Guidelines §482.62(d)(2)

Guidance is pending and will be updated in future release

A-1704

(Rev.)

§482.62(d)(2) . . . There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

Interpretive Guidelines §482.62(d)(2)

The evaluation of sufficient numbers and level of RNs, LPNs and mental health workers is based on the patient characteristics as seen in structured observations of patients in the sample and other patients in the hospital, patient interviews, and as evidenced in medical records and other data related to patients (e.g. incident reports, seclusion/restraint reports). Patient care assignments should be appropriate to the skills and qualifications of the nursing personnel providing patient care.

There should be evidence that all nursing personnel have education, experience and/or training in psychiatric care. Mental health workers spend the majority of their workday interacting with patients. Expect to see evidence that they are receiving on-going supervision and training. Mental health workers should be assigned patient care duties and therapeutic modalities that reflect their educational level, psychiatric training, and experience.

Survey Procedure §482.62(d)(2)

The nursing staffing patterns should be reviewed on a sample of approximately 25% of the certified wards. The staffing, including levels of nursing personnel, should be reviewed for the day(s) of the survey and evaluated based on the level of needs presented by the patients. Additional staffing patterns shall be reviewed if a problem or concern is evidenced. Decisions regarding extent of additional data (number of wards and dates) to be reviewed shall be based on the degree of problem/concern. Patient need assessment/patient acuity shall be reviewed for any wards as deemed necessary based on problems/concerns found in the sampling review.

If your observations and/or interviews indicate a staffing problem, you may want to consider the following variables in assessing adequacy of nursing personnel coverage:

1. Organization and types of services provided to patients by the nursing department;
2. Number and levels of nursing care needs of patients, including average length of stay, acuity of patients and nursing care requirements;
3. Number and levels of nursing personnel based on the roles and functions required of nursing;
4. Number of suicidal/assaultive patients;
5. Seclusion/restraint incidents;
6. Number of admissions and discharges;
7. Number and type of accidents and/or injuries;
8. Amount and complexity of medication regimens;
9. Medication errors;
10. Use of P.R.N. (as needed) medications;
11. Medical (physical) procedures;
12. Assignment and utilization of “pool” nursing personnel (those staff who are hired through a contract service and are not employees of the hospital). Contractual staff should receive orientation and training necessary for assigned functions, and should be supervised by employees of the hospital;
13. Availability of RNs to supervise/consult with nursing/non-nursing personnel about patient care;
14. Availability of RNs to assess and implement care in crisis situations;
15. Availability of RNs to interact with patients in structured activities; and
16. Involvement of patients with personnel.

A-1710
(Rev.)

§482.62(e) Standard: Psychological Services.

The hospital must provide or have available psychological services to meet the needs of the patients.

Interpretive Guidelines §482.62(e)

Psychology services may include the following: diagnostic testing and diagnostic formulations on request from physicians; provision of individual, group and family

therapies; participation in multi-disciplinary treatment conferences; and program development and evaluation.

The number of full-time, part-time and consulting psychologists must be adequate to provide necessary services to patients. Arrangements with outside resources must assure that necessary patient services will be provided.

Survey Procedures §482.62(e)

Did the patients in the sample have a need for psychological services or testing? Were they provided in a timely manner and with sufficient intensity?

Did any of the patients in the sample indicate a need for psychological services, but none were requested?

What types of psychological services are offered? (e.g., assessments, therapy)

Do certain groups of patients receive testing routinely? Dementia?, Children?, Adolescents? Why?

Once tests are performed, are results reported in sufficient time to be integrated in the patient's active treatment and treatment plan?

How does the hospital or Psychological Service Department determine whether or not: it meets the needs of patients? Its services are underutilized or over-utilized?

Why have psychological services staff been deployed in the manner that they have?

***A-1715
(Rev.)***

§482.62(f) Standard: Social Services. There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

Interpretive Guidelines §482.62(f)

Social work functions may include the following functions: Intake or admission screening, psychosocial assessment of a newly admitted patient; developing an update or detailed re-assessment of the patient; high-social risk case finding; contact with family and others significant in the patient's life. Such functions may include patient and family education, support, and advocacy; providing coordination/liaison with community-based social and mental health agency(ies) regarding the pre-admission status of the patient; participating as a member of the treatment team in development of treatment planning and subsequent planned interventions (modalities). Such modalities may include supportive, individual, couple, family, or group therapy, aimed at meeting specified goals identified in the treatment plan.

Continuity of care is an important social work principle and may be demonstrated through case management and a major role in discharge planning. Activities, in conjunction with the patient wishes, may include contact with patient's family, identifying and assisting in referral of the patient to community-based agency(ies) at the time of discharge. Finally, post-discharge follow-up may be done to assure that linkage of the patient with community resources has occurred to reduce re-hospitalization.

Determine who completed the assessment required by §482.61(a)(4) and initiated preliminary discharge planning. When staff other than a Social Worker perform these duties, the Director of Social Work or a Master's level social worker (MSW) qualified supervisory staff member should be involved to oversee the quality and appropriateness of service provided.

Patient and staff interviews, structured observations and review of selected medical records yield the information necessary to determine how well social work has met the needs of the patients. The surveyor should evaluate these data to determine adequacy of qualified and support staff deployed to patient areas and their duties.

The social work policies for service provision to the patient should describe: the organizational structure of the department (program) and the range of services performed by the department.

Survey Procedure §482.62(f)

Just prior to the end of the survey, schedule a meeting with the Director of Social Work. By the time of the meeting, you should already have conducted required observations, interviews and record reviews for at least a majority of the patients in the sample. Collect any additional information that is necessary to consider in light of outcomes observed for patients, including: the qualifications of the director; the leadership exhibited for the scope of services needed by the patient; and the rationale for social work staffing coverage.

How does the director periodically audit the quality of social work services furnished?

What are the outcomes of audits conducted? What percentage of psychosocial assessments was completed and available in written form at the time of the interdisciplinary treatment plan? How does the patient's social needs as addressed by the social worker in the psychosocial assessment compare against the goals developed in the interdisciplinary treatment plan?

Has social work staff provided active treatment in accordance with the patient's treatment plan?

Accepted standards of practice are based on policy statements adopted by the National Association of Social Workers and a definition of social work practice in health care

adapted by the Consortium of Health Care Social Work Organizations. Staff should adhere to the facility's personnel requirements.

A-1716
(Rev.)

§482.62(f)(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a master's degree in social work, at least one staff member must have this qualification.

Interpretive Guidelines §482.62(f)(1)

The duties, functions, and responsibilities of the director of social services/social work should be clearly delineated and documented in the facility's policies and procedures. If the director is not MSW qualified and at least one staff member is MSW qualified, verify the duties, functions, and responsibilities of the MSW.

Survey Procedures §482.62(f)(1)

What are the director's qualifications, experience and scope of duties within this position?

If a MSW staff member, other than the director, is performing any of these duties, what are this staff member's experience and scope of duties performed? Why were these duties delegated?

To what extent is the director's knowledge of the social work needs of the various wards? Why has the social work staff and services provided throughout the hospital been deployed in the manner it has?

A-1717
(Rev.)

§482.62(f)(2) Social service staff responsibilities must include, but are not limited to, participating in discharge, planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

Interpretive Guidelines §482.62(f)(2)

Social work contact with the patient, family, and significant others should occur during, or as soon as possible, after the admission. High-risk case finding should result in significant data being available for early integration into the treatment plan and subsequent social work action as indicated. The treatment team should consider, for possible inclusion into the patient's treatment plan, the anticipated social work role and expected interventions as recommended in the psychosocial assessment . Treatment and

discharge planning activities, liaison/follow-up efforts should be based upon the goals, including discharge goals, and staff responsibilities specified in the treatment plan.

Survey Procedures §482.62(f)(2)

Are social work staff routinely involved in providing services to the patient that are identified in the treatment plan?

To what extent do social work staff provide discharge planning services to the patient in the way of: supportive individual, couple, family, or group therapy focused on discharge goals of the patient? Carrying out a liaison role with community resource providers?

Have social work staff assured that adequate information is provided to post-hospital patient service providers?

A-1720

(Rev.)

§482.62(g) Standard: Therapeutic Activities.

The hospital must provide a therapeutic activities program.

Interpretive Guidelines §482.62(g)

A variety of therapeutic and rehabilitative activities are selectively used as therapeutic tools in providing active treatment to the psychiatric patients. Therapeutic activities focus upon the development and maintenance of adaptive skills that will improve the patient's functioning. In contrast, leisure activities provide the patient with individualized opportunities to acquire knowledge, skills and attitudes about meaningful leisure involvement and experiences. A patient may need treatment and/or remediation of functional behavior(s) prior to leisure involvement. However, for some psychiatric patients the priority need may be for leisure education and activities.

A-1725

(Rev.)

§482.62(g)(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

Interpretive Guidelines §482.62(g)(1)

The hospital is responsible for ensuring consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient needs.

The selection of individualized therapeutic and rehabilitative staff modalities should be based on patient need and goals set in the patient's treatment plan. Rehabilitative services may include educational, occupational, recreational, physical, art, dance, music, and speech therapies and vocational rehabilitation evaluation and counseling. There are other disciplines that also serve *patients*. Consultants include but are not limited to the

following: educational instructors, registered occupational therapist/certified occupational therapy assistant, certified therapeutic recreation specialist, certified therapeutic recreation assistant, speech-language pathologist has certificate of clinical competence, registered and certified music therapist, registered art therapist, and registered physical therapist. The qualified vocational specialist may perform duties of a rehabilitation counselor, vocational evaluator, or the work adjustment specialist.

A-1726
(Rev.)

§482.62(g)(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

Interpretive Guidelines §482.62(g)(2)

Qualified staff should complete their respective discipline assessments for use in multidisciplinary treatment planning. Specific role(s) and modalities to be implemented by rehabilitative staff must be determined by goals set in the patient's treatment plan.

Qualified therapists who provide clinical services and administrative staff should utilize established monitoring and evaluation mechanisms to conduct consistent timely review of the quality and appropriateness of therapeutic and rehabilitative services delivered to patients.

Survey Procedures §482.62(g)(2)

Is there evidence that sampled patients and staff are familiar with the goals and staff interventions described in the patient's treatment plan? Are these observed interventions being carried out? What is the patient's response? Are these interventions and activities of sufficient frequency and intensity to achieve maximum therapeutic benefit?

What are the qualifications, experience, duties and responsibilities of the Therapeutic Activities Director and discipline supervisor(s)?

How is the program organized?

Did the patients in the sample have a need for any therapeutic activities? Were their needs met?

Did any of the patients in the sample indicate a need for therapeutic activities, but none were considered?

What kinds of services are provided to the patient population?

Are activity areas/sites accessible and available to meet the patient's individual needs? Are the facilities and resources adequate to enable implementation of goals set in the patient's treatment plan?

Does the program utilize available community resources to provide opportunities for socialization, leisure, and therapeutic and/or rehabilitation activities for patients who can participate outside the hospital setting?

Are current activity schedules clearly posted for patient and staff reference and use? Are the scheduled activities related to the particular patient area and specific treatment needs of patients?

Are patient needs met consistently at all times including evenings and weekends?

If a large number of patients are assigned to the same therapeutic activity, do patients have individualized goals within their treatment plans?

Why have therapeutic activities staff been deployed in the manner they have?

State Operations Manual

Appendix B – Guidance for Surveyors: Home Health Agencies (HHAs)

(Rev.)

Subpart A--General Provisions

§484.1 Basis and scope

§484.2 Definitions

Pseudo patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must demonstrate the general characteristics of the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.

Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

G420

(Rev.)

§484.50(a)(3)

[Removed and reserved, see 84 FR 51732, at 51825 (Sept. 30, 2019)]

G440

(Rev.)

§484.50(c)(7) Be advised, *orally and in writing*, of—

(i) The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other Federally-funded or Federal aid program known to the HHA,

(ii) The charges for services that may not be covered by Medicare, Medicaid, or any other Federally-funded or Federal aid program known to the HHA,

(iii) The charges the individual may have to pay before care is initiated; and

(iv) Any changes in the information provided in accordance with paragraph (c)(7) of this section when they occur. The HHA must advise the patient and representative (if any), of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and 42 CFR 411.408(f).

Interpretive Guidelines §484.50(c)(7)

Guidance is pending and will be updated in a future release.

G560

(Rev.)

§ 484.58 Condition of participation: Discharge planning.

G562

(Rev.)

(a) Standard: Discharge planning. A home health agency must develop and implement an effective discharge planning process. For patients who are transferred to another HHA or who are discharged to a SNF, IRF or LTCH, the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The HHA must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

G564
(Rev.)

(b) Standard: Discharge or transfer summary content.

(1) The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.

(2) The HHA must comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

G768
(Rev.)

§484.80(c)(1)

§484.80(c) Standard: Competency evaluation.

An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

- (1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient *or pseudo-patient*. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient, *or with a pseudo-patient as part of a simulation*.**

Interpretive Guidelines §484.80(c)

Guidance is pending and will be updated in a future release.

G816
(Rev.)

§484.80(h)(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, *retraining and* a competency evaluation *related to the deficient skill(s)*.

State Operations Manual

Appendix D - Guidance for Surveyors: Portable X-Ray (PXR) *(Rev.)*

H0021 *(Rev.)*

§486.104(a) Standard - Qualifications of Technologists.

All operators of the portable X-ray equipment meet the requirements of paragraphs (a)(1) or (2) of this section:

(1) Successful completion of a program of formal training in X-ray technology *at which the operator received appropriate training and demonstrated competence in the use of equipment and administration of portable x-ray procedures; or*

(2) *Successful completion of 24 full months of training and experience under the direct supervision of a physician who is certified in radiology or who possesses qualifications which are equivalent to those required for such certification.*

H0037 *(Rev.)*

§486.106 Condition for Coverage: Referral for service and preservation of records.

All portable X-ray services performed for Medicare beneficiaries are ordered by a physician or a non-physician practitioner as provided in §410.32(a) of this chapter or by a non-physician practitioner as provided in §410.32(a)(2) and records are properly preserved.

Interpretive Guidelines §486.106

Guidance is pending and will be updated in a future release.

H0038 *(Rev.)*

§486.106(a) Standard - referral by a physician *or non-physician practitioners.*

Portable X-ray examinations are performed only on the order of a *physician* licensed to practice in the State *or by a non-physician practitioner acting within the scope of State law. Such non-physician practitioners may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.* The supplier's records show that:

- (1) The *portable* X-ray test was ordered by *a physician or a non-physician practitioner acting within the State scope of law*; and
- (2) *Such physician or non-physician practitioner's order meets the requirements at § 410.32 of this chapter, and includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.*

H0039
(Rev.)

§486.106(b) Standard - records of examinations performed.

The supplier makes for each patient a record of the date of the *portable* X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician *or non-physician practitioner*, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

State Operations Manual

Appendix G - Guidance *for* Surveyors: Rural Health Clinics (RHCs)

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[§ 491.8(b) Physician responsibilities. The physician performs the following:]

- (2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's . . . written policies and the services provided to Federal program patients.

[§ 491.8(c) Physician assistant and nurse practitioner responsibilities.]

(1) The physician assistant and the nurse practitioner members of the clinic's . . . staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic . . . furnishes;

[§ 491.9(b) Patient care policies . . .]

(1) The clinic's ... health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic . . . staff.

(4) These policies are reviewed at least *biennially* by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic . . .

Interpretative Guidelines § 491.8(b)(2) & (c)(1)(i), § 491.9(b)(1), (2) & (4)

The clinic must have written policies governing the clinical services provided. At least one RHC physician and one RHC PA or NP must participate in the development of the clinic's written policies and providing advice to the RHC's management on appropriate clinical policies. In addition, there must be at least one physician, NP, or PA who is not on the RHC's staff who participates in the development of the clinical policies. The clinic must identify in writing the names of all individuals involved in developing clinical policies. The clinical practitioners who participate in the policy development provide advice to the RHC's leadership. The RHC's leadership is not required to accept this advice, but if it exercises its authority to reject or modify the patient care policy advice of the practitioners it must be able to ensure that any changes it makes are clinically appropriate and supportable.

The clinic's patient care policies must be reviewed at least *biennially* or more frequently when appropriate, by a group that also contains at least one RHC physician, one RHC NP or PA, and one outside healthcare practitioner.

Survey Procedures § 491.8(b)(2) & (c)(1)(i), § 491.9(b)(1), (2) & (4)

- Review meeting minutes or other documentation to verify that the required types of practitioners actually participated at least *biennially* in developing the policies and recommending policies to the RHC's leadership.

- Ask the RHC's leadership if it ever rejects the advice of the practitioners. If yes, how does it ensure that any changes made are clinically appropriate? Does it document the rationale for its rejection of the advice? Is there documentation of the policies recommended by the practitioners as well as of any changes made by the RHC's leadership?

J-0125

(Rev.)

[§ 491.9(b) Patient care policies.]

(3) The policies include:

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

Interpretive Guidelines § 491.9(b)(3)(iii)

The RHC's written patient care policies must address storage, handling, and administration of drugs and biologicals within the RHC. The policies must be in accordance with accepted professional principles of pharmacy and medication administration practices. Accepted professional principles include compliance with applicable Federal and State law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (USP) (www.usp.org); the American Society of Health-System Pharmacists (<http://www.ashp.org/>); the Institute for Safe Medication Practices (<http://www.ismp.org/default.asp>); the National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (<http://www.ihl.org/ihl>); and the Infusion Nurses Society (<http://www.insl.org>).

The RHC's policies must address the following:

Storage of drugs and biologicals

Consistent with accepted professional principles, RHC's must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

Proper environmental conditions

Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the RHC is expected to follow the labelled conditions. RHC's must exercise caution in administering any drug or biological that is not labelled to indicate proper storage conditions or that may have been stored under inadequate conditions.

Security

The RHC must have policies and procedures that are consistent with State and Federal law to address how drugs and biologicals are stored and secured, including who is authorized access to the drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional, they are generally considered secure. Areas restricted to authorized personnel only would generally be considered “secure areas.”

RHCs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff members are actively providing care to patients or preparing to receive patients, i.e. setting up for injections, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked, in accordance with state and Federal law.

If the RHC uses cart(s) containing drugs or biologicals, whenever the cart is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be within close eyesight of and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and RHC policy is authorized access to the drugs and biologicals in the cart. That individual must monitor the cart and be aware of other people’s activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

Record keeping for the receipt and disposition of all scheduled drugs.

The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five “schedules,” ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.

The RHC is required to accurately track the receipt and disposition of all scheduled drugs used in the RHC. Components of a record system for scheduled drugs would include:

- Locked storage of scheduled drugs when not in use;
- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs;

- Tracking movement of all scheduled drugs from the point of entry into the RHC to the point of departure either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
- Prompt reconciliation of any discrepancies in count. The RHC is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

Handling drugs and biologicals.

“Handling” includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug’s manufacturer.

Compounding

“Handling” also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either facility staff or a contracted pharmacy service.

Generally, RHCs are not settings that use compounded sterile preparations (CSPs) nor are CSPs typically furnished as part of the RHC’s services. However, some RHCs may provide additional services beyond RHC services and these might include use of CSPs. If an RHC uses CSPs, it is responsible to ensure that compounding is performed consistent with accepted professional principles.

Generally even if an RHC uses CSPs, it would not be likely to have its own pharmacy that could meet the *standards of practice* for preparation of CSPs; it is more likely that an RHC that uses CSPs would be acquiring them from an external source. The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an “outsourcing facility.” The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities:

- Must comply with the FDA’s Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA’s publishes the most current versions of its draft and final regulations and guidance related to compounding on its website:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>;

- Will be inspected by FDA according to a risk-based schedule; and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

In a January 2014 letter to purchasers of compounded medications (available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm>), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that, “[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling.”

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at: <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding>.

Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.”

Use of Compounding Pharmacies

If an RHC uses compounded medications and obtains them from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the RHC must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- Ensuring that the RHC has access to quality assurance data verifying that the vendor is adhering to *standards of practice for compounding medications*, and can the *RHC* document that it obtains and reviews such data?
- Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

Note that these types of compounding pharmacies are also popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board.

Expiration & Beyond Use Dates

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer’s approved labeling.

A drug or biological is also outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available.

Basic safe practices for medication administration within the RHC

The RHC’s patient care policies must reflect accepted standards of practice that require the following information be confirmed prior to each administration of medication that takes place in the RHC (such as administration of vaccines or medications via injection):

- **Right patient:** ensuring the patient’s identity. Acceptable patient identifiers include, but are not limited to: the patient’s full name; an identification number assigned by the RHC; or date of birth. Identifiers must be confirmed by patient identification card, patient statement (when possible), or other means outlined in the RHC’s policy. The patient’s identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.
- **Right medication:** the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;
- **Right dose:** the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);

- Right route: the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc. - is the appropriate one for that particular medication and patient; and
- Right time: the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

Note: the “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error.

RHCs are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly.

Survey Procedures § 491.9(b)(3)(iii)

- Are drugs and biologicals stored in a secure manner?
 - Are drugs stored in areas not accessible to unauthorized personnel?
 - When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked up?
 - Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.
- When applicable, determine if the RHC has a system that tracks movement of all scheduled drugs from the point of entry into the RHC to the point of departure, either through administration to the patient, destruction of the drug, or return to the manufacturer.
 - Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs?
 - Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the RHC to reconcile and address the discrepancies?
- Interview the person responsible for drug storage as well as other RHC staff to determine their understanding of the RHC’s controlled drug policies.

- If the RHC uses CSPs and obtains them from an external source that is not an FDA registered outsourcing facility, can it demonstrate that it systematically evaluates and monitors whether these sources adhere to accepted professional principles for safe compounding?
- Spot-check to identify if expired or unusable medications, including when applicable medications that are past their BUD, are being used for patient care in the RHC.
- Ask what type of personnel administer drugs and biologicals within the RHC, including, if applicable, IVs. Are they practicing within their permitted scope?
- Observe medication administration to verify whether staff members confirm the “5 rights” of medication administration, i.e., the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the RHC’s policies and procedures?

J-0161

(Rev.)

§491.11(a) The clinic . . . carries out, or arranges for, a *biennial* evaluation of its total program.

(b) The evaluation includes review of:

- (1) The utilization of clinic . . . services, including at least the number of patients served and the volume of services;**
- (2) A representative sample of both active and closed clinical records; and**
- (3) The clinic’s . . . health care policies.**

(c) The purpose of the review is to determine whether:

- (1) The utilization of services was appropriate;**
- (2) The established policies were followed; and**
- (3) Any changes are needed.**

Interpretative Guidelines §491.11(a) - (c)

The clinic’s program evaluation must be reviewed at least biennially. This evaluation may be done by RHC staff or through arrangement with other appropriate professionals. The RHC must have documentation of who conducts the review or portions of the review, and what their qualifications are to do so.

The evaluation must include, at a minimum, the number of patients served and the volume of services provided. The evaluation should be able to determine whether the RHC provides appropriate types and volume of services based upon the needs of its patient population. It should also be able to evaluate whether RHC patient policies were followed and whether or not changes to the policies or to procedures are warranted.

A RHC that has been certified for less than one year may not have done a program evaluation. However, the RHC must have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered within the evaluation.

The evaluation must also include a review of a representative sample of both active and closed clinical records of RHC patients. The sample must also include at least 5 percent of the RHC's current patients or 50 records, whichever is less. The purpose of the review is to determine whether utilization of the RHC's services was appropriate, i.e., whether practitioners adhere to accepted standards of practice and adhere to the RHC's guidelines for medical management when diagnosing or treating patients. The review also must evaluate whether all personnel providing direct patient care adhere to the RHC's patient care policies. The evaluation of practitioners must be conducted by an MD or DO; if there is only one MD or DO practicing in the RHC, it is expected that the RHC will arrange for an outside MD/DO to review the selected sample of records of RHC patients cared for by the RHC's MD/DO. The evaluation of whether the RHC's patient care policies were followed may be conducted by an MD/DO, a non-physician practitioner, an RN, or other personnel who meet the RHC's qualifications criteria.

The evaluation findings must be documented in a summary report, and must include recommendations, if any, for corrective actions to address problems identified in the evaluation. If a RHC has developed a QAPI program and that program meets/exceeds the regulatory requirements for a Program Evaluation, the QAPI program would be acceptable.

Survey Procedures § 491.11 (a) - (c)

- Is there evidence that the evaluation *is completed at least biennially and* includes review of the number of patients served and the volume of services provided?
- Is there evidence of a review of a representative sample of RHC records?
- Does the sample include the required minimum number of records?
- Who conducts which portions of the review? Are they qualified to do so?
- Is there evidence of findings and recommendations from the review, and do the findings address each required component?

State Operations Manual

Appendix H – Guidance to Surveyors: End-Stage Renal Disease Facilities

(Rev.)

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Part II - ESRD Core Survey Process

Note: Publication of the ESRD Facility survey process is pending and will be updated in a future release.

Part I - Regulation & Interpretive Guidance

Subpart A - General Provisions

§ 494.10 Basis and Scope

(a) Statutory basis. This part is based on the following provisions:

(1) Section 299I of the Social Security Amendments of 1972 (Pub. L. 92-603), which extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation.

(2) Section 1861(e)(9) of the Act, which requires hospitals to meet such other requirements as the Secretary finds necessary in the interest of health and safety of individuals who are furnished services in the institution.

(3) Section 1861(s)(2)(F) of the Act, which describes “medical and other health services” covered under Medicare to include home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B)), including such renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid under section 1881(b)(14) to an individual with acute kidney injury (as defined in section 1834(r)(2)).

(4) Section 1862(a) of the Act, which specifies exclusions from coverage.

(5) Section 1881 of the Act, which authorizes Medicare coverage and payment for the treatment of ESRD in approved facilities, including institutional dialysis services, transplantation services, self-care home dialysis services, and the administration of erythropoiesis-stimulating agent(s).

(6) Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113), which requires Federal agencies to use technical standards that are developed or adopted by voluntary consensus standards bodies, unless their use would be inconsistent with applicable law or otherwise impractical.

(7) Section 1861(s)(2)(F) of the Act, which authorizes coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI.

(b) Scope. The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

§ 494.10 Definitions

Dialysis facility means an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in §413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services.

Discharge means the termination of patient care services by a dialysis facility or the patient voluntarily terminating dialysis when he or she no longer wants to be dialyzed by that facility.

Furnishes directly means the ESRD facility provides the service through its own staff and employees or through individuals who are under direct contract to furnish these services personally for the facility.

Home dialysis means dialysis performed at home by an ESRD patient or caregiver who has completed an appropriate course of training as described in §494.100(a) of this part.

Self-dialysis means dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in §494.100(a) of this part.

Transfer means a temporary or permanent move of a patient from one dialysis facility to another that requires a transmission of the patient's medical record to the facility receiving the patient.

V100 (Rev.)

§494.20 - Condition: Compliance with Federal, State, and local laws and regulations.

Interpretive Guidelines §494.20
Guidance is pending and will be updated in future release.

V101 (Rev.)

§494.20 – Condition: Compliance with Federal, State, and local laws and regulations.
The facility and its staff must operate and furnish services in compliance with applicable Federal, State, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements.

Interpretive Guidelines §494.20
Guidance is pending and will be updated in future release.

Subpart B—Patient Safety

V110

(Rev.)

§494.30 - Condition: Infection control.

Interpretive Guidance §494.30

Guidance is pending and will be updated in future release.

V111

(Rev.)

§494.30 - The dialysis facility must provide and monitor a sanitary environment to minimize the transmission of infectious agents within and between the unit and any adjacent hospital or other public areas.

Interpretive Guidance §494.30

Guidance is pending and will be updated in future release.

V112

(Rev.)

§494.30(a) - Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—

(1)(i) The recommendations (with the exception of screening for hepatitis C), found in “Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients,” developed by the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, volume 50, number RR05, April 27, 2001, pages 18 to 28. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. The recommendation found under section header “HBV-Infected Patients”, found on pages 27 and 28 of RR05 (“Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients”), concerning isolation rooms, must be complied with by February 9, 2009.

Interpretive Guidelines § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V113

(Rev.)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Wear disposable gloves when caring for the patient or touching the patient's equipment at the dialysis station. Staff must remove gloves and wash hands between each patient or station.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V114

(Rev.)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

A sufficient number of sinks with warm water and soap should be available to facilitate hand washing.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V115

(Rev.)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Staff members should wear gowns, face shields, eye wear, or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (e.g., during initiation and termination of dialysis, cleaning of dialyzers, and centrifugation of blood). Staff members should not eat, drink, or smoke in the dialysis treatment area or in the laboratory.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V116

(Rev.)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Items taken into the dialysis station should either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.

-- Non-disposable items that cannot be cleaned and disinfected (e.g., adhesive tape, cloth covered blood pressure cuffs) should be dedicated for use only on a single patient.

-- Unused medications (including multiple dose vials containing diluents) or supplies (syringes, alcohol swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V117

(Rev.)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Clean areas should be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled. Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.

When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient. Do not carry multiple dose medication vials from station to station.

Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V118

(Rev.)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V119
(Rev.)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

If a common supply cart is used to store clean supplies in the patient treatment area, this cart should remain in a designated area at a sufficient distance from patient stations to avoid contamination with blood. Such carts should not be moved between stations to distribute supplies.

Do not carry medication vials, syringes, alcohol swabs or supplies in pockets.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V120
(Rev.)

From CDC RR-05, as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Use external venous and arterial pressure transducer filters/protectors for each patient treatment to prevent blood contamination of the dialysis machines' pressure monitors.

If the external transducer protector becomes wet, replace immediately and inspect the protector. If fluid is visible on the side of the transducer protector that faces the machine, have qualified personnel open the machine after the treatment is completed and check for contamination. This includes inspection for possible blood contamination of the internal pressure tubing set and pressure sensing port. If contamination has occurred, the machine must be taken out of service and disinfected using either 1:100 dilution of bleach (300–600 mg/L free chlorine) or a commercially available, EPA-registered tuberculocidal germicide before reuse.

Change filters/protectors between each patient treatment, and do not reuse them. Internal transducer filters do not need to be changed routinely between patients.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V121
(Rev.)

§494.30(a)(4) – [Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—] Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—

(i) Handling, storage and disposal of potentially infectious waste; and

Interpretive Guidance § 494.30(a)(4)(i)

Guidance is pending and will be updated in future release.

V122

(Rev.)

§494.130(a)(4) – [Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—] [Maintaining procedures, in accordance with applicable State and local laws and accepted public health procedures, for the—](ii) Cleaning and disinfection of contaminated surfaces, medical devices, and equipment.

Interpretive Guidance § 494.30(a)(4)(ii)

Guidance is pending and will be updated in future release.

No Tag

§494.30(a)(3) [Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—] Patient isolation procedures to minimize the spread of infectious agents and communicable diseases;

Interpretive Guidance § 494.30(a)(3)

Guidance is pending and will be updated in future release.

V124

(Rev.)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Routine Testing for Hepatitis B

The HBV serological status (i.e. HBsAg, total anti-HBc and anti-HBs) of all patients should be known before admission to the hemodialysis unit.

Routinely test all patients [as required by the referenced schedule for routine testing for Hepatitis B Virus].

Promptly review results, and ensure that patients are managed appropriately based on their testing results.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V125
(Rev.)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Routine Testing for Hepatitis B

When a seroconversion occurs, review all patients' routine laboratory test results to identify additional cases. Investigate potential sources for infection to determine if transmission might have occurred within the dialysis unit, including review of newly infected patients' recent medical history (e.g., blood transfusion, hospitalization), history of high-risk behavior (e.g., injecting-drug use, sexual activity), and unit practices and procedures.

V126
(Rev.)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Hepatitis B Vaccination

Vaccinate all susceptible patients and staff members against hepatitis B.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V127
(Rev.)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Hepatitis B Screening: Patients and Staff

Test all vaccines [patients and staff] for anti-HBs 1-2 months after last primary vaccine dose.

-- If anti-HBs is <10 mIU/mL, consider patient or staff member susceptible, revaccinate with an additional three doses, and retest for anti-HBs.

-- If anti-HBs are ≥10 mIU/mL, consider immune, and retest patients annually.

-- Give booster dose of vaccine to patients if anti-HBs declines to <10 mIU/mL and continue to retest patients annually.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V128

(Rev.)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Isolation of HBV+ Patients

To isolate HBsAg positive patients, designate a separate room for their treatment.

For existing units in which a separate room is not possible, HBsAg positive patients should be separated from HBsAg susceptible patients in an area removed from the mainstream of activity.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V129

(Rev.)

§494.30(a)(1)(ii) - When dialysis isolation rooms as required by (a)(1)(i) are available locally that sufficiently serve the needs of patients in the geographic area, a new dialysis facility may request a waiver of such requirement. Isolation room waivers may be granted at the discretion of, and subject to, additional qualifications as may be deemed necessary by the Secretary.

Interpretive Guidance § 494.30(a)(1)(ii)

Guidance is pending and will be updated in future release.

V130

(Rev.)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i):

Isolation of HBV+ Patients

To isolate HBsAg positive patients... dedicate machines, equipment, instruments, supplies, and medications that will not be used by HBV susceptible patients.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V131

(Rev.)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Isolation of HBV+ Patients

Staff members caring for HBsAg positive patients should not care for HBV susceptible patients at the same time, including during the period when dialysis is terminated on one patient and initiated on another.

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V132

(Rev.)

From CDC RR-05, Requirements as Adopted by Reference 42 CFR 494.30(a)(1)(i):

Infection Control Training and Education

Infection control practices for hemodialysis units: intensive efforts must be made to educate new staff members and reeducate existing staff members regarding these practices.

END CDC RR-05 REQUIREMENTS

Interpretive Guidance § 494.30(a)(1)(i)

Guidance is pending and will be updated in future release.

V142

(Rev.)

§494.30(b) Standard: Oversight. The facility must—

(1) Monitor and implement biohazard and infection control policies and activities within the dialysis unit;

Interpretive Guidance § 494.30(b)(1)

Guidance is pending and will be updated in future release.

V143

(Rev.)

§494.30(b)(2) – [Standard: Oversight. The facility must -] Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

Interpretive Guidance § 494.130(b)(2)

Guidance is pending and will be updated in future release.

V144

(Rev.)

§494.30(b)(3) – [Standard: Oversight. The facility must -] Require all clinical staff to report infection control issues to the dialysis facility’s medical director (see §494.150 of this part) and the quality improvement committee.

Interpretive Guidance § 494.30(b)(3)

Guidance is pending and will be updated in future release.

V145

(Rev.)

§494.30(c) - Standard: Reporting. The facility must report incidences of communicable diseases as required by Federal, State, and local regulations.

Interpretive Guidance § 494.30(c)

Guidance is pending and will be updated in future release.

V146

(Rev.)

§494.30(a) – [Standard: Procedures for infection control. The facility must demonstrate that it follows standard infection control precautions by implementing—] (2) The “Guidelines for the Prevention of Intravascular Catheter-Related Infections” entitled “Recommendations for Placement of Intravascular Catheters in Adults and Children” parts I – IV; and “Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients,” Morbidity and Mortality Weekly Report, volume 51 number RR-10, pages 16 through 18, August 9, 2002. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection as the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). Copies may be obtained at the CMS Information Resource Center. For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html

Interpretive Guidance § 494.30(a)(2)

Guidance is pending and will be updated in future release.

V147

(Rev.)

From CDC RR-10 Requirements, as Adopted by Reference 42 CFR 494.30 (a)(2):

Recommendations for Placement of Intravascular Catheters in Adults and Children

I. Health care worker education and training

- A. Educate health-care workers regarding the ... appropriate infection control measures to prevent intravascular catheter-related infections.*
- B. Assess knowledge of and adherence to guidelines periodically for all persons who ... manage intravascular catheters.*

II. Surveillance

- A. Monitor the catheter sites visually or by palpation ... of individual patients. If patients have tenderness at the insertion site, fever without obvious source, or other manifestations suggesting local or BSI [blood stream infection], the dressing should be removed to allow thorough examination of the site.*

Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.

VI. Catheter and catheter-site care

- B. Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI (catheter related blood stream infections).*

Interpretive Guidance § 494.30(a)(2)

Guidance is pending and will be updated in future release.

VI48

(Rev.)

From CDC RR-10 Requirements, as Adopted by Reference 42 CFR 494.30(a)(2):

Central Venous Catheters, Including PICCs, Hemodialysis, and Pulmonary Artery Catheters in Adult and Pediatric Patients.

I. Surveillance

- A. Conduct surveillance ... to determine CRBSI rates, monitor trends in those rates, and assist in identifying lapses in infection-control practices.*
- B. Express ... data as the number of catheter-associated BSIs per 1,000 catheter-days for both adults and children ... to facilitate comparisons with national data in comparable patient populations and health-care settings.*
- C. Investigate events leading to unexpected life- threatening or fatal outcomes. This includes any process variation for which a recurrence would likely present an adverse outcome.*

END CDC RR-10 REQUIREMENTS

Interpretive Guidance § 494.30(a)(2)

Guidance is pending and will be updated in future release.

VI75
(Rev.)

§494.40 – Condition: Water and dialysate quality.

Interpretive Guidance § 494.40

Guidance is pending and will be updated in future release.

VI76
(Rev.)

§494.40 - The facility must be able to demonstrate the following—

(a) Standard: Water purity. Water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, “Dialysate for hemodialysis,” ANSI/AAMI RD52:2004. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552 (a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

VI77
(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4 Fluid quality

4.1 Water

4.1.1 Maximum level of chemical contaminants in water

Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall not contain chemical contaminants at concentrations in excess of those listed in ANSI/AAMI RD62 ... which is reproduced in Table 1 below.

Table 1—Maximum allowable chemical contaminant levels in water used to prepare dialysate and concentrates from powder at a dialysis facility and to reprocess dialyzers for multiple uses (Reproduced from ANSI/AAMI RD62:2001)

Contaminant	Maximum concentration (mg/L)
Calcium	2 (0.1 mEq/L)
Magnesium	4 (0.3 mEq/L)
Potassium	8 (0.2 mEq/L)
Sodium	70 (3.0 mEq/L)
Antimony	0.006
Arsenic	0.005
Barium	0.10
Beryllium	0.0004
Cadmium	0.001
Chromium	0.014
Lead	0.005
Mercury	0.0002
Selenium	0.09
Silver	0.005
Aluminum	0.01
Chloramines	0.10
Free Chlorine	0.50
Copper	0.10
Fluoride	0.20
Nitrate (as N)	2.0
Sulfate	100
Thallium	0.002
Zinc	0.10

NOTE—American National Standards are revised every three to five years. Users should consult the most recent edition of ANSI/AAMI RD62 to ensure that the levels listed in this table are still valid.

The manufacturer or supplier of a complete water treatment system should recommend a system that is capable of meeting the requirements of this clause at the time of installation given the analysis of the feed water. The system design should reflect possible seasonal variations in feed water quality.

Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the levels of chemical contaminants in the water and for complying with the requirements of this standard.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

VI78
(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4.1.2 Bacteriology of water: Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL

The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL. If those action levels are observed in the product water, corrective measures shall promptly be taken to reduce the levels

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V179

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4.1.2 Bacteriology of water

The facility medical director is responsible to ensure the manufacturer or supplier of a complete water treatment and distribution system demonstrates that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation

Following installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this standard, including those requirements related to action levels.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V180

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4.3.2.1 Bacteriology of conventional dialysate

Conventional dialysate should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration of lower than 2 EU/mL.

The action level for the total viable microbial count in conventional dialysate should be 50 CFU/mL and the action level for the endotoxin concentration should be 1 EU/mL. If levels exceeding the action levels are observed in the dialysate, corrective measures, such as disinfection and retesting, should promptly be taken to reduce the levels.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V181

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

4.3.2.2 Bacteriology of ultrapure dialysate: Ultrapure dialysate should contain a total viable microbial count lower than 0.1 CFU/mL and an endotoxin concentration lower than 0.03 EU/mL. If those limits are exceeded in ultrapure dialysate, corrective measures should be taken to reduce the levels into an acceptable range. The user is responsible for monitoring the dialysate bacteriology of the system following installation. It is incumbent on the user to establish a regular monitoring routine.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V182

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5 Equipment

5.1 General:

A dialysis facility should develop contingency plans to cover the failure of its water purification and distribution system or a critical component of that system. Such contingency plans should describe how to deal with events that completely prevent dialysis from being performed, such as failure of the facility's municipal water supply or electrical service following a natural disaster or water main break. Other plans should address how to deal with sudden changes in municipal water quality, as well as with failure of a critical component of the water purification and distribution system.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

No tag

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2 Water purification systems

5.2.1 General

Water purification systems consist of three basic sections: a pretreatment section that conditions the water supplied to the primary purification device, which may be followed by other devices that polish final water quality. The pre-treatment section commonly includes a sediment filter, cartridge filters capable of retaining particles of various sizes, a softener, and carbon adsorption beds. The primary purification process most commonly used is reverse osmosis, which may be followed by deionization and ultrafiltration for polishing the product water from the reverse osmosis system.

Whether a particular device is included in an individual water purification system will be dictated by local conditions.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V184

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

8 Environment

The water purification and storage system should be located in a secure area that is readily accessible to authorized users. The location should be chosen with a view to minimize the length and complexity of the distribution system. Access to the purification system should be restricted to those individuals responsible for monitoring and maintenance of the system.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V185
(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

8 Environment (access to ports and meters)

The layout of the water purification system should provide easy access to all components of the system, including all meters, gauges, and sampling ports used for monitoring system performance.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V186
(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

8 Environment (alarms in the treatment area)

Critical alarms, such as those associated with deionizer exhaustion or low water levels in a storage tank, should be configured to sound in the patient treatment area, as well as in the water treatment room.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V187
(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

8 Environment (schematic diagrams and labels)

Water systems should include schematic diagrams that identify components, valves, sample ports, and flow direction.

Additionally, piping should be labeled to indicate the contents of the pipe and direction of flow.

If water system manufacturers have not done so, users should label major water system components in a manner that not only identifies a device but also describes its function, how performance is verified, and what actions to take in the event performance is not within an acceptable range.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V188

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.2 Sediment filters (equipment configuration)

6.2.2 Sediment filters (monitoring)

5.2.2 Sediment filters:

Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet.

6.2.2 Sediment filters:

Sediment filters should be monitored on a periodic basis... [for a] pressure drop (ΔP) across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A backwash cycle is used to remove particulate matter from the sediment filter. The frequency of backwashing should follow the manufacturer's recommendations.

Sediment filter monitoring should include daily verification that the timer used to initiate backwashing cycles is set to the correct time of day. A log sheet should be developed to record the pressure drop measurements and timer verifications.

[Refer to RD62:2001, 4.3.8 Sediment filters:] Sediment filters shall have an opaque housing or other means to inhibit proliferation of algae.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V189

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40

(a):

5.2.3 Cartridge filters (equipment configuration)

6.2.3 Cartridge filters (monitoring)

5.2.3 Cartridge filters

The cartridge is contained within an opaque filter housing with seals to separate the feed and product water streams.

When the maximum [pressure drop] ΔP recommended by the filter manufacturer is reached, the cartridge should be replaced according to the manufacturer's instructions.

6.2.3 Cartridge filters

Cartridge filters should be monitored on a periodic.... basis for a [pressure drop] ΔP across the filter [that] can be used to determine when the filter is retaining particulate matter to the point that the filter will no longer allow the required water flow without an excessive reduction in pressure at the outlet of the filter. A marked decrease in ΔP without a corresponding decrease in flow rate may indicate a loss of filter integrity. Follow the manufacturer's recommendations concerning when to replace cartridge filters.

Replacement of the cartridge will usually be indicated by an increase in ΔP to some specified value. A log sheet should be developed to record the pressure drop measurements.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

VI90

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR

494.40(a):

5.2.4 Softeners: (auto regen/timers/salt/salt level)

6.2.4 Softeners (monitoring)

Prior to exhaustion, softeners should be restored; that is, new exchangeable sodium ions are placed on the resin by a process known as “regeneration,” which involves exposure of the resin bed to a saturated sodium chloride solution.

5.2.4 Softeners (Refer to RD62:2001, 4.3.10)

Automatically regenerated water softeners: Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.

The face of the timers used to control the regeneration cycle should be visible to the user.

6.2.4 Softeners

Timers should be checked at the beginning of each day and should be interlocked with the RO system so that the RO is stopped when a softener regeneration cycle is initiated.

The softener brine tank should be monitored daily to ensure that a saturated salt solution exists in the brine tank. Salt pellets should fill at least half the tank. Salt designated as rock salt should not be used for softener regeneration since it is not refined and typically contains sediments and other impurities that may damage O-rings and pistons and clog orifices in the softener control head.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V191 (Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40 (a):

6.2.4 Softeners: (Testing hardness/log)

Users should ensure that test accuracy and sensitivity are sufficient to satisfy the total hardness monitoring requirements of the reverse osmosis machine manufacturer. Total hardness of the water exiting the water softener should be measured at the end of each treatment day.

Water hardness test results should be recorded in a water softener log.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V192

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.5 Carbon adsorption

Two carbon beds shall be installed in series with a sample port following the first bed. A sample port shall also be installed following the second bed for use in the event of free chlorine or chloramine breaking through the first bed.

Refer to RD62:2001, 4.3.9 Carbon adsorption media: Carbon adsorption systems shall be adapted specifically to the maximum anticipated water flow rate of the system. Two carbon adsorption beds shall be installed in a series configuration.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V193

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40 (a):

5.2.5 Carbon adsorption: (banks of tanks)

Carbon beds are sometimes arranged as series-connected pairs of beds so that they need not be overly large. The beds within each pair are of equal size and water flows through them are parallel. In this situation, each pair of beds should have a minimum empty bed contact time of 5 minutes at the maximum flow rate through the bed. When series connected pairs of beds are used, the piping should be designed to minimize differences in the resistance to flow from inlet and outlet between each parallel series of beds to ensure that an equal volume of water flows through all beds.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V194

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.5 Carbon adsorption: (Iodine #900/replacement)

When granular activated carbon is used as the media, it shall have a minimum iodine number of 900. Other forms of carbon should not be used unless there is performance data to demonstrate that each adsorption bed has the capacity to reduce the chloramine concentration in the feed water to less than 0.1 mg/L when operating at the maximum anticipated flow rate for the maximum time interval between scheduled testing of the product water for chloramines.

Regenerated carbon shall not be used for hemodialysis applications.

Refer to RD62:2001, 4.3.9 Carbon adsorption media: Exhausted carbon adsorption media shall be discarded and replaced with new media according to a replacement schedule determined by regular monitoring.

Interpretive Guidelines §494.40(a)

Guidance is pending and will be updated in future release.

V195

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.5 Carbon adsorption: (10 minute EBCT)

Refer to RD62:2001, 4.3.9 Carbon adsorption media: When granulated activated carbon is used as the adsorption medium... each adsorption bed shall have an [empty bed contact time] EBCT of at least 5 minutes at the maximum product water flow rate (a total EBCT of at least 10 minutes).

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V196

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.2.5 Carbon adsorption (monitoring and testing frequency)

Testing for free chlorine, chloramine, or total chlorine should be performed at the beginning of each treatment day prior to patients initiating treatment and again prior to the beginning of each patient shift. If there are no set patient shifts, testing should be performed approximately every 4 hours.

Results of monitoring of free chlorine, chloramine, or total chlorine should be recorded in a log sheet.

Testing for free chlorine, chloramine, or total chlorine can be accomplished using the N,N-diethyl-p-phenylene-diamine (DPD) based test kits or dip-and-read test strips. On-line monitors can be used to measure chloramine concentrations. Whichever test system is used, it must have sufficient sensitivity and specificity to resolve the maximum levels described in [AAMI] 4.1.1 (Table 1) [which is a maximum level of 0.1 mg/L].

Samples should be drawn when the system has been operating for at least 15 minutes. The analysis should be performed on-site, since chloramine levels will decrease if the sample is not assayed promptly.

Interpretive Guidelines § 494.40(a)

Guidance is pending and will be updated in future release.

V197
(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.5 Carbon adsorption: (positive sample of chlorine or chloramine)

When samples from the first sampling port are positive for chlorine or chloramine, operation may be continued for a short time (up to 72 hours) until a replacement bed is installed, provided that samples from the second sampling port remain negative. The replacement bed should be placed in the second position, and the existing second bed should be moved to the first position to replace the exhausted bed. If it is not possible to rotate the position of the beds, both beds should be replaced.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V198
(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40 (a):

5.2.6 Chemical injection systems

6.2.6 Chemical injection systems

5.2.6 Chemical injection systems

Chemical injection systems consist of a reservoir that contains the chemical to be injected, a metering pump, and a mixing chamber located in the main water line. Chemical injection systems also include some means of regulating the metering pump to control the addition of a chemical. This system should be designed to tightly control the addition of the chemical. The control system should ensure that a chemical is added only when water is flowing through the pretreatment cascade and that it is added in fixed proportion to the water flow or based on some continuously monitored parameter, such as pH, using an automated control system. If an automated control system is used to inject the chemical, the controlling parameter should be independently monitored. There should also be a means of verifying that the concentrations of any residuals arising from the chemical added to the water are reduced to a safe level before the water reaches its point of use.

When acid is added to adjust pH, a mineral acid should be used.

6.2.6 Chemical injection systems

Systems for chemical injection should be monitored according to the manufacturer's instructions. If a facility designs its own system, procedures should be developed to ensure proper preparation of the chemical, adequate mixing of the injected chemical with the water flowing through the pretreatment cascade, and reduction to a safe level of the concentration of any chemical residuals before the point of water use. The facility should also verify that the injected chemical does not degrade the performance of downstream devices, including the primary purification process. The adequacy of these procedures must be verified using an independent laboratory. Verification can be accomplished by testing samples from the chemical reservoir and the water line after the point of injection for at least three batches of chemical.

When the chemical to be injected is prepared at a facility from powder or by dilution of a liquid concentrate, the chemical injection reservoir must be labeled with the name of the chemical and its concentration, the date the solution was prepared, and the name of the person who mixed the solution.

Each batch of chemical should be tested for correct formulation before use. A batch of chemical must not be used or transferred to the injection system reservoir until all tests are completed. The test results—and verification that they meet all applicable criteria—should be recorded and signed by the individual performing the tests.

Protective clothing and an appropriate environment, including ventilation adequate to meet applicable OSHA environmental exposure limits, should be provided when chemicals for injection are prepared in a dialysis facility.

Interpretive Guidelines § 494.40(a)

Guidance is pending and will be updated in future release.

V199

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.7 Reverse osmosis (configuration)

6.2.7 Reverse osmosis (monitoring)

Refer to RD62:2001, 4.3.7 Reverse osmosis: When used to prepare water for hemodialysis applications, either alone or as the last stage in a purification cascade, reverse osmosis systems shall be shown to be capable, at installation, of meeting the requirements of Table 1, when tested with the typical feed water of the user, in accordance with the methods of [AAMI] 5.2.2.

5.2.7 Reverse osmosis

Users should carefully follow the manufacturer's instructions for feed water treatment and monitoring to ensure that the RO is operated within its design parameters.

6.2.7 Reverse osmosis

All results of measurements of RO performance should be recorded daily in an operating log that permits trending and historical review.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V200

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.7 Reverse osmosis: (alarms)

6.2.7 Reverse osmosis (monitoring)

Refer to RD62:2001, 4.3.7 Reverse osmosis: Reverse osmosis devices shall be equipped with on-line monitors that allow determination of rejection rates and product water conductivity. The product water conductivity monitor should activate audible and visual alarms when the product water conductivity exceeds the preset alarm limit. The audible alarm must be audible in the patient care area when reverse osmosis is the last chemical purification process in the water treatment system. Monitors that measure resistivity or TDS may be used in place of conductivity monitors.

5.2.7 Reverse osmosis:

Refer to RD62:2001, 4.3.7 Reverse osmosis: When a reverse osmosis system is the last chemical purification process in the water treatment system, it [should] include a means to prevent patient exposure to unsafe product water, such as diversion of the product water to drain, in the event of a product water conductivity or rejection alarm.

6.2.7 Reverse osmosis:

Reverse osmosis systems should be monitored daily using continuous-reading monitors that measure product water conductivity (or total dissolved solids (TDS)).

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V201

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.2.7 Reverse osmosis: (Chemical analysis: frequency)

Chemical analysis for the contaminants listed in 4.1.1 (Table 1) should be done when the RO system is installed, when membranes are replaced, and at not less than annual intervals thereafter to ensure that the limits specified in 4.1.1 are met (see Table 1). Chemical analyses should be done when seasonal variations in source water suggest worsening quality or when rejection rates fall below 90%.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V202

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.8 Deionization: (continuous monitor resistivity)

6.2.8 Deionization (monitoring)

Refer to RD62:2001, 4.3.6 Deionization: Deionization systems, when used to prepare water for hemodialysis applications, shall be monitored continuously to produce water of one megohm/cm or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25°C.

5.2.8 Deionization

Deionization may be used to polish product water from a reverse osmosis system or may be used as a standby if the reverse osmosis system fails.

6.2.8 Deionization

Deionizers shall be monitored continuously using resistivity monitors that compensate for temperature and are equipped with audible and visual alarms. Resistivity monitors shall have a minimum sensitivity of 1.0 megohm-cm. Patients shall not be dialyzed on deionized water with resistivity less than 1.0 megohm-cm measured at the output of the deionizer

Resistivity monitor readings should be recorded on a log sheet twice each treatment day.

Interpretive Guidelines § 494.40(a)

Guidance is pending and will be updated in future release.

V203

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.8 Deionization (alarms/divert to drain)

Refer to RD62:2001, 4.3.6 Deionization:

An audible and visual alarm shall be activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use, for example by being diverted to drain. The alarm must be audible in the patient care area.

The resistivity monitor following the final deionizer bed shall be connected to an audible and visible alarm in the dialysis treatment area, and the DI system shall divert product water to drain or otherwise prevent product water from entering the

distribution system should an alarm condition occur. Under no circumstances shall DI be used when the product water of the final bed has a resistivity below 1 megohm-cm.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V204

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR

494.40(a):

5.2.8 Deionization (carbon adsorption and ultrafilter)

Systems that include deionizers as a component shall also contain carbon adsorption upstream of the deionizer to avoid formation of carcinogenic nitrosamines.

In all instances, deionizers shall be followed by an ultrafilter or other bacteria- and endotoxin-reducing device to remove microbiological contaminants that may originate in the deionizer resin bed.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V205

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR

494.40(a):

5.2.8 Deionization (utilization as polisher or backup)

The usual application for a deionizer is as a polisher following reverse osmosis or as a standby process if the reverse osmosis system fails. Use of deionization as the primary means of purification in an outpatient facility is not recommended because of the inability of deionization and ultrafiltration to remove certain low-molecular-weight toxic bacterial products, such as microcystins.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V206

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.2.8 Deionization (chemical analysis: frequency)

When deionization is employed as the primary method for removing inorganic contaminants (reverse osmosis is not employed), or when deionization is necessary to polish RO-treated water, chemical analyses to ensure that the requirements of AAMI 4.1.1 (Table 1) are met should be performed when the system is installed and at annual intervals thereafter.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V207

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.2.9 Ultrafiltration (effective/opaque housing)

6.2.9 Ultrafiltration (monitoring)

Refer to RD62:2001, 4.3.12 Ultrafilters: When used in a water purification system for hemodialysis applications, an ultrafilter shall be shown to reduce the concentrations of bacteria and endotoxin in the feed water to the ultrafilter by factors at least as great as those specified in the manufacturer's labeling.

5.2.9 Ultrafiltration

Refer to RD62:2001, 4.3.12 Ultrafilters: Ultrafilters [should] have an opaque housing or that other means be used to inhibit proliferation of algae.

Ultrafilters should be included in routine disinfection procedures to prevent uncontrolled proliferation of bacteria in the feed water compartment of the filter.

6.2.9 Ultrafiltration

The pressure drop across the ultrafilter (ΔP) should be measured using simple inlet and outlet pressure gauges. Ultrafilters operated in the cross-flow mode should also be monitored in terms of the flow rate of water being directed to drain (concentrate).

Results of pressure measurements and bacteria and endotoxin levels should be recorded in a log.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V208

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3 Water storage and distribution

5.3.1 General: Design

A water storage and distribution system should be designed specifically to facilitate bacterial control, including measures to prevent bacterial colonization and to allow for easy and frequent disinfection.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V209

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.2 Water storage: tank shape/configuration

When used, storage tanks should have a conical or bowl- shaped base and should drain from the lowest point of the base. Storage tanks should have a tight-fitting lid and be vented through a hydrophobic 0.2 µm air filter. The filter should be changed on a regular schedule according to the manufacturer's instructions. A means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

7.1 General strategies for bacterial control [in storage tanks]:

An ultrafilter, distal to the storage tank, or some other form of bacterial control device is recommended.

Storage tanks are therefore not recommended for use in dialysis systems unless they are frequently drained and adequately disinfected.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V210

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.3 Water storage and distribution

6.3.2 Water storage (monitoring)

Routine monitoring of water storage tanks for bacteria and endotoxin levels is generally accomplished indirectly by monitoring the water at the first outlet to the distribution loop (see 6.3.3). If direct monitoring of a water storage tank is performed as part of a troubleshooting process, bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3). All bacteria and endotoxin results should be recorded on a log sheet.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V211

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.3 Water distribution systems (continuous flow rates)

7 Strategies for bacterial control

7.1 General

5.3.3 Water distribution systems

Water distribution systems should be configured as a continuous loop and designed to minimize bacterial proliferation and biofilm formation. A centrifugal pump made of inert materials is necessary to distribute the purified water and aid in effective disinfection.

7 Strategies for bacterial control

7.1 General

To minimize biofilm formation, there should always be flow in a piping system. A minimum velocity of 3 ft/sec in the distal portion of the loop of an indirect feed system and a minimum velocity of 1.5 ft/s in the distal portion of a direct feed system are recommended when the system is operating under conditions of peak demand.

Dead-end pipes and unused branches and taps that can trap fluid must be eliminated because they act as reservoirs of bacteria and are capable of continuously inoculating the entire volume of the system. These measures also minimize the possibility that pockets of residual disinfectant could remain in the piping system after disinfection.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V212

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.3 Water distribution systems (no added burden)

Product water distribution systems shall be constructed of materials that do not contribute chemicals, such as aluminum, copper, lead, and zinc, or bacterial contaminants to the purified water.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V213

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.3.3 Water distribution systems (bacteria and endotoxin testing)

Water distribution piping systems should be monitored for bacteria and endotoxin levels. Bacteria and endotoxins shall not exceed the levels specified in [AAMI] 4.1.2. [(i.e., bacteria <200 CFU/mL and endotoxin <2 EU/mL)]

Bacteria and endotoxin testing should be conducted at least monthly. For a newly-installed water distribution piping system, or when a change has been made to an existing system, it is recommended that weekly testing be conducted for 1 month to verify that bacteria or endotoxin levels are consistently within the allowed limits.

Monitoring should be accomplished by taking samples from the first and last outlets of the water distribution loop and the outlets supplying reuse equipment and bicarbonate

concentrate mixing tanks. If the results of this testing are unsatisfactory, additional testing (e.g., ultrafilter inlet and outlet, RO product water, and storage tank outlet) should be undertaken as a troubleshooting strategy to identify the source of contamination, after which appropriate corrective actions can be taken.

Bacteria and endotoxin levels shall be measured as specified in ANSI/AAMI RD62:2001 (see 2.3).

All bacteria and endotoxin results should be recorded on a log sheet to identify trends that may indicate the need for corrective action.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V214

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.4 Bacterial control devices

5.3.4.1 Ultraviolet irradiators

Refer to RD62:2001, 4.3.13 Ultraviolet irradiators: When used to control bacterial proliferation in water storage and distribution systems, UV irradiation devices shall be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt-sec/cm², [except in the case described below]. The device shall be sized for the maximum anticipated flow rate according to the manufacturer's instructions.

5.3.4.1 Ultraviolet irradiators

If the irradiator includes a meter as described above, the minimum dose of radiant energy should be at least 16 milliwatt-sec/cm².

To prevent the use of sublethal doses of radiation that may lead to the development of resistant strains of bacteria, UV irradiators shall be equipped with a calibrated ultraviolet intensity meter ...or with an on-line monitor of radiant energy output that activates a visible alarm, which indicates that the lamp should be replaced.

Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output.

6.3.4 Bacterial control devices

6.3.4.1 Ultraviolet irradiators

Ultraviolet irradiators intended for use as a direct means of bacterial control shall be monitored for radiant energy output. UV irradiators should be monitored at the frequency recommended by the manufacturer. A log sheet should be used to indicate that monitoring has been performed.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V215

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.4.1 Ultraviolet irradiators (filter)

UV irradiators [shall] be followed by a means of reducing endotoxin concentrations, such as an ultrafilter in the purified water distribution system or reverse osmosis in the pretreatment cascade.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V216

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.4.2 Ozone generators: system requirements/monitoring

6.3.4 Bacterial control devices

Ozone can be used for bacterial control only in systems constructed from ozone-resistant materials (see AAMI 5.3.3 for suitable piping materials).

5.3.4.2 Ozone generators

Refer to RD62:2001, 4.3.15 Ozone disinfection systems: When used to control bacterial proliferation in water storage and distribution systems, an ozone generator shall be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer.

6.3.4 Bacterial control devices

6.3.4.2 Ozone generators

Ozone generators should be monitored for ozone output at a level specified by the manufacturer. The output of the ozone generator should be measured by the ozone concentration in the water. A test based on indigo trisulfonate chemistry, or the equivalent, should be used to measure the ozone concentration ...each time disinfection is performed. An ozone-in-ambient-air test should be conducted on a periodic basis, as recommended by the manufacturer, to ensure compliance with the OSHA permissible exposure limit of 0.1 ppm. A log sheet should be used to indicate that monitoring has been performed.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V217

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.3.4.3 Hot water disinfection systems

Refer to RD62:2001, 4.3.14 Hot water disinfection systems: When used to control bacterial proliferation in water treatment, storage, and distribution systems, the water heater of a hot water disinfection system shall be capable of delivering hot water at the temperature and for the exposure time specified by the manufacturer.

5.3.4.3 Hot water disinfection systems

Hot water disinfection systems can be used only in systems constructed from heat-resistant materials, such as cross-linked polyethylene, polypropylene, and stainless steel (see [AAMI] 5.3.3).

The manufacturer's instructions for using hot water disinfection systems should be followed. If no manufacturer's instructions are available, the effectiveness of the system can be demonstrated by verifying that the system maintains a specified temperature for a specified time and by performing ongoing surveillance with bacterial cultures and endotoxin testing.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V218

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.3.4 Bacterial control devices

6.3.4.3 Hot water disinfection systems: monitoring

Hot water disinfection systems should be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Also, hot water disinfection should be performed at least as often as recommended by the manufacturer. The temperature of the water should be recorded at a point farthest from the water heater—that is, where the lowest water temperature is likely to occur...and measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection should be maintained. Successful completion is defined as meeting temperature and time requirements specified by the equipment manufacturer.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V219

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7 Strategies for bacterial control

7.1 General (disinfection and frequency)

Routine low-level disinfection of the pipes should be performed to control bacterial contamination of the distribution system. The frequency of disinfection will vary with the design of the system and the extent to which biofilm has already formed in existing systems, but disinfection must be performed at least monthly.

A mechanism should be incorporated in the distribution system to ensure that disinfectant does not drain from pipes during the disinfection period.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V220

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7 Strategies for bacterial control

7.1 General (disinfection of machine supply line)

Users should establish a procedure for regular disinfection of [the line between the outlet from the water distribution system and the back of the dialysis machine].

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

No tag

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4 Concentrate preparation

5.4.1 General

Dialysate is customarily prepared from two concentrates: the bicarbonate concentrate, which contains sodium bicarbonate (and sometimes additional sodium chloride), and the acid concentrate, which contains all remaining ions, acetic acid, and sometimes glucose.

Acid concentrate can be supplied by the manufacturer in bulk (usually 55 gallon containers) or in gallon containers.

There are systems available that allow a user at a dialysis facility to prepare acid concentrate from packaged powder and purified water using a mixer. Acid concentrate prepared at the dialysis facility from powder and water is the responsibility of the user.

Bicarbonate concentrate can be supplied by the manufacturer in one of three ways:

- 1. In gallon containers,*
- 2. As packaged powder that is mixed with purified water at the dialysis facility, and*
- 3. In powder cartridges that are used to prepare concentrate on-line at the time of dialysis.*

Interpretive Guidance § 494.40(a)

This is an informational tag outlining the methods used for bicarbonate and acid concentrate delivery.

V222

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4 Concentrate preparation

5.4.3 Bulk storage tanks (acid concentrate)

Procedures should be in place to control the transfer of the acid concentrate from the delivery container to the storage tank to prevent the inadvertent mixing of different concentrate formulations. If possible, the tank and associated plumbing should form an integral system to prevent contamination of the acid concentrate. The storage tanks and inlet and outlet connections, if remote from the tank, should be secure and labeled clearly.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V223

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4 Concentrate preparation

5.4.2 Materials compatibility

All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves, and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides or germicidal procedure used to disinfect the equipment. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, and aluminum, are specifically prohibited.

V224

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems

Concentrate mixing systems require a purified water source, a suitable drain, and a ground fault protected electrical outlet.

V225

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems: (safe environment/PPE)

Protective measures should be used to ensure a safe work environment.

Operators should at all times use appropriate personal protective equipment, such as face shields, masks, gloves, gowns, and shoe protectors, as recommended by the manufacturer.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V226

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems

6.4.1 Mixing systems (monitoring)

5.4.4.1 Mixing systems

If a concentrate mixing system is used, the preparer should follow the manufacturer's instructions for mixing the powder with the correct amount of water.

If a concentrate mixing system is used, the number of bags or the weight of powder added should be determined and recorded.

Manufacturer's recommendations should be followed regarding any preventive maintenance and sanitization procedures. Records should be maintained indicating the date, time, person performing the procedure, and results (if applicable).

6.4.1 Mixing systems

Systems for preparing either bicarbonate or acid concentrate from powder should be monitored according to the manufacturer's instructions.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V227

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.4.1 Mixing systems (self-designed)

If a facility designs its own system, procedures should be developed and demonstrated to ensure proper mixing of the concentrate, including establishment of acceptable limits for tests of proper concentration. The adequacy of those procedures must be verified using an independent laboratory that is capable of meeting the requirements of ANSI/AAMI RD61:2000 (see 2.4). Verification can be accomplished by testing a sample from each batch prepared over a 3-day period.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V228

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40 (a):

5.4.4.1 Mixing systems (labeling)

Labeling strategies should permit positive identification by anyone using the contents of mixing tanks, bulk storage/dispensing tanks, and small containers intended for use with a single hemodialysis machine.

Mixing tanks: Prior to batch preparation, a label should be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling should remain on the mixing tank until the tank has been emptied.

Bulk storage/dispensing tanks: These tanks should be permanently labeled to identify the chemical composition or formulation of their contents.

Concentrate jugs: At a minimum, concentrate jugs should be labeled with sufficient information to differentiate the contents from other concentrate formulations used at the facility.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V229

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.1 Mixing systems (permanent records)

6.4.1 Mixing systems (verification testing)

5.4.4.1 Mixing systems

In addition to container labeling, there should be permanent records of batches produced. These records should include the concentrate formula produced, the volume of the batch, the lot numbers of powdered concentrate packages, the manufacturer of the powdered concentrate, the date and time of mixing, any test results, the person performing the mixing, the person verifying mixing and test results, and the expiration date (if applicable).

6.4.1 Mixing systems

Acid and bicarbonate concentrates may be tested by using conductivity or by using a hydrometer.

Concentrates should not be used or transferred to holding tanks or distribution systems until all tests are completed. The test results and verification that they meet all applicable criteria should be recorded and signed by the individuals performing the tests.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V230

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.4.1 Mixing systems (cleaning)

Concentrate mixing equipment should be either: (1) completely emptied, cleaned, and disinfected according to the manufacturer's instructions; or (2) cleaned and disinfected using a procedure demonstrated by the facility to be effective in routinely producing concentrate meeting [these regulations related to allowable bacterial and endotoxin levels].

The disinfection data should be recorded for each ... disinfection cycle using a dedicated log.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V231

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.2 Acid concentrate mixing systems: empty completely/prevent corrosion

Acid concentrate mixing tanks should be designed to allow the inside of the tank to be completely emptied and rinsed according to the manufacturer's instructions when concentrate formulas are changed.

Acid concentrate mixing tanks should be emptied completely before mixing another batch of concentrate.

Because concentrate solutions are highly corrosive, mixing systems should be designed and maintained to prevent corrosion.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V232

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.3 Bicarbonate concentrate mixing systems: empty/ disinfect/prevent corrosion

Bicarbonate concentrate mixing tanks should be designed to drain completely.

Mixing tanks should have a tight-fitting lid and should be designed to allow all internal surfaces to be disinfected and rinsed.

Because concentrate solutions are highly corrosive, mixing systems should be designed and maintained to prevent corrosion.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V233

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.3 Bicarbonate concentrate mixing systems

7 Strategies for bacterial control

7.1 General

5.4.4.3 Bicarbonate concentrate mixing systems

Once mixed, bicarbonate concentrate should be used within the time specified by the manufacturer of the concentrate.

7 Strategies for bacterial control

7.1 General

Storage times for bicarbonate concentrate should be minimized, as well as the mixing of fresh bicarbonate concentrate with unused portions of concentrate from a previous batch. The manufacturer's instructions should be followed if they are available.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V234

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.4.3 Bicarbonate concentrate mixing systems

Over-agitating or over-mixing of bicarbonate concentrate should be avoided, as this can cause CO₂ loss and can increase PH.

ANSI/AAMI RD52:2004

5.4.4.3 Bicarbonate concentrate mixing systems

Systems designed for mixing dry acid concentrates may use methods that are too vigorous for dissolving dry bicarbonate.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V235

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.5 Additives: mixing spikes

Concentrate additives should be mixed with liquid acid concentrates according to the manufacturer's instructions, taking care to ensure that the additive is formulated for use in concentrates of the appropriate dilution ratio. When liquid additives are used, the volume contributed by the additive should be considered when calculating the effect of dilution on the concentration of the other components in the resulting concentrate. When powder additives are used, care should be taken to ensure that the additive is completely dissolved and mixed before the concentrate is used.

Interpretive Guidance §494.40(a)

Guidance is pending and will be updated in future release.

V236

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.4.5 Additives (labeling)

5.4.4.1 Concentrate jugs

If a chemical spike is added to an individual container to increase the concentration of an electrolyte, the label should show the added electrolyte, the date and time added, and the name of the person making the addition.

Containers should be labeled to indicate the final concentration of the added electrolyte... This information should also be recorded in a permanent record. Labels should be affixed to the containers when the mixing process begins.

6.4.2 Additives

When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate should be labeled with the name of the patient, the final concentration of the added electrolyte, the date on which the prescribed concentrate was made, and the name of the person who mixed the additive.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V237

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5 Concentrate distribution:

5.5.1 Materials compatibility

All components used in concentrate distribution systems (including concentrate jugs, storage tanks, and piping) that contact the fluid shall be fabricated from nonreactive materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, and aluminum, are specifically prohibited.

V238

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.2 System configurations: elevated tanks

Elevated tanks for bicarbonate concentrate distribution should be equipped with conical or bowl-shaped bottoms, tight-fitting lids, a spray mechanism, and high- and low-level alarms. Any air vents should have 0.2 µm hydrophobic vent filters.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V239

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems: weekly disinfection/dwell times/conc

Bicarbonate concentrate delivery systems should be disinfected on a regular basis to ensure that the dialysate routinely achieves the level of bacteriological purity [required by these regulations].

For piped distribution systems, the entire system, including patient station ports, should be purged of bicarbonate concentrate before disinfection. Each patient station port should be opened and flushed with disinfectant and then rinsed; otherwise, it would be a “dead leg” in the system.

Appropriate dwell times and concentrations should be used as recommended by the manufacturer of the concentrate system. If this information is not available, bleach may be used at a dilution of 1:100 and proprietary disinfectants at the concentration recommended by the manufacturer for disinfecting piping systems.

6.5 Concentrate distribution:

The interval between disinfection should not exceed 1 week. If the manufacturer does not supply disinfection procedures, the user must develop and validate a disinfection protocol.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V240
(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems (Ultraviolet Irradiation)

UV irradiation devices that are used to control bacteria proliferation in the pipes of bicarbonate concentrate distribution systems should be fitted with a low-pressure mercury lamp that emits light at a wavelength of 254 nm and provides a dose of radiant energy of 30 milliwatt- sec/cm². The device should be sized for the maximum anticipated flow rate according to the manufacturer’s instructions and be equipped

with an on-line monitor of radiant energy output that activates a visual alarm indicating that the lamp should be replaced.

Alternatively, the lamp should be replaced on a predetermined schedule according to the manufacturer's instructions to maintain the recommended radiant energy output. Disinfection of the bicarbonate concentrate distribution system should continue to be performed routinely.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V241

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems (Ozone Disinfection)

When used to disinfect the pipes of a bicarbonate concentrate delivery system, an ozone generator should be capable of delivering ozone at the concentration and for the exposure time specified by the manufacturer.

When ozone disinfection systems are used, ambient air should be monitored for ozone as required by the U.S. Occupational Safety and Health Administration (OSHA).

V242

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.5 Concentrate distribution (Initial Bicarbonate Monitoring)

Once a bicarbonate distribution system has been activated, dialysate should be monitored weekly until sufficient data has been obtained to demonstrate consistent compliance with acceptable levels of contamination. The frequency of monitoring may then be reduced, but monitoring should be performed at least monthly. If elevated bacteria or endotoxin levels are found in the dialysate, all systems involved in dialysate preparation, including the bicarbonate concentrate distribution system should be evaluated and appropriate action, such as disinfection, should be taken. The frequency of monitoring should then be increased until it can be demonstrated that the problem has been resolved.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V243

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6.5 Concentrate distribution (Bicarbonate Jugs – Rinsing)

Bicarbonate concentrate jugs should be rinsed with treated water and stored inverted at the end of each treatment day. Pick-up tubes should also be rinsed with treated water and allowed to air dry at the end of each treatment day.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V244

(rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems (disinfection of bicarbonate jugs)

6.5 Concentrate distribution

7 Strategies for bacterial control

7.1 General

5.5.4 Bicarbonate concentrate distribution systems (disinfection of bicarbonate jugs)

When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be rinsed free of residual concentrate before disinfection.

6.5 Concentrate distribution

When reusable concentrate jugs are used to distribute bicarbonate concentrate, they should be disinfected at least weekly.

7 Strategies for bacterial control

7.1 General

Following disinfection, jugs should be drained, rinsed, and inverted to dry.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V245

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.3 Acid concentrate distribution systems (labeling)

Acid concentrate delivery piping should be labeled and color-coded red at the point of use (at the jug filling station or the dialysis machine connection).

All joints should be sealed to prevent leakage of concentrate. If the acid system remains intact, no rinsing or disinfection is necessary.

More than one type of acid concentrate may be delivered, and each line should clearly indicate the type of acid concentrate it contains.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V246

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.4 Bicarbonate concentrate distribution systems (color-coded)

Bicarbonate concentrate delivery piping should be color-coded blue at the point of use (at the jug filling station or dialysis machine connection). All joints should be sealed to prevent leakage of concentrate.

V247

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.5.5 Concentrate outlets (designated outlets and labeling)

6.5 Concentrate distribution

5.5.5 Concentrate outlets: separate/labeled/connection safety

To prevent mix-ups with delivery of two or more types of acid concentrate, each concentrate should have its own outlet. Concentrate outlets should be compatible with the dialysis machine and have a means of minimizing the risk that the wrong concentrate will be connected to an outlet. The dispensing outlets should be labeled with the appropriate symbol (see AAMI Table 3) indicating the proportioning ratio for the dialysis machine and should be color-coded blue for bicarbonate, red for acid.

6.5 Concentrate distribution

A daily check to ensure that the appropriate acid and bicarbonate concentrate is connected to the corresponding concentrate delivery line is recommended if the storage tank is not permanently connected to its distribution piping.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V248

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.6 Dialysate proportioning

The acid and bicarbonate concentrates [must] be matched with respect to the proportioning ratio and with the model and setup configuration of the dialysis machine.

Several types of three-stream concentrates are available, with different ratios of acid concentrate to bicarbonate concentrate to water (see Table 3). The different proportioning types are not compatible with one another.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V249

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.6 Dialysate proportioning (dialysis machine recalibration)

6.6 Dialysate proportioning

5.6 Dialysate proportioning (dialysis machine recalibration)

Changing from one proportioning ratio to another requires recalibration for some models of dialysis machines. For those machines, the type of concentrate should be labeled on the machine or clearly indicated by the machine display. It is strongly recommended that facilities configure every machine to use only one type of concentrate.

6.6 Dialysate proportioning

Dialysate proportioning should be monitored following the procedures specified by the equipment manufacturer. The user should maintain a record of critical parameters such as conductivity and approximate pH. When the user has specific requirements for monitoring dialysate proportioning, such as when dialysis machine settings are changed to allow the use of concentrates with a different proportioning ratio, the user should develop procedures for routine monitoring of dialysate electrolyte values.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V250

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

5.6 Dialysate proportioning (dialysate conductivity and pH measurement)

It is necessary for the operator to follow the manufacturer's instructions regarding dialysate conductivity and to measure approximate pH with an independent method before starting the treatment of the next patient.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

No tag

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6 Monitoring

6.1 General

Quality control and quality assurance procedures should be established to ensure ongoing conformance to policies and procedures regarding dialysate quality. This

clause defines some of the monitoring activities to be conducted at the dialysis facility as part of the quality assurance process. The test methods described in [AAMI] 6.2 do not represent the only acceptable methods available, but are intended to provide examples of acceptable methods. The frequency of monitoring is generally recommended by the equipment manufacturer. Table 4 can be used as a guideline for setting up a quality assurance monitoring program in the absence of a manufacturer's recommendations or to supplement those recommendations.

Interpretive Guidance §494.40(a)

This is an informational tag. Expected monitoring is listed under each water system and dialysate component; there may be some variation from this Table based on specific equipment in use.

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

6 Monitoring

6.1 General

Table 4—Monitoring guidelines for water purification equipment and distribution systems and dialysate

NOTE—Refer to footnote for an explanation of the use of Xs in the Specification column.

<i>Item to monitor</i>	<i>What to monitor</i>	<i>Special interval</i>	<i>Normal interval</i>	<i>Specification</i>
<i>Sediment filter</i>	<i>Pressure drop across the filter</i>	<i>NA</i>	<i>Daily</i>	<i>Pressure drop less than XXXX</i>
<i>Sediment filter backwashing cycle</i>	<i>Backwash cycle timer setting</i>	<i>NA</i>	<i>Daily—beginning of the day</i>	<i>Backwash clock set to XX:XX</i>
<i>Cartridge filter</i>	<i>Pressure drop across the filter</i>	<i>NA</i>	<i>Daily</i>	<i>Pressure drop less than XXXX</i>
<i>Water softener</i>	<i>Product water softness</i>	<i>NA</i>	<i>Daily—end of the day</i>	<i>Hardness as calcium carbonate less than 1 grain/gal, unless otherwise specified by the manufacturer of the reverse osmosis equipment</i>
<i>Water softener brine tank</i>	<i>Level of undissolved salt in tank</i>	<i>NA</i>	<i>Daily—end of the day</i>	<i>Salt level at XXX</i>
<i>Water softener regeneration cycle</i>	<i>Regeneration cycle timer setting</i>	<i>NA</i>	<i>Daily—beginning of the day</i>	<i>Softener timer set to XX:XX</i>

<i>Item to monitor</i>	<i>What to monitor</i>	<i>Special interval</i>	<i>Normal interval</i>	<i>Specification</i>
<i>Carbon adsorption beds</i>	<i>Product water free chlorine and/or total chlorine between the beds</i>	<i>NA</i>	<i>Prior to beginning each patient shift</i>	<i>< 0.1 mg/L of total chlorine</i>
<i>Chemical injection system</i>	<i>Level of chemical in the reservoir, injector function, value of the controlling parameter (e.g., pH)</i>	<i>NA</i>	<i>Daily</i>	<i>Chemical level in reservoir \geq XXX; controlling parameter in range XX–XX</i>
<i>Reverse osmosis</i>	<i>Product water conductivity, total dissolved solids (TDS), or resistivity and calculated rejection</i>	<i>NA</i>	<i>According to the manufacturer's recommendations (continuous monitors)</i>	<i>Rejection \geq XX%</i>
<i>Reverse osmosis</i>	<i>Product and reject flow rates, and calculated recovery</i>	<i>NA</i>	<i>Daily (continuous monitors)</i>	<i>Product water flow rate > X.X gpm; recovery in the range XX–XX %</i>
<i>Deionizers</i>	<i>Product water resistivity</i>	<i>NA</i>	<i>Continuous</i>	<i>Resistivity > 1 megohm-cm</i>
<i>Ultrafilters</i>	<i>Pressure drop across the filter</i>	<i>NA</i>	<i>Daily</i>	<i>Pressure drop less than XXXX</i>
<i>Water storage tanks</i>	<i>Bacterial growth and pyrogens</i>	<i>Weekly, until a pattern of consistent compliance with limits can be demonstrated</i>	<i>NA</i>	<i>Bacterial count \leq 50 CFU/mL; endotoxin \leq 1 EU/mL</i>
<i>Water distribution piping system</i>	<i>Bacterial growth and pyrogens</i>	<i>Weekly, until a pattern of consistent compliance with limits can be demonstrated</i>	<i>Monthly</i>	<i>Bacterial count \leq 50 CFU/mL; endotoxin \leq 1 EU/mL</i>
<i>UV light sources</i>	<i>Energy output</i>	<i>NA</i>	<i>Monthly</i>	<i>Light output > XXX</i>
<i>Ozone generators</i>	<i>Concentration in the water</i>	<i>NA</i>	<i>During each disinfection</i>	<i>Ozone concentration > XXX</i>
<i>Hot water disinfection systems</i>	<i>Temperature and time of exposure of the system to hot water</i>	<i>NA</i>	<i>During each disinfection</i>	<i>Temperature not less than XX °C; minimum exposure time at temperature \geq XX minutes</i>
<i>Dialysate</i>	<i>Bacterial growth and endotoxin in the dialysate</i>	<i>NA</i>	<i>Monthly, rotated among machines so that at least two machines are tested each month and so that each machine is tested</i>	<i>Bacterial growth \leq 50 CFU/mL; endotoxin \leq 1 EU/mL</i>

<i>Item to monitor</i>	<i>What to monitor</i>	<i>Special interval</i>	<i>Normal interval</i>	<i>Specification</i>
			at least once per year	
<i>Dialysate</i>	<i>Conductivity and pH</i>	<i>NA</i>	<i>Each treatment</i>	<i>Conductivity within \pm 5% of the nominal machine value; pH in the range 6.9–7.6</i>

NOTE: It is not possible to specify universally acceptable operating ranges for each device listed in the table, since some of these values will be system-specific. In those cases (denoted by Xs in the Specification column of the table), the facility should define an acceptable operating range based on manufacturer's instructions or measurements of system performance.

V252

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2 Microbial monitoring methods

7.2.1 General

7.2.2 Sample collection

7.2.1 General

Culture water ...weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.

Monitoring can be accomplished by direct plate counts, in conjunction with the measurement of bacterial endotoxin.

7.2.2 Sample collection

Water samples should be collected directly from outlet taps situated in different parts of the water distribution system. In general, the sample taps should be opened and the water should be allowed to run for at least 60 seconds before a sample is collected in a sterile, endotoxin-free container. A minimum of 50 mL of water, or the volume specified by the laboratory performing the test, should be collected. Sample taps should not be disinfected.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V253

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2 Microbial monitoring methods

7.2.1 General: Dialysate (dialysate sampling frequency)

Culture ... dialysate fluid weekly for new systems until a pattern has been established. For established systems, culture monthly unless a greater frequency is dictated by historical data at a given institution.

Samples of water should be collected from several places to give an indication of the microbial quality of the water throughout the water distribution system. In general, samples should be collected in the following areas: from the first and last outlets of the water distribution loop, where water enters equipment used to reprocess dialyzers, and where water enters equipment used to prepare bicarbonate concentrate or from the bicarbonate concentrate mixing tank.

Additional testing, such as at the end of the water purification cascade and at the outlet of the storage tank, if one is used, may be necessary during initial qualification of a system or when troubleshooting the cause of contamination within the distribution loop.

Dialysate samples should be collected from at least two machines monthly and from enough machines so that each machine is tested at least once per year. If testing of any dialysis machine reveals a level of contamination above the action level, an investigation should be conducted that includes retesting the offending machine, reviewing compliance with disinfection and sampling procedures, and evaluating microbiological data for the previous 3 months to look for trends. The medical director also should be notified. An example of a decision tree for this process is given in Figure 1.

7.2.2 Sample collection

Dialysate samples should be collected from a dialysate port of the dialyzer... [or] dialysate sampling ports that can be accessed using a syringe. At least 25 mL of fluid, or the volume specified by the laboratory performing the test, should be collected in sterile endotoxin-free specimen containers.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V254

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2 Microbial monitoring methods

7.2.1 General

Samples should always be collected before sanitization/disinfection of the water treatment system and dialysis machines.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release

V255

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2 Microbial monitoring methods

7.2.1 General (repeat cultures)

Cultures should be repeated when bacterial counts exceed the allowable levels. If culture growth exceeds permissible standards, the water system and dialysis machines should be cultured weekly until acceptable results are obtained. Additional samples should be collected when there is a clinical indication of a pyrogenic reaction or septicemia, and following a specific request by the clinician or the infection control practitioner.

If repeat cultures are performed after the system has been disinfected (e.g., with formaldehyde, hydrogen peroxide, chlorine, or peracetic acid), the system should be flushed completely before collecting samples. Drain and flush storage tanks and the distribution system until residual disinfectant is no longer detected before collecting samples.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V256

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2.3 Heterotrophic plate count (dip samplers)

Dip samplers may be used for bacterial surveillance... in conjunction with a quality assurance program designed to ensure their appropriate use. Elements of the quality assurance program should include staff training in areas such as the correct methods of inoculation, incubation, and interpretation, and verification involving duplicate samples sent to a certified laboratory on at least an annual basis. Plates shall be incubated at 35 °C for 48 hours.

Colonies should be counted using a magnifying device.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V257

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2.3 Heterotrophic plate count

Samples that cannot be cultured within 1 to 2 hours can be refrigerated for up to 24 hours.

Use of a calibrated loop to apply the sample to the agar plate is not permitted.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V258

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

7.2.4 Bacterial endotoxin test

At a minimum, two tubes should be run each time the assay is performed. The first tube contains LAL reagent and the sample to be tested. The second tube contains LAL

reagent, a known amount of endotoxin, and the sample to be tested. The second tube acts as a positive control to confirm the absence of any interference that might lead to a false negative result.

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

V259

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

9 Personnel (policies and procedures)

Policies and procedures that are understandable and accessible are mandatory.

V260

(Rev.)

From ANSI/AAMI RD52:2004 Requirements, as Adopted by Reference 42 CFR 494.40(a):

9 Personnel (components of the training program)

A training program that includes quality testing, the risks and hazards of improperly prepared concentrate, and bacterial issues is mandatory.

Operators should be trained in the use of the equipment by the manufacturer or should be trained using materials provided by the manufacturer.

The training should be specific to the functions performed (i.e., mixing, disinfection, maintenance, and repairs).

Periodic audits of the operators' compliance with procedures should be performed.

The user should establish an ongoing training program designed to maintain the operator's knowledge and skills.

End of ANSI/AAMI RD52:2004 Requirements

Interpretive Guidance § 494.40(a)

Guidance is pending and will be updated in future release.

No Tag

§ 494.40(b) - Standard: chlorine/chloramines.

(1) The water treatment system must include a component or carbon tank which removes chlorine/chloramine along with a backup component or second carbon tank in series for chlorine/chloramine removal.

(2)(i) If the test results from the port of the initial component or carbon tank referred to in section 6.2.5 of AAMI RD52:2004 are greater than 0.5 mg/L for free chlorine or 0.1 mg/L for chloramines, or equal to or greater than 0.1 mg/L of total chlorine, then the second component or carbon tank which removes chlorine/chloramine must be tested;

Interpretive Guidance § 494.40(b)(1) and (2)(i)

Guidance is pending and will be updated in future release.

V270

(Rev.)

§ 494.40(b)(2)(ii) - If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(A) Immediately take corrective action to bring chlorine or chloramine levels into compliance with paragraph (b)(2)(i) of this section and confirm through testing that the corrective action has been effective, or terminate dialysis treatment to protect patients from exposure to chlorine/chloramine;

Interpretive Guidance § 494.40(b)(2)(ii)(A)

Guidance is pending and will be updated in future release.

V271

(Rev.)

§494.40(b)(2)(ii) - If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(B) Only allow use of purified water in a holding tank, if appropriate, and if testing shows water chlorine or chloramine levels that are in compliance with paragraph (b)(2)(i) of this section; and

Interpretive Guidance § 494.40(b)(2)(ii)(B)

Guidance is pending and will be updated in future release.

V272

(Rev.)

§494.40(b)(2)(ii) - If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(C) Immediately notify the medical director; and

Interpretive Guidance § 494.40(b)(2)(ii)(C)

Guidance is pending and will be updated in future release.

V273

(Rev.)

§494.40(b)(2)(ii) - If the test results from the last component or carbon tank are greater than the parameters for chlorine or chloramine specified in paragraph (b)(2)(i) of this section the facility must—

(D) Take corrective action to ensure ongoing compliance with acceptable chlorine and chloramine levels as described in paragraph (b)(2)(i) of this section.

Interpretive Guidance § 494.40(b)(2)(ii)(D)

Guidance is pending and will be updated in future release.

V274

(Rev.)

§ 494.40(c) - Corrective action plan. Water testing results including, but not limited to, chemical, microbial, and endotoxin levels which meet AAMI action levels or deviate from the AAMI standards must be addressed with a corrective action plan that ensures patient safety.

Interpretive Guidance § 494.40(c)

Guidance is pending and will be updated in future release.

V275

(Rev.)

§ 494.40(d) - Adverse events. A dialysis facility must maintain active surveillance of patient reactions during and following dialysis. When clinically indicated (for example, after adverse patient reactions) the facility must—

- (1) Obtain blood and dialysate cultures and endotoxin levels;**
- (2) Evaluate the water purification system; and**

(3) Take corrective action.

Interpretive Guidance § 494.40(d)

Guidance is pending and will be updated in future release.

V276

(Rev.)

§ 494.40(e) – Standard: In-center use of preconfigured hemodialysis systems. When using a preconfigured, FDA-approved hemodialysis system designed, tested and validated to yield AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate, the system’s FDA-approved labeling must be adhered to for machine use and monitoring of the water and dialysate quality...

Interpretive Guidance § 494.40(e)

Guidance is pending and will be updated in future release.

V277

(Rev.)

§ 494.40(e) - Standard: In-center use of preconfigured hemodialysis systems.... The facility must meet all AAMI RD52:2004 requirements for water and dialysate....

Interpretive Guidance § 494.40(e)

Guidance is pending and will be updated in future release.

V278

(Rev.)

§ 494.40(e) - Standard: In-center use of preconfigured hemodialysis systems.... Moreover, the facility must perform bacteriological and endotoxin testing on a quarterly, or more frequent basis, as needed, to ensure that the water and dialysate are within AAMI limits.

Interpretive Guidance § 494.40(e)

Guidance is pending and will be updated in future release.

V300

(Rev.)

§ 494.50 - Condition: Reuse of hemodialyzers and bloodlines.

Interpretive Guidance § 494.50

Guidance is pending and will be updated in future release.

V301

(Rev.)

§ 494.50(a) – Standard: General requirements for the reuse of hemodialyzers and bloodlines: Certain hemodialyzers and bloodlines–

(1) May be reused for certain patients with the exception of Hepatitis B positive patients;

Interpretive Guidance § 494.50(a)(1)

Guidance is pending and will be updated in future release.

No tag

§ 494.50(a)(2) [Certain hemodialyzers and bloodlines --] Must be reused only for the same patient; and

Interpretive Guidance § 494.50(a)(2)

This tag is informational. This requirement is addressed in the ANSI/AAMI RD: 47 guideline at V327 and should be cited there.

V303

(Rev.)

§ 494.50(a)(3) - [Certain hemodialyzers and bloodlines --] Must be labeled for multiple reuse in accordance with the premarket notification provisions of section 510(k) of the Food, Drug, and Cosmetics Act and 21 CFR 876.5860.

Interpretive Guidance § 494.50(a)(3)

Guidance is pending and will be updated in future release.

V304

(Rev.)

§ 494.50(b) - Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines: A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(1) Meet the requirements of AAMI published in “Reuse of Hemodialyzers,” third edition, ANSI/AAMI RD47:2002 and RD47:2002/A1:2003. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. This publication is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://code_of_regulations/ibr_locations.html. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201- 4598.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V305

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

4 Records

All records described in this recommended practice shall meet the requirements for medical records, including completeness, legibility, and security. A place should be provided for the signature or other unique mark of identification of the person completing each step of the reprocessing procedure (i.e., the person performing preventive maintenance procedures, the person[s] investigating complaints, and the person[s] conducting quality assurance [QA] and quality control [QC] activities). Maintaining these records is the responsibility of the medical director.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V306

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

4.1 Dialyzer reprocessing manual

The dialyzer reprocessing manual should be a compilation of all specifications, policies, training materials, manuals, methodologies, and procedures that may be integrated into the dialysis facility's policy and procedures manual. The dialyzer reprocessing manual should also contain samples of forms and labels, if appropriate. The operational logs, manuals, and files may be kept separate from the dialyzer reprocessing manual. The dialyzer manufacturer's labeling should be consulted to determine if a specific dialyzer requires special considerations.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V307

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

5 Personnel qualifications and training

5.1 Qualifications

Personnel shall possess adequate education, training, or experience to understand and perform procedures outlined by the individual dialysis facility relevant to the facility's multiple-use program. Education shall be geared to meet the needs of this wide range of personnel.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V308

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

5.2 Training

5.2.1 Curriculum

The dialysis facility's physician or director shall establish a training course for the persons performing hemodialyzer reprocessing. A written document should give details about the curriculum and, in particular, address the potential risks to patients and staff members of not following correct procedures. The curriculum should include at least the following information:

- a. the facility's specific reprocessing procedure, including a rationale for each step;*
- b. basic documentation requirements of the program;*
- c. the operation and maintenance of the facility's specific equipment for reprocessing hemodialyzers and, if appropriate, the dialysis systems and components;*
- d. microbiology with respect to aseptic technique, the collection and handling of samples, and personnel safety precautions for infectious hazards;*
- e. the risks and hazards of multiple use of hemodialyzers;*
- f. the consequences of not performing tasks properly;*
- g. the risks and hazards associated with toxic substances used in reprocessing hemodialyzers, proper handling of these substances, and procedures for handling spills and proper disposal of toxic substances;*
- h. the use and location of protective eyewear, respirators, masks, and special clothing;*
- i. emergency procedures as required by the facility; and*
- j. the principles of dialysis, emphasizing the characteristics of the hemodialyzer and the effect of reuse on these characteristics.*

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V309

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

5.2.2 Documentation

Each person performing procedures for the multiple use of dialyzers shall have successfully completed the dialysis facility's training course relevant to that person's task and demonstrated competence in the area covered by his or her training. Successful completion of training shall be certified by the medical director or his or her designated representative and recorded in the trainee's personnel file along with verification of the trainee having received the instruction. Retraining is necessary

when new procedures are undertaken. Annual review of competence is required with appropriate retraining if deficiencies are found.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V310

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50 (b)(1):

4 Records

4.4 Personnel health monitoring records

A file must be kept of the results of medical examinations of personnel that are required by OSHA or other regulatory agencies.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V311

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50 (b)(1):

6 Patient considerations

6.1 Medical issues

An order to reprocess hemodialyzers shall be made by a physician knowledgeable about reprocessing and its medical and economic implications. Because the current human immunodeficiency virus (HIV), hepatitis B, or hepatitis C status of a patient cannot be known with certainty, all staff potentially exposed to the patient's blood shall observe Standard Precautions. Precautions for all infectious hazards should be emphasized and included in the reprocessing procedures. Written procedures should stipulate whether and how reprocessing will be done for patients who have shown sensitivity to materials used in the reprocessing of hemodialyzers.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V312

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

6.2 Informed consent

All patients in a dialysis facility will be fully informed regarding reuse of dialyzers. Printed material such as brochures describing the facility's services should contain a statement about dialyzer reprocessing if reuse is performed.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V313

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7 Equipment

Each piece of equipment used for reprocessing shall be appropriately designed, constructed, and tested to perform its intended task. Satisfactory operation of manual and automated systems shall be ensured by appropriate functional tests. Strict QC and QA shall be maintained for any type of dialyzer reprocessing equipment. Additionally, complete documentation of system function, operating procedures, potential system failures, and dialyzer-reuse criteria shall be included in the dialyzer reprocessing manual, known to the operator, and available for review.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V314

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.1 Water systems

The system providing water for reprocessing shall meet all of the requirements for pressure and flow rate for operating the reprocessing equipment under minimal and peak load conditions. Product water used for rinsing, cleaning, filling, and diluting the germicide shall be shown to comply with the chemical and microbiological quality requirements [specified in these regulations].

Water bacteriology monitoring shall be carried out where the dialyzer is connected to the reuse system or as close as possible to that point.

11.4 Germicide

11.4.1.5 Water quality monitoring

The water used to rinse and clean dialyzers and dilute the germicide should be tested for bacterial contamination and pyrogens according to the requirements [of these regulations] before a reprocessing program is undertaken. Once dialysis with the reprocessed hemodialyzers has begun, testing for bacterial contamination should be frequent (e.g., weekly). Less frequent testing, but not less than monthly, may be appropriate if there is a documented history of at least 3 months of results consistently below the required levels.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V315

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.2 Reprocessing systems

7.2.1 Utility requirements

The quality, pressure, flow rate, and temperature of the water used for reprocessing should be specified in the dialyzer reprocessing manual, established before the initiation of a reprocessing program, and maintained thereafter. The manufacturer or designer's recommendations for the water supply should be followed. Provision should also be made for adequate drains, ventilation, and electrical power.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V316

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.2.3 Maintenance (written procedures for maintenance)

4 Records

4.3 Equipment maintenance record

7.2.3 Maintenance

Written maintenance procedures and a schedule of preventive maintenance activities designed to minimize equipment malfunctions should be established. In the case of purchased reprocessing equipment or safety equipment, the recommendations of the vendor should be followed unless documented experience supports alternative approaches. If the manufacturer's recommendations are not available, reuse equipment and safety equipment should be inspected on a semiannual basis.

4 Records

4.3 Equipment maintenance record

Records shall be maintained of the dates of preventive maintenance procedures and the results of scheduled testing in order to ensure the proper functioning of reprocessing equipment, environmental-control equipment, safety equipment, or other equipment.

4 Records

A place should be provided for the signature or other unique mark of identification of the person...performing preventative maintenance procedures.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V317

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.2.4 Repairs

If the reprocessing system fails to function as expected, qualified personnel should investigate and repair the problem. The reprocessing system function testing should be

repeated after repairs of automated equipment and, if appropriate, after repairs of manual equipment before either the dialyzer is reprocessed or the reprocessed dialyzer is used for clinical dialysis.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V318

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50 (b)(1):

8 Physical plant and environmental safety considerations

8.1 Reprocessing area and ventilation

The reprocessing area should be designed to suit the operation carried out and maintain acceptable ambient concentrations of harmful substances (see Table 1). The area should be kept clean and sanitary. It may be part of the dialysis treatment area, as long as equipment used is properly designed and vented to meet the requirements for environmental safety (see [AAMI] 8.5).

Table 1—OSHA environmental exposure limits (29 CFR 1910, 1 July 1998), except as indicated

<i>Substance/material</i>	<i>Limits (PEL)^a</i>
<i>Acetic acid</i>	<i>10 ppm TWA^b</i>
<i>Chlorine dioxide (syn: chlorine oxide)</i>	<i>0.1 ppm TWA</i>
<i>Citric acid</i>	<i>None developed</i>
<i>Formaldehyde</i>	<i>0.75 ppm TWA 2 ppm STEL^c(15 min) 0.5 ppm action level</i>
<i>Glutaraldehyde</i>	<i>0.2 ppm ceiling NIOSH/OSHA</i>
<i>Hydrogen peroxide</i>	<i>1 ppm TWA</i>
<i>Peracetic acid</i>	<i>None developed</i>
<i>Phenol</i>	<i>5 ppm TWA</i>

ppm = parts per million

^a) PEL (permissible exposure limit) represents the limit of what employees can be exposed to; PELs can be TWAs or STELs.

b) TWA (time-weighted average) represents the limit of what an employee can be exposed to in an eight-hour period.

c) STEL (short-term exposure limit) represents the limit of what an employee can be exposed to in any 15-minute time period.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V319

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

8.5 Environmental safety

The dialysis facility shall have written procedures for safe storage and handling of chemicals used in reprocessing (see National Institute for Occupational Safety and Health [NIOSH]/OSHA, 1980; Sax, 1979; material safety data sheets [MSDS]).

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V320

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

8.4 Personnel protection: gear

Personnel shall wear durable gloves and protective clothing when handling the dialyzer during initiation and termination of dialysis and during the reprocessing procedure. Standard Precautions shall be observed.

Personnel shall wear eye protection when performing steps that may result in spills or splashes of substances of known or suspected toxicity. These agents shall be handled only in areas with adequate ventilation, washing facilities, eyewash stations, appropriate respirators, and spill control materials. When personnel are handling concentrated toxic substances, they shall wear aprons impervious to these substances.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V321

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

8.2 Storage area

Reprocessing materials, hemodialyzers awaiting reprocessing, and reprocessed hemodialyzers should be stored so as to minimize deterioration, contamination, or breakage. New, used, and reprocessed dialyzers should be segregated to make clear the status of each group of dialyzers. Environmental contamination of the storage area should be controlled and monitored, if the personnel determine those actions to be necessary. Storage areas for new dialyzers and reprocessing materials should be designed to facilitate rotation of stock and cleaning. Storage arrangements should also take into account fire safety considerations, OSHA regulations, and other appropriate regulations.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V322

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

9 Reprocessing supplies

9.1 Specifications and testing

Each reprocessing material should meet a written specification. The fulfillment of that requirement may be determined by certification by the product's supplier that the product meets necessary specifications, labeling for its intended purpose, or by testing procedures by trained personnel, as appropriate. The requirement may also be complied with by purchasing a specific grade as specified by the process, such as USP citric acid. When the user performs testing, he or she should maintain a log of the date of test, the identifying number (lot number) of the batch, the person performing any testing, and the test results.

When bleach is purchased from a commercial outlet, the labeled concentration should be between 5.25% and 6.15%, and the formula should not contain fragrances or scents.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V323

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

9.2 Inventory control

Reprocessing supplies should be used on a first-in, first- out basis, and outdated supplies should be identified and discarded.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V324

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50 b)(1):

7.2.2 Process control testing: methods established

7.2.2.1 Dialyzer test methods

Dialyzer test methods ([AAMI] 11.3) shall be established before clinical use of the reprocessed dialyzers.

Verification of tests should be repeated after each significant change in the reprocessing system. For automated systems, adherence to the manufacturer's instructions can verify the tests. For manual systems, confirmation of the accuracy of total cell volume (TCV) measurement and the membrane integrity test can verify the tests.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V325

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

7.2.2 Process control testing: concentration of germicide

7.2.2.2

The test for the concentration of germicide or chemical shall be established before clinical use of the reprocessed dialyzers ([AAMI] 11.4.1.6 and 12.3.2). For systems using heat disinfection, verifiable evidence shall be available before the next use that dialyzers have been exposed to the appropriate temperature for the time required. If chemicals are used to enhance heat disinfection, both a presence test and a verification of time and temperature shall be performed.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V326

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

4 Records

4.2 Reprocessing record: complete/available to patient

Records shall be kept that identify the new dialyzer, the date of each reprocessing step, the person performing the procedure, his or her signature or other identifying mark, and the results of tests of device performance and safety. This information should be recorded in a reprocessing log or the patient's chart, whichever is more convenient. Patients must be permitted to read records pertaining to the reprocessing and reuse of their own dialyzers.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V327

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

10 Hemodialyzer labeling

Each reprocessed hemodialyzer shall be used for only one patient. The labeling shall uniquely identify the patient who is using the dialyzer. The dialyzer should also be labeled with other information essential to proper reuse procedure.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V328

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

10.1 Time of labeling

Each hemodialyzer shall be labeled before or at the first use of the device, and the label shall be updated after each use (see AAMI 10.3).

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V329

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

10.2 Label composition

Markings should be resistant to normal reprocessing and dialysis procedures. The dialyzer labeling should not obscure the manufacturer's model number, lot number, or indicators of the direction of blood or dialysate flow or other pertinent information unless provision is made for recording this information on the label. The label on

hemodialyzers with transparent casings should permit the blood path to be readily inspected.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V330

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

10.3 Information recorded on label/similar name warning

The dialyzer shall be labeled with the patient's name, the number of previous uses, and the date of the last reprocessing. Dialyzers of patients with similar last names should have a warning to the user to take extra care in ensuring that the name or other identifying information on the label corresponds to that of the patient. If there is sufficient room, the dialyzer may also be labeled with the results of tests, the signature or other unique means of identifying the person performing the various steps in the reprocessing procedure, and the reference values for performance parameters. If this information appears on the label, a permanent record should also be kept (see [AAMI] 4.2) Electronic records are acceptable. If records are electronic, the test results should be available to the user.

Home dialysis patients are exempted from the recommendation that the patient's name appear on the label, unless the dialyzers are taken to a dialysis facility for reprocessing.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V331

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11 Reprocessing

11.1 Transportation and handling

Persons handling used dialyzers during transportation shall do so in a clean and sanitary manner maintaining Standard Precautions until the dialyzer is disinfected both internally and externally. To inhibit bacterial growth, dialyzers that cannot be

reprocessed within 2 hours should be refrigerated and not allowed to freeze. Other transportation and handling issues (such as prolonged delays in reprocessing) not described in this recommended practice shall be validated and documented by the responsible party.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V332

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.2 Rinsing/cleaning

11.2.1

When pre-cleaning is done, it is part of the reprocessing procedures.

All applicable requirements for design and maintenance of equipment included in this document should be adhered to for pre-cleaning of equipment. The maximum pressures for the dialyzer, or other limits set by the manufacturer, should be adhered to.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V333

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.2 Rinsing/cleaning

11.2.3

Pre-cleaning the dialyzer (rinsing and cleaning) shall be done with a fluid or fluids made with water that meets the requirements of these regulations related to allowable bacterial and endotoxin levels.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V334

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.1.2 Dialyzer header cleaning and disinfection

The cleaning and disinfection of the header space should be done only when necessary and only before the dialyzer is reprocessed. The manufacturer's instructions should be followed. Header caps and O-rings shall be kept with their respective dialyzers.

If the header cap is removed to clean the header space, cleaning shall be done with water meeting the requirements of these regulations related to allowable bacterial and endotoxin levels.

Once the O-ring and the header cap are cleaned and before they are reassembled at the end of the dialyzer, they should be disinfected. The disinfectant shall not be rinsed and shall be allowed to remain on the dialyzer components as they are reassembled. If any cracking of the header occurs, the process should be evaluated.

If the header space is cleaned with the header cap in place, it is necessary to ensure that the end of the fiber bundle is not damaged. If water is used, it shall meet the requirements of these regulations.

If automated equipment is used, the manufacturer's instruction for use shall be followed.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V335

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.2 Rinsing/cleaning: chemicals used/rinse after each

11.2.4

Diluted solutions of hydrogen peroxide, sodium hypochlorite, peracetic acid, or other chemicals may be used as cleaning agents for the blood compartment, provided that the cleaning agent has been shown to be reduced to safe levels by subsequent flushing and has no significant adverse effects on the structural integrity and performance of the dialyzer.

Each chemical shall be rinsed from the dialyzer before the next chemical is added, unless mixing is known to be safe and effective for reprocessing.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V336

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.3 Performance measurements

11.3.1 Performance test after each use

Total cell volume (TCV) may be used for hollow-fiber dialyzers. The acceptable TCV is at least 80% of the original TCV. The dialyzer prescription should take into account the 10% loss in clearance (20% loss in TCV) that may occur with dialyzer reuse.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V337

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.3.3 Blood path integrity test

A membrane integrity test such as an air pressure leak test shall be done between uses.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V338

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4 Germicide

The rinsed and cleaned dialyzer shall be treated by a process that prevents adverse effects caused by microbial contamination. The blood and dialysate compartments of the dialyzer shall be sterilized or subjected to high-level disinfection because an inadequate germicidal process may result in infection in the patient. Low-level disinfection is sufficient for the exterior of the device.

The user shall consult the dialyzer labeling for contraindications or warnings regarding methods and applicability of specific germicidal processes or chemicals.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V339

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.1 Interior (blood/dialysate compartment)

11.4.1.1 Germicidal process

Chemical germicides or other procedures used for disinfecting of hemodialyzers have been shown to accomplish at least high-level disinfection when tested in dialyzers artificially contaminated with appropriate microorganisms.

If the germicide has an expiration date from the manufacturer, staff members should be sure that the chemical is not outdated. Some germicides have recommendations for maximum storage time after dilution or activation and before usage. If this is the case, the expiration date of the prepared germicide solution should be marked on the outside of the germicide solution container, and that date should be checked at the beginning of each day, before reprocessing begins.

The disinfection process shall not adversely affect the integrity of the dialyzer. Germicides shall be rinsed from the dialyzer to below known toxic levels within a rinse-out period established for the particular germicide (see AAMI 12.4). To prevent injury, staff members shall take care not to mix reactive materials such as sodium hypochlorite and formaldehyde.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V340

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.1.4 Chemical germicidal procedure

If applicable, the hemodialyzer shall be filled with the germicide solution until the concentration in the hemodialyzer is at least 90% of the prescribed concentration.

The ports of chemically disinfected dialyzers shall be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer, or with any other germicide approved by the FDA as a disinfectant that does not adversely affect the materials of the dialyzer.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V341

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.1.6 Chemical germicide concentration

Reprocessing systems in which each batch of germicide is manually prepared, each batch of germicide shall be tested before use to verify the proper concentration of the germicide. This requirement does not apply in cases in which each dialyzer is tested for concentration before setup.

When the germicide is diluted on-line, its concentration in the hemodialyzer immediately after reprocessing should be checked at least monthly for each reprocessing system.

When the germicide is partially or fully diluted by the user ... the solution [should] be thoroughly mixed.

Interpretive Guidance 494.50(b)(1)

Guidance is pending and will be updated in future release.

V342

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.4.2 Exterior: low-level disinfection

The outside of the dialyzer should be soaked or wiped clean of visible blood and other foreign material. For chemically disinfected dialyzers, a low-level germicide that is compatible with the dialyzer's materials of construction should be used for this purpose.

Interpretive Guidance 494.50(b)(1)

Guidance is pending and will be updated in future release.

V343

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.5 Inspection: after reprocessing

The hemodialyzer shall be examined after reprocessing to ensure that the external surface is clean, the dialyzer is not damaged, and the rinsing of blood has been satisfactorily completed. The dialyzer should also be aesthetically acceptable in appearance to patients and staff.

11.5.1

The dialyzer jacket should be free of visible blood or other foreign material.

11.5.2

There shall be no leaks or cracks in the dialyzer jacket or the blood or dialysate ports.

11.5.3

No more than a few dark, clotted fibers should be evident on inspection of the exterior of the hollow fibers.

11.5.4

The headers of hollow-fiber dialyzers should be free of all but small peripheral clots or other deposits.

11.5.5

Blood and dialysate ports shall be capped without evidence of leakage.

11.5.6

The label shall be properly filled out and legible.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V344

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.6 Disposition of rejected dialyzers

Reprocessed dialyzers that have been rejected for failure to meet performance, inspection, or other release criteria should either be immediately discarded or further reprocessed and subjected to the performance requirements of [AAMI] 11.3, 11.4, and 11.5. If the dialyzer is to be further reprocessed, rather than discarded, it shall be labeled as rejected and stored in a quarantine area to preclude use until requirements are met.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V345
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11.7 Storage

Reprocessed dialyzers that meet the performance and inspection criteria for multiple use should be stored according to the provisions of [AAMI] 8.2. Prolonged storage (greater than 1 month) should be documented to be safe and effective.

Dialyzers that have exceeded the facility's maximum storage time shall be reprocessed or discarded. The dialyzer and disinfectant labeling should be consulted regarding proper storage conditions.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V346
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12 Preparation for dialysis and testing for chemical germicides and potentially toxic residues

A written procedure that has been shown to be effective shall be followed.

12.5 Written procedure for tests for germicide or other residues

There shall be a written procedure for all tests employed in preparing the dialyzer for use, including mention of each test's sensitivity. The germicide manufacturer's instructions for use should be consulted in determining the maximum residual level. The physician in charge of the reuse program shall approve any alterations in the procedures.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V347
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.1 Visual inspection (dialyzer inspection prior to use)

The dialyzer should be inspected before it is prepared for use. Completion of this inspection should be recorded in the reprocessing record (see [AAMI] 4.2), along with the signature or other unique means of identifying the person completing the inspection. The inspection should include the following:

- a. The reprocessed dialyzer shall be legibly labeled with the information recommended in [AAMI] 10.3.*
- b. There should be no indication of structural damage or tampering with the dialyzer.*
- c. The ports of the dialyzer should be properly capped.*
- d. The presence of germicide in the dialysate and blood compartments, including headers, should be confirmed, and there should be no evidence of leakage from the ports or other portions of the dialyzer.*
- e. The duration and conditions of storage should be appropriate for the agent or method used to sterilize or disinfect the dialyzer; and*
- f. The cosmetic appearance of the dialyzer should be aesthetically acceptable to the staff and the patient.*

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V348
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.2 Verification of patient identification

Except in the case of home dialysis, two persons should check that the first and last names on the dialyzer and any other appropriate identifying information correspond to the identifying information on the patient's permanent record. If possible, one of the persons checking identification should be the patient. Completion of this step shall be

recorded, along with the signature or other unique means of identifying the person verifying patient identification.

NOTE—This step may be done later in the procedure but shall precede initiation of dialysis.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V349

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.3 Verification of germicidal contact

The contact time of the germicide or disinfection procedure shall comply with the facility's protocol and the manufacturer's recommendations.

The presence of chemical germicide in each hemodialyzer shall be ensured through either direct testing or an on-line process and procedural control. If other disinfection (e.g., heat) procedures are used, there shall be methods to ensure that each hemodialyzer has been properly subjected to the disinfection process. A record shall be kept indicating that the dialyzer has undergone the appropriate storage time, and the record shall be appropriately verified.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V350

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.3.1 Presence test of each hemodialyzer

Certain germicide manufacturers require testing for the presence of germicide in each hemodialyzer before the rinsing step. These instructions should be followed.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V351

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.3.2 Process control and sampling (testing for presence of germicide)

[If a germicide manufacturer does not require testing each hemodialyzer for the presence of germicide], the presence of germicide may be ensured by [either] a direct presence test of each hemodialyzer or the use of process control and sampling of the dialyzer for germicide.

12.3.2.1 Process control

- a. Use hemodialyzer germicide filling equipment with on-line automatic monitors during the germicide dilution and hemodialyzer filling process; or***
- b. Use an indicator substance (e.g., FD&C Blue #1), which has been added to the germicide, and that reliably indicates the presence of germicide. If blue dye is used, it should be added to the germicide concentrate before dilution, not to the fully diluted solution.***

12.3.2.2 Sampling for process validation

- a. Sample at least one hemodialyzer per patient shift per reuse system with a direct presence test (do not use a Schiff test for formaldehyde for this purpose because it will detect the presence of inadequate concentrations of formaldehyde). Samples should be taken immediately after the dialyzers have been reprocessed.***
- b. For germicide prepared in batches, sample at least one hemodialyzer from each batch with a direct presence test. Samples should be taken immediately after the dialyzers have been reprocessed.***
- c. Sampling and testing are to be accomplished before patients use any hemodialyzers processed on this shift.***

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V352

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.4 Priming the dialyzer and rinsing the germicide

If the manufacturer's instructions so require, a germicide presence test shall be performed before the germicide is rinsed from the dialyzer.

The dialyzer shall be rinsed and primed according to a written procedure that has been documented to produce a reduction in the concentration of germicide to an acceptable level and result in a physiological solution in the blood and dialysate compartments. The dialyzer manufacturer's instructions should be considered in developing these procedures.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V353

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

12.4.1 Testing for residual germicide

Residual germicide shall be measured by a test of appropriate sensitivity according to a written procedure to ensure that the germicide level is below the maximum recommended residual concentration. Completion of this step shall be documented, along with the signature or other unique means of identifying the person performing the test.

A written policy should establish the maximum allowable time between rinsing the germicide from the dialyzer and beginning dialysis. The priming, removal, and residual testing process should be reinstated after a delay sufficient to bring concentrations of germicide above the recommended level (rebound). Additional rinsing should be performed to yield a germicide level below the maximum recommended concentration before initiating of dialysis.

A rinse procedure should be defined and documented step by step, and all personnel should be familiar with and follow it.

If heat disinfection is used, the dialyzer should be cool to the touch before it is primed with saline.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V354

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13 Monitoring

13.1 Dialysis

The clinical course of the patient should be observed and recorded during each dialysis to identify possible complications caused by new or reprocessed dialyzers.

Dialyzer failures should be recorded and systematically evaluated. Applicable home dialysis patients and their assistants should be instructed in the appropriate observation, recording requirements, and reporting procedures.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V355

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13.2 Symptoms

13.2.1 Fever and chills

Patients' temperatures should be measured and recorded at least before and after dialysis with new and reprocessed dialyzers. A temperature of over 37.8° C or 100° F, taken orally, or chills should be reported to the physician, [advanced practice registered nurse or physician assistant]. Any patient with an unexplained fever and/or chills should be evaluated for the possibility of a pre-existing infection (e.g., [at an] access site). The dialysis procedure should also be evaluated to rule out the use of contaminated water, errors in treatment delivery, or incorrect dialyzer reprocessing.

13.2.2 Other symptoms

Other unexplained symptoms such as pain in the blood- access arm at the onset of dialysis should be evaluated by the physician, [advanced practice registered nurse or physician assistant] and consideration given to the possibility that the symptom may be attributed to residual disinfectant in the new or reprocessed dialyzer or contamination of the water treatment equipment.

Suspected reactions to the residual germicide should prompt reevaluation of the rinsing procedure and a test for residual germicide (see [AAMI] 12.4.1).

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V356

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13.2.3 Recording

Any significant events such as the occurrence of symptoms listed in [AAMI] 13.2.1 and 13.2.2 should be recorded on an incident report form which would include the results of any evaluations conducted by the physician and others, and the event should be considered for reporting to the manufacturer(s) in accordance with the FDA's Medical Device User Reporting procedures. The resolution of actual or suspected problems caused by reprocessed dialyzers should be indicated. This form should be kept in the complaint investigation record file (see [AAMI] 4.5).

4 Records

4.5 Complaint investigation record

Records shall be kept of all complaints by patients and staff members about failures of preprocessed and reprocessed dialyzers or possible adverse reactions to any dialyzers; the results of a comprehensive investigation of these alleged problems; and, if appropriate, the corrective actions taken. The records shall be reviewed periodically for trends of adverse reactions. Compliance with the FDA's Medical Device User Reporting procedures shall be demonstrated.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release

V357

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13.3 Dialyzer failures (blood leaks)

Dialyzer blood leaks should be recorded in a log kept in the complaint investigation record file (see [AAMI] 4.5). If there is excessive deviation from the expected performance, testing should be repeated (see [AAMI] 11.3.1) and appropriate adjustments made in the reprocessing procedure.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V358

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

13.4 Clinical results (monitoring patient results; Kt/V)

Monitoring of relevant patient results is recommended to ensure that all parameters relating to hemodialyzer clearance are being met. Specifically, examination of urea reduction ratio (URR) or Kt/V over time is necessary. The failure of these results to meet the expectations of the dialysis prescription should be investigated. Deterioration of a patient's clinical condition or variability of routine dialysis procedures (heparinization, ultrafiltration, erythropoietin requirement) requires investigation of all practices, including reuse. Reports of investigations should be filed in the complaint log.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release

V359

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

11 Reprocessing
11.3.2 Ultrafiltration

If the expected weight loss is not achieved with the reprocessed dialyzer, the reprocessing method and all other weight removal variables should be reevaluated.

Interpretive Guidance § 494.50(b)(1)
Guidance is pending and will be updated in future release

V360
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14 Quality assurance (internal standards and clinical outcomes)

The criteria chosen as the internal standards of a facility shall be documented in its policy and/or procedure manual. Process review should be part of the activity of the individual carrying out the process, and oversight of that review by another qualified member of the staff or a group of staff members should affirm, modify, or repeat these observations to confirm or improve the process.

Clinical outcomes serve as the most important indicator of quality of all dialysis treatment practices including reuse. Final oversight is the responsibility of the medical director. See Table 2 for a summary of the audit schedule.

14.1 Records

A record of review, comments, trend analysis, and conclusions arising from QA practices serve as a foundation for future review and as documentation to external evaluation.

Interpretive Guidance § 494.50(b)(1)
Guidance is pending and will be updated in future release.

V361
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.2 Schedule of quality assurance activities

Problems in a particular aspect of operations should be reviewed and tracked until a solution is in place and demonstrated to be effective. The medical director is responsible for scheduling review, endorsing findings, and, when appropriate, implementing changes.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V362

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.3 Patient considerations

Personnel should audit at least annually compliance with the facility's policy to inform patients of the facility's reuse practices.

V363

(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.4 Equipment Manuals and Procedures

Designated staff members should audit written procedures and manuals for relevance at least annually and whenever adverse findings could be attributed to equipment failure. Designated staff should also audit maintenance and repair policies at least annually.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V364
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.5 Physical plant and environmental safety considerations (audit frequency)

Designated staff members should audit the provisions of [AAMI] 8.1, [Reprocessing area and ventilation], at least annually. The provisions of [AAMI] 8.2, [Storage area], and [AAMI] 8.4, [Personnel protection] should be audited quarterly.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V365
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.6 Reprocessing supplies (audit frequency)

Designated staff members should audit the provisions of [AAMI] section 9[: Reprocessing supplies: Specifications and testing, and inventory control] at least semiannually.

V366
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.7 Hemodialyzer labeling (audit frequency)

Designated staff members should audit the provisions of [AAMI] section 10.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V367
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.8 Reprocessing (audit frequency)

Initially, designated staff members should audit the written procedures for the various steps in this process and verify implementation at least monthly. Subsequently, semiannual audits may be sufficient if there is a documented history of favorable results. Trend analysis should be performed.

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V368
(Rev.)

From ANSI/AAMI RD47:2002/A1:2003 Requirements, as Adopted by Reference 42 CFR 494.50(b)(1):

14.9 Preparation for dialysis (audit frequency)

At least quarterly, designated personnel should audit the written procedures and verify their implementation. At least quarterly, designated staff members should verify the tests for the presence of germicide and the test for residual germicide by using positive and negative control solutions, on those products that are not specifically intended for use in dialyzer reuse germicide indicator tests and which have not been cleared by the FDA.

End ANSI/AAMI RD:47:2002/A1:2003 Requirements

Interpretive Guidance § 494.50(b)(1)

Guidance is pending and will be updated in future release.

V378
(Rev.)

§ 494.50(b) Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines. A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(2) Reprocess hemodialyzers and bloodlines –

(i) By following manufacturer’s recommendations; or

(ii) Using an alternate method and maintaining documented evidence that the method is safe and effective.

Interpretive Guidance § 494.50(b)(2)

Guidance is pending and will be updated in future release.

V379

(Rev.)

§ 494.50(b) Standard: Reprocessing requirements for the reuse of hemodialyzers and bloodlines. A dialysis facility that reuses hemodialyzers and bloodlines must adhere to the following reprocessing guidelines:

(3) Not expose hemodialyzers to more than one chemical germicide, other than bleach (used as cleaner in this application), during the life of the dialyzer. All hemodialyzers must be discarded before a different chemical germicide is used in the facility.

No Tag

§ 494.50(c) Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.

In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:

(1) Monitor patient reactions during and following dialysis.

Interpretive Guidance § 494.50(c)(1)

This tag is informational, as this requirement is addressed in the ANSI/AAMI RD:47:2002, section 13, at tags V354 and V355.

V381

(Rev.)

§ 494.50(c) Standard: Monitoring, evaluation, and reporting requirements for the reuse of hemodialyzers and bloodlines.

In addition to the requirements for hemodialyzer and bloodline reuse specified in paragraphs (a) and (b) of this section, the dialysis facility must adhere to the following:

(2) When clinically indicated (for example, after adverse patient reactions), the facility must –

(i) Obtain blood and dialysate cultures and endotoxin levels; and

Interpretive Guidance § 494.50(c)(2)(i)

Guidance is pending and will be updated in future release.

V382

(Rev.)

§ 494.50(c)(2) When clinically indicated (for example, after adverse patient reactions), the facility must –

(ii) - Undertake evaluation of its dialyzer reprocessing and water purification system.

When this evaluation suggests a cluster of adverse patient reactions is associated with hemodialyzer reuse, the facility must suspend reuse of hemodialyzers until it is satisfied the problem has been corrected.

Interpretive Guidance § 494.50(c)(2)(ii)

Guidance is pending and will be updated in future release.

V383

(Rev.)

§ 494.50(c)(2) When clinically indicated (for example, after adverse patient reactions), the facility must –

(iii) Report the adverse outcomes to the FDA and other Federal, State or local government agencies as required by law.

Interpretive Guidance § 494.50(c)(2)(iii)

Guidance is pending and will be updated in future release.

V400

(Rev.)

§494.60 Condition: Physical environment

Interpretive Guidance §494.60

Guidance is pending and will be updated in future release.

V401

(Rev.)

§494.60 Condition: Physical environment.

The dialysis facility must be designed, constructed, equipped, and maintained to provide dialysis patients, staff, and the public a safe, functional, and comfortable treatment environment.

Interpretive Guidance §494.60

Guidance is pending and will be updated in future release.

V402

(Rev.)

§494.60 (a) Standard: Building. The building in which dialysis services are furnished must be constructed and maintained to ensure the safety of the patients, the staff and the public.

Interpretive Guidance §494.60(a)

Guidance is pending and will be updated in future release.

V403

(Rev.)

§494.60(b) Standard: Equipment maintenance. The dialysis facility must implement and maintain a program to ensure that all equipment (including emergency equipment, dialysis machines and equipment, and the water treatment system) are maintained and operated in accordance with the manufacturer's recommendations.

Interpretive Guidance §494.60(b)

Guidance is pending and will be updated in future release.

V404

(Rev.)

§ 494.60 (c) Standard: Patient care environment.

(1) The space for treating each patient must be sufficient to provide needed care and services, prevent cross-contamination, and to accommodate medical emergency equipment and staff.

Interpretive Guidance §494.60(c)(1)

Guidance is pending and will be updated in future release.

V405

(Rev.)

§ 494.60(c)(2) - The dialysis facility must:

(i) Maintain a comfortable temperature within the facility; and

(ii) Make reasonable accommodations for the patients who are not comfortable at this temperature.

Interpretive Guidance §494.60(c)(2)

Guidance is pending and will be updated in future release.

V406

(Rev.)

§ 494.60(c)(3) - The dialysis facility must make accommodations to provide for patient privacy when patients are examined or treated and body exposure is required.

Interpretive Guidance § 494.60(c)(3)

Guidance is pending and will be updated in future release.

V407

(Rev.)

§ 494.60(c)(4) Patients must be in view of staff during hemodialysis treatment to ensure patient safety, (video surveillance will not meet this requirement).

Interpretive Guidance §494.60(c)(4)

Guidance is pending and will be updated in future release.

V417

(Rev.)

§ 494.60(d) - Standard: Fire safety. (1) Except as provided in paragraph (d)(2) of this section, dialysis facilities that do not provide one or more exits to the outside at grade

level from the patient treatment area level, must comply with provisions of the Life Safety Code (NFPA 101 and its Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4) applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

Interpretive Guidance § 494.60(d)(1)

Guidance is pending and will be updated in future release.

V418

(Rev.)

§ 494.60(d)(2) - Notwithstanding paragraph (d)(1) of this section, dialysis facilities participating in Medicare as of October 14, 2008 that require sprinkler systems are those housed in multi-story buildings construction Types II(000), III(200), or V(000), as defined in the Life Safety Code, section 21.1.6.1, which were constructed after January 1, 2008, and those housed in high rise buildings over 75 feet in height, which were constructed after January 1, 2008.

Interpretive Guidance §494.60(d)(2)

Guidance is pending and will be updated in future release.

V419

(Rev.)

§ 494.60(d)(3) - If CMS finds that a fire and safety code imposed by the facility's State law adequately protects a dialysis facility's patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the Life Safety Code.

Interpretive Guidance § 494.60(d)(3)

Guidance is pending and will be updated in future release.

V420

(Rev.)

§494.60(d)(4) – In consideration of a recommendation by the State survey agency or at the discretion of the Secretary, the Secretary may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ESRD facility, but only if the waiver will not adversely affect the health and safety of the patients.

Interpretive Guidance § 494.60(d)(4)

Guidance is pending and will be updated in future release.

V421
(Rev.)

§ 494.60(d)(5) – No dialysis facility may operate in a building that is adjacent to an industrial high hazard area, as described in sections 20.1.3.7 and 21.1.3.7 of the Health Care Facilities Code (NFPA 99 and its Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6).

Interpretive Guidance § 494.60(d)(5)
Guidance is pending and will be updated in future release.

V422
(Rev.)

§ 494.60(e) - Standard: Building Safety. (1) Dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level must meet the applicable provisions of the Health Care Facilities Code, regardless of the number of patients served.

Interpretive Guidance §494.60(e)
Guidance is pending and will be updated in future release.

No tag

§ 494.60(e)(2) – Chapters 7,8,12, and 13 of the Health Care Facilities Code do not apply to a dialysis facility.

V423
(Rev.)

§ 494.60(e)(3) – If application of the Health Care Facilities Code would result in unreasonable hardship for the dialysis facility, CMS may waive specific provisions of the Health Care Facilities Code for such facility, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidance §494.60(e)(3)
Guidance is pending and will be updated in future release.

V424
(Rev.)

§ 494.60 (f): Incorporation by reference. – The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of

the Federal Register in accordance with 5 U.S.C 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: www.archives.gov/federal_register/cfr/ibr-locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

(I) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1-617-770-3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

Interpretive Guidance §494.60(f)

Guidance is pending and will be updated in future release.

E-0003

(Rev.)

§ 494.62 Condition of participation: Emergency preparedness.

The dialysis facility must comply with all applicable Federal, State, and local emergency preparedness requirements. These emergencies include, but are not limited

to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.

The dialysis facility must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

Interpretive Guidance § 494.62
Refer to Appendix Z for guidance.

E-0004
(Rev.)

§ 494.62(a) Emergency plan. The dialysis facility must develop and maintain an emergency preparedness plan that must be evaluated and updated at least every 2 years. The plan must do all of the following:

Interpretive Guidance § 494.62(a)
Refer to Appendix Z for guidance.

E-0006
(Rev.)

§ 494.62(a)(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.
(2) Include strategies for addressing emergency events identified by the risk assessment.

Interpretive Guidance § 494.62(a)(1) and (2)
Refer to Appendix Z for guidance.

E-0007
(Rev.)

§ 494.62(a)(3) Address patient population, including, but not limited to, the type of services the dialysis facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

Interpretive Guidance § 494.62(a)(3)
Refer to Appendix Z for guidance.

E-0009
(Rev.)

§ 494.62(a)(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.

Interpretive Guidance § 494.62(a)(4)
Refer to Appendix Z for guidance.

E-0013
(Rev.)

§ 494.62(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area. At a minimum, the policies and procedures must address the following:

Interpretive Guidance § 494.62(b)
Refer to Appendix Z for guidance.

E-0018
(Rev.)

§ 494.62(b)(1) A system to track the location of on-duty staff and sheltered patients in the dialysis facility's care during and after an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the dialysis facility must document the specific name and location of the receiving facility or other location.

Interpretive Guidance § 494.62(b)(1)
Refer to Appendix Z for guidance.

E-0020
(Rev.)

§ 494.62(b)(2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.

Interpretive Guidance § 494.62(b)(2)

Refer to Appendix Z for guidance.

E-0022

(Rev.)

§ 494.62(b)(3) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

Interpretive Guidance § 494.62(b)(3)

Refer to Appendix Z for guidance.

E-0023

(Rev.)

§ 494.62(b)(4) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

Interpretive Guidance § 494.62(b)(4)

Refer to Appendix Z for guidance.

E-0024

(Rev.)

§ 494.62(b)(5) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

Interpretive Guidance § 494.62(b)(5)

Refer to Appendix Z for guidance.

E-0025

(Rev.)

§ 494.62(b)(6) The development of arrangements with other dialysis facilities or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to dialysis facility patients.

Interpretive Guidance § 494.62(b)(6)

Refer to Appendix Z for guidance.

E-0026
(Rev.)

§ 494.62(b)(7) The role of the dialysis facility under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

Interpretive Guidance § 494.62(b)(7)
Refer to Appendix Z for guidance.

E-0027
(Rev.)

§ 494.62(b)(8) How emergency medical system assistance can be obtained when needed.

Interpretive Guidance § 494.62(b)(8)
Refer to Appendix Z for guidance.

E-0028
(Rev.)

§ 494.62(b)(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

Interpretive Guidance § 494.62(b)(9)
Refer to Appendix Z for guidance.

E-0029
(Rev.)

§ 494.62(c) Communication plan. The dialysis facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

Interpretive Guidance § 494.62(c)
Refer to Appendix Z for guidance.

E-0030

(Rev.)

§ 494.62(c) [The communication plan must include all of the following:]

(1) Names and contact information for the following:

- (i) Staff.***
- (ii) Entities providing services under arrangement.***
- (iii) Patients' physicians.***
- (iv) Other dialysis facilities.***
- (v) Volunteers.***

Interpretive Guidance § 494.62(c)(1)

Refer to Appendix Z for guidance.

E-0031

(Rev.)

§ 494.62(c) [The communication plan must include all of the following:]

(2) Contact information for the following:

- (i) Federal, State, tribal, regional or local emergency preparedness staff.***
- (ii) Other sources of assistance.***

Interpretive Guidance § 494.62(c)(2)

Refer to Appendix Z for guidance.

E-0032

(Rev.)

§ 494.62(c) [The communication plan must include all of the following:]

(3) Primary and alternate means for communicating with the following:

- (i) Dialysis facility's staff.***
- (ii) Federal, State, tribal, regional, or local emergency management agencies.***

Interpretive Guidance § 494.62(c)(3)

Refer to Appendix Z for guidance.

E-0033

(Rev.)

§ 494.62(c) [The communication plan must include all of the following:]

(4) A method for sharing information and medical documentation for patients under the dialysis facility's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

Interpretive Guidance § 494.62(c)(4),(5) and (6)

Refer to Appendix Z for guidance.

E-0034

(Rev.)

§ 494.62(c) [The communication plan must include all of the following:]

(7) A means of providing information about the dialysis facility's needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

Interpretive Guidance § 494.62(c)(7)

Refer to Appendix Z for guidance.

E-0036

(Rev.)

§ 494.62(d) Training, testing, and orientation. The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing, and patient orientation program must be evaluated and updated at least every 2 years.

Interpretive Guidance § 494.62(d)

Refer to Appendix Z for guidance.

E-0038

(Rev.)

§ 494.62(d)(1) Training program. The dialysis facility must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Demonstrate staff knowledge of emergency procedures, including informing patients of—

- (A) What to do;*
- (B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;*
- (C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and*
- (D) How to disconnect themselves from the dialysis machine if an emergency occurs.*
 - (iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and*
 - (v) Properly train its nursing staff in the use of emergency equipment and emergency drugs.*
 - (vi) Maintain documentation of the training.*
 - (vii) If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures.*

Interpretive Guidance § 494.62(d)(1)

Refer to Appendix Z for guidance.

E-0039

(Rev.)

§ 494.62(d)(2) Testing. The dialysis facility must conduct exercises to test the emergency plan at least annually. The dialysis facility must do all of the following:

- (i) Participate in a full-scale exercise that is community-based every 2 years; or*
 - (A) When a community-based exercise is not accessible, an individual, and a facility-based functional exercise every 2 years; or*
 - (B) If the dialysis facility experiences an actual or man-made emergency that requires activation of the emergency plan, the dialysis facility is exempt from engaging in its next required full scale community-based or individual, facility-based functional exercise following the onset of the emergency event.*
- (ii) Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:*
 - (A) A second full scale exercise that is community-based or an individual, facility-based functional exercise; or*
 - (B) A mock disaster drill; or*
 - (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.*

(iii) Analyze the dialysis facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the dialysis facility's emergency plan, as needed.

Interpretive Guidance § 494.62(d)(2)

Refer to Appendix Z for guidance.

E-0040

(Rev.)

§ 494.62(d)(3) Patient orientation: Emergency preparedness patient training. The facility must provide appropriate orientation and training to patients, including the areas specified in paragraph (d)(1) of this section.

Interpretive Guidance § 494.62(d)(3)

Refer to Appendix Z for guidance.

E-0042

(Rev.)

§ 494.62(e) Integrated healthcare systems. If a dialysis facility is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the dialysis facility may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include all of the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

Interpretive Guidance § 494.62(e)
Refer to Appendix Z for guidance.

Subpart C – Patient Care

V450
(Rev.)

§ 494.70 Condition: Patients' rights.

Interpretive Guidance §494.70
Guidance is pending and will be updated in future release.

V451
(Rev.)

§ 494.70 - The dialysis facility must inform patients (or their representatives) of their rights (including their privacy rights) and responsibilities when they begin their treatment and must protect and provide for the exercise of those rights.

Interpretive Guidance § 494.70
Guidance is pending and will be updated in future release.

V452
(Rev.)

§ 494.70(a) - Standard: Patients' rights. The patient has the right to— (1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with ESRD;

Interpretive Guidance §494.70(a)(1)
Guidance is pending and will be updated in future release.

V453
(Rev.)

§ 494.70(a)(2) - Receive all information in a way that he or she can understand;

Interpretive Guidance §494.70(a)(2)
Guidance is pending and will be updated in future release.

V454

(Rev.)

§ 494.70(a)(3) - Privacy and confidentiality in all aspects of treatment;

Interpretive Guidance §494.70(a)(3)

Guidance is pending and will be updated in future release.

V455

(Rev.)

§ 494.70(a)(4) - Privacy and confidentiality in personal medical records;

Interpretive Guidance §494.70(a)(4)

Guidance is pending and will be updated in future release.

V456

(Rev.)

§ 494.70(a)(5) - Be informed about and participate, if desired, in all aspects of his or her care, and be informed of the right to refuse treatment, to discontinue treatment, and to refuse to participate in experimental research;

Interpretive Guidance §494.70(a)(5)

Guidance is pending and will be updated in future release.

V457

(Rev.)

§ 494.70(a)(6) - Be informed about his or her right to execute advance directives, and the facility's policy regarding advance directives;

Interpretive Guidance §494.70(a)(6)

Guidance is pending and will be updated in future release.

V458

(Rev.)

§ 494.70(a)(7) - Be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent peritoneal dialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis), and in-facility hemodialysis. The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients;

Interpretive Guidance §494.70(a)(7)

Guidance is pending and will be updated in future release.

V459

(Rev.)

§ 494.70(a)(8) - Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

Interpretive Guidance §494.70(a)(8)

Guidance is pending and will be updated in future release.

V460

(Rev.)

§ 494.70(a)(9) - Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

Interpretive Guidance §494.70(a)(9)

Guidance is pending and will be updated in future release.

V461

(Rev.)

§ 494.70(a)(10) - Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;

Interpretive Guidance §494.70(a)(10)

Guidance is pending and will be updated in future release.

V462

(Rev.)

§ 494.70(a)(11) - Be informed of services available in the facility and charges for services not covered under Medicare;

Interpretive Guidance §494.70 (a)(11)

Guidance is pending and will be updated in future release.

V463

(Rev.)

§ 494.70(a)(12) - Receive the necessary services outlined in the patient plan of care described in § 494.90;

Interpretive Guidance §494.70 (a)(12)

Guidance is pending and will be updated in future release.

V464

(Rev.)

§ 494.70(a)(13) - Be informed of the rules and expectations of the facility regarding patient conduct and responsibilities;

Interpretive Guidance §494.70 (a)(13)

Guidance is pending and will be updated in future release.

V465

(Rev.)

§ 494.70(a)(14) - Be informed of the facility's internal grievance process;

Interpretive Guidance §494.70 (a)(14)

Guidance is pending and will be updated in future release.

V466

(Rev.)

§ 494.70(a)(15) - Be informed of external grievance mechanisms and processes, including how to contact the ESRD Network and the State survey agency;

Interpretive Guidance §494.70 (a)(15)

Guidance is pending and will be updated in future release.

V467

(Rev.)

§ 494.70(a)(16) - Be informed of his or her right to file internal grievances or external grievances or both without reprisal or denial of services; and (17) Be informed that he or she may file internal or external grievances, personally, anonymously or through a representative of the patient's choosing.

Interpretive Guidance §494.70 (a)(16) and (17)

Guidance is pending and will be updated in future release.

V468

(Rev.)

*§ 494.70(b) - Standard: Right to be informed regarding the facility's discharge and transfer policies. The patient has the right to –
(1) Be informed of the facility's policies for transfer, routine or involuntary discharge, and discontinuation of services to patients; and*

Interpretive Guidance §494.70(b)(1)

Guidance is pending and will be updated in future release.

V469

(Rev.)

(2) Receive written notice 30 days in advance of an involuntary discharge, after the facility follows the involuntary discharge procedures described in § 494.180(f)(4). In the case of immediate threats to the health and safety of others, an abbreviated discharge procedure may be allowed.

Interpretive Guidance §494.70(b)(2)

Guidance is pending and will be updated in future release.

V470

(Rev.)

(c) Standard: Posting of rights. The dialysis facility must prominently display a copy of the patient's rights in the facility, including the current State agency and ESRD

network mailing addresses and telephone complaint numbers, where it can be easily seen and read by patients.

Interpretive Guidance §494.70(c)

Guidance is pending and will be updated in future release.

V500

(Rev.)

§ 494.80 Condition: Patient assessment.

Interpretive Guidance § 494.80

Guidance is pending and will be updated in future release.

V501

(Rev.)

The facility's interdisciplinary team, consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

Interpretive Guidance §494.80

Guidance is pending and will be updated in future release.

V502

(Rev.)

(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: (1) Evaluation of current health status and medical condition, including co-morbid conditions.

Interpretive Guidance §494.80 (a)(1)

Guidance is pending and will be updated in future release.

V503

(Rev.)

(2) Evaluation of the appropriateness of the dialysis prescription,

Interpretive Guidance §494.80 (a)(2)

Guidance is pending and will be updated in future release.

V504

(Rev.)

Blood pressure, and fluid management needs.

Interpretive Guidance §494.80

Guidance is pending and will be updated in future release.

V505

(Rev.)

(3) Laboratory profile,

Interpretive Guidance §494.80(a)(3)

Guidance is pending and will be updated in future release.

V506

(Rev.)

Immunization history, and medication history.

Interpretive Guidance §494.80

Guidance is pending and will be updated in future release.

V507

(Rev.)

(4) Evaluation of factors associated with anemia, such as hematocrit, hemoglobin, iron stores, and potential treatment plans for anemia, including administration of erythropoiesis-stimulating agent(s).

Interpretive Guidance §494.80 (a)(4)

Guidance is pending and will be updated in future release.

V508

(Rev.)

(5) Evaluation of factors associated with renal bone disease.

Interpretive Guidance §494.80(a)(5)

Guidance is pending and will be updated in future release.

V509

(Rev.)

(6) Evaluation of nutritional status by a dietitian.

Interpretive Guidance §494.80 (a)(6):

Guidance is pending and will be updated in future release.

V510

(Rev.)

(7) Evaluation of psychosocial needs by a social worker.

Interpretive Guidance §494.80(a)(7):

Guidance is pending and will be updated in future release.

V511

(Rev.)

(8) Evaluation of dialysis access type and maintenance (for example, arteriovenous fistulas, arteriovenous grafts and peritoneal catheters).

Interpretive Guidance §494.80(a)(8)

Guidance is pending and will be updated in future release.

V512

(Rev.)

(9) Evaluation of the patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes.

Interpretive Guidance §494.80(a)(9)

Guidance is pending and will be updated in future release.

V513

(Rev.)

(10) Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If the patient is not suitable for transplantation referral, the basis for non-referral must be documented in the patient's medical record.

Interpretive Guidance §494.80(a)(10)

Guidance is pending and will be updated in future release.

V514

(Rev.)

(11) Evaluation of family and other support systems.

Interpretive Guidance §494.80(a)(11)

Guidance is pending and will be updated in future release.

V515

(Rev.)

(12) Evaluation of current patient physical activity level.

(13) Evaluation for referral to vocational and physical rehabilitation services.

Interpretive Guidance §494.80(a)(12)(13)

Guidance is pending and will be updated in future release.

V516

(Rev.)

(b) Standard: Frequency of assessment for patients admitted to the dialysis facility. (1) An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 hemodialysis sessions beginning with the first dialysis session.

Interpretive Guidance §494.80(b)(1)

Guidance is pending and will be updated in future release.

V517
(Rev.)

(2) A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90.

Interpretive Guidance §494.80(b)(2)
Guidance is pending and will be updated in future release.

V518
(Rev.)

(c) Standard: Assessment of treatment prescription. The adequacy of the patient's dialysis prescription, as described in § 494.90(a)(1), must be assessed on an ongoing basis as follows:

(1) Hemodialysis patients. At least monthly by calculating delivered Kt/V or an equivalent measure.

(2) Peritoneal dialysis patients. At least every 4 months by calculating delivered weekly Kt/V or an equivalent measure.

Interpretive Guidance §494.80(c)(1)(2)
Guidance is pending and will be updated in future release.

V519
(Rev.)

(d) Standard: Patient reassessment. In accordance with the standards specified in paragraphs (a)(1) through (a)(13) of this section, a comprehensive reassessment of each patient and a revision of the plan of care must be conducted— (1) At least annually for stable patients; and

Interpretive Guidance §494.80(d)
Guidance is pending and will be updated in future release.

V520
(Rev.)

(2) At least monthly for unstable patients including, but not limited to, patients with the following: (i) Extended or frequent hospitalizations; (ii) Marked deterioration in health status; (iii) Significant change in psychosocial needs; or (iv) Concurrent poor nutritional status, unmanaged anemia and inadequate dialysis.

Interpretive Guidance §494.80(d)(2)(i)(ii)(iii)(iv)
Guidance is pending and will be updated in future release.

V540
(Rev.)

§ 494.90 Condition: Patient plan of care.

Interpretive Guidance § 494.90
Guidance is pending and will be updated in future release.

V541
(Rev.)

The interdisciplinary team as defined at § 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence based professionally-accepted clinical practice standards.

Interpretive Guidance § 494.90
Guidance is pending and will be updated in future release.

V542
(Rev.)

(a) Standard: Development of patient plan of care. The interdisciplinary team must develop a plan of care for each patient.

Interpretive Guidance § 494.90(a)
Guidance is pending and will be updated in future release.

V543
(Rev.)

The plan of care must address, but not be limited to, the following: (1) Dose of dialysis. The interdisciplinary team must provide the necessary care and services to manage the patient's volume status; and

Interpretive Guidance § 494.90 (a)(1)

Guidance is pending and will be updated in future release.

V544

(Rev.)

Achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2 and a peritoneal dialysis weekly Kt/V of at least 1.7 or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V545

(Rev.)

(2) Nutritional status. The interdisciplinary team must provide the necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight must be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

Interpretive Guidance § 494.90(a)(2)

Guidance is pending and will be updated in future release.

V546

(Rev.)

(3) Mineral metabolism. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.

Interpretive Guidance § 494.90(a)(3)

Guidance is pending and will be updated in future release.

V547

(Rev.)

(4) Anemia. The interdisciplinary team must provide the necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The

patient's hemoglobin/hematocrit must be measured at least monthly. The dialysis facility must conduct an evaluation of the patient's anemia management needs.

Interpretive Guidance § 494.90(a)(4)

Guidance is pending and will be updated in future release.

V548

(Rev.)

For a home dialysis patient, the facility must evaluate whether the patient can safely, aseptically, and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration if necessary.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V549

(Rev.)

The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, must be monitored on a routine basis.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V550

(Rev.)

(5) Vascular access. The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access. The hemodialysis patient must be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors, and whether the patient is a potential candidate for arteriovenous fistula placement.

Interpretive Guidance § 494.90 (a) (5)

Guidance is pending and will be updated in future release.

V551

(Rev.)

The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

Interpretive Guidance § 494.90

Guidance is pending and will be updated in future release.

V552

(Rev.)

(6) Psychosocial status. The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.

Interpretive Guidance § 494.90 (a)(6):

Guidance is pending and will be updated in future release.

V553

(Rev.)

(7) Modality. (i) Home dialysis. The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.

Interpretive Guidance § 494.90 (a)(7)(i):

Guidance is pending and will be updated in future release.

V554

(Rev.)

(ii) Transplantation status. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the–
(A) Plan for transplantation, if the patient accepts the transplantation referral;
(B) Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or
(C) Reason(s) for the patient's nonreferral as a transplantation candidate as documented in accordance with § 494.80(a)(10).

Interpretive Guidance § 494.90 (a)(7)(ii)

Guidance is pending and will be updated in future release.

V555

(Rev.)

(8) Rehabilitation status. The interdisciplinary team must assist the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, including the educational needs of pediatric patients (patients under the age of 18 years), and make rehabilitation and vocational rehabilitation referrals as appropriate.

Interpretive Guidance § 494.90 (a)(8):

Guidance is pending and will be updated in future release.

V556

(Rev.)

(b) Standard: Implementation of the patient plan of care.

(1) The patient's plan of care must—

(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and

(ii) Be signed by the team members, including the patient or the patient's designee; or, if the patient chooses not to sign the plan of care, this choice must be documented on the plan of care, along with the reason the signature was not provided.

Interpretive Guidance § 494.90 (b)(1)(i)(ii)

Guidance is pending and will be updated in future release.

V557

(Rev.)

(2) Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.

Interpretive Guidance § 494.90 (b)(2)

Guidance is pending and will be updated in future release.

V558

(Rev.)

Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.80(d).

Interpretive Guidance § 494.90:

Guidance is pending and will be updated in future release.

V559

(Rev.)

(3) If the expected outcome is not achieved, the interdisciplinary team must adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team must—

(i) Adjust the plan of care to reflect the patient's current condition;

(ii) Document in the record the reasons why the patient was unable to achieve the goals; and

(iii) Implement plan of care changes to address the issues identified in paragraph (b)(3)(ii) of this section.

Interpretive Guidance § 494.90 (b)(3)(i)(ii)(iii)

Guidance is pending and will be updated in future release.

V560

(Rev.)

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

Interpretive Guidance § 494.90 (b)(4):

Guidance is pending and will be updated in future release.

V561

(Rev.)

(c) Standard: Transplantation referral tracking. The interdisciplinary team must—

(1) Track the results of each kidney transplant center referral;

(2) Monitor the status of any facility patients who are on the transplant wait list; and

(3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status.

Interpretive Guidance § 494.90 (c)(1)(2)(3)

Guidance is pending and will be updated in future release.

V562

(Rev.)

(d) Standard: Patient education and training. The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.

Interpretive Guidance § 494.90 (d)

Guidance is pending and will be updated in future release.

V580

(Rev.)

§ 494.100 Condition: Care at home.

Interpretive Guidance § 494.100:

Guidance is pending and will be updated in future release.

V581

(Rev.)

A dialysis facility that is certified to provide services to home patients must ensure through its interdisciplinary team, that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of this part.

Interpretive Guidance § 494.100:

Guidance is pending and will be updated in future release.

V582

(Rev.)

(a) Standard: Training. The interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10) and when the home dialysis caregiver or home dialysis modality changes.

Interpretive Guidance § 494.100 (a):

Guidance is pending and will be updated in future release.

V583

(Rev.)

The training must— (1) Be provided by a dialysis facility that is approved to provide home dialysis services;

Interpretive Guidance §494.100 (a)(1):

Guidance is pending and will be updated in future release.

V584

(Rev.)

(2) Be conducted by a registered nurse who meets the requirements of § 494.140(b)(2); and

Interpretive Guidance § 494.100 (a)(2):

Guidance is pending and will be updated in future release.

V585

(Rev.)

(3) Be conducted for each home dialysis patient and address the specific needs of the patient, in the following areas:

(i) The nature and management of ESRD.

(ii) The full range of techniques associated with the treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective administration of erythropoiesis-stimulating agent(s) (if prescribed) to achieve and maintain a target level hemoglobin or hematocrit as written in patient's plan of care.

(iii) How to detect, report, and manage potential dialysis complications, including water treatment problems.

(iv) Availability of support resources and how to access and use resources.

(v) How to self-monitor health status and record and report health status information.

(vi) How to handle medical and non-medical emergencies.

(vii) Infection control precautions.

(viii) Proper waste storage and disposal procedures.

Interpretive Guidance § 494.100 (a)(3)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii):

Guidance is pending and will be updated in future release.

V586
(Rev.)

(b) Standard: Home dialysis monitoring. The dialysis facility must – (1) Document in the medical record that the patient, the caregiver, or both received and demonstrated adequate comprehension of the training;

Interpretive Guidance § 494.100 (b)(1):
Guidance is pending and will be updated in future release.

V587
(Rev.)

(2) Retrieve and review complete self-monitoring data and other information from self-care patients or their designated caregiver(s) at least every 2 months; and
(3) Maintain this information in the patient’s medical record.

Interpretive Guidance § 494.100 (b)(2)(3):
Guidance is pending and will be updated in future release.

V588
(Rev.)

(c) Standard: Support services. (1) A home dialysis training facility must furnish (either directly, under agreement, or by arrangement with another ESRD facility) home dialysis support services regardless of whether dialysis supplies are provided by the dialysis facility or a durable medical equipment company.

Interpretive Guidance § 494.100 (c)(1):
Guidance is pending and will be updated in future release.

V589
(Rev.)

Services include, but are not limited to, the following: (i) Periodic monitoring of the patient’s home adaptation, including visits to the patient’s home by facility personnel in accordance with the patient’s plan of care.

Interpretive Guidance § 494.100 (c)(1)(i):
Guidance is pending and will be updated in future release.

V590
(Rev.)

(ii) Coordination of the home patient's care by a member of the dialysis facility's interdisciplinary team.

*Interpretive Guidance § 494.100 (c)(1)(ii):
Guidance is pending and will be updated in future release.*

V591
(Rev.)

(iii) Development and periodic review of the patient's individualized comprehensive plan of care that specifies the services necessary to address the patient's needs and meets the measurable and expected outcomes as specified in § 494.90 of this part.

*Interpretive Guidance § 494.100 (c)(1)(iii):
Guidance is pending and will be updated in future release.*

V592
(Rev.)

(iv) Patient consultation with members of the interdisciplinary team, as needed.

*Interpretive Guidance § 494.100 (c)(1)(iv):
Guidance is pending and will be updated in future release.*

V593
(Rev.)

(v) Monitoring of the quality of water and dialysate used by home hemodialysis patients including conducting an onsite evaluation and

*Interpretive Guidance § 494.100 (c)(1)(v):
Guidance is pending and will be updated in future release.*

V594
(Rev.)

*testing of the water and dialysate system in accordance with—
(A) The recommendations specified in the manufacturers' instructions; and*

(B) The system's FDA-approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramine testing) water and dialysate.

Interpretive Guidance § 494.100 (c)(1)(v)(A)(B):

Guidance is pending and will be updated in future release.

V595

(Rev.)

The facility must meet testing and other requirements of ANSI/AAMI RD52:2004. In addition, bacteriological and endotoxin testing must be performed on a quarterly, or more frequent basis as needed, to ensure that the water and dialysate are within the AAMI limits.

Interpretive Guidance § 494.100 (c)(1)(v)(B):

Guidance is pending and will be updated in future release.

V596

(Rev.)

(C) The dialysis facility must correct any water and dialysate quality problem for the home hemodialysis patient, and if necessary, arrange for backup dialysis until the problem is corrected if—

(1) Analysis of the water and dialysate quality indicates contamination; or

(2) The home hemodialysis patient demonstrates clinical symptoms associated with water and dialysate contamination.

Interpretive Guidance § 494.100 (c)(1)(v)(C)(1)(2):

Guidance is pending and will be updated in future release.

V597

(Rev.)

(vi) Purchasing, leasing, renting, delivering, installing, repairing and maintaining medically necessary home dialysis supplies and equipment (including supportive equipment) prescribed by the attending physician.

Interpretive Guidance § 494.100 (c)(1)(vi):

Guidance is pending and will be updated in future release.

V598
(Rev.)

(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.

Interpretive Guidance § 494.100 (c)(1)(vii):
Guidance is pending and will be updated in future release.

V599
(Rev.)

(2) The dialysis facility must maintain a recordkeeping system that ensures continuity of care and patient privacy. This includes items and services furnished by durable medical equipment (DME) suppliers referred to in § 414.330(a)(2) of this chapter.

Interpretive Guidance § 494.100 (c)(1)(vii)(2):
Guidance is pending and will be updated in future release.

V625
(Rev.)

§ 494.110 Condition: Quality assessment and performance improvement.

Interpretive Guidance § 494.110:
Guidance is pending and will be updated in future release.

V626
(Rev.)

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

Interpretive Guidance § 494.110:
Guidance is pending and will be updated in future release.

V627
(Rev.)

(a) Standard: Program scope.

(1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

Interpretive Guidance § 494.110 (a)(1):

Guidance is pending and will be updated in future release.

V628
(Rev.)

(2) The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:

Interpretive Guidance § 494.110 (a)(2):

Guidance is pending and will be updated in future release.

V629
(Rev.)

(i) Adequacy of dialysis.

Interpretive Guidance § 494.110 (a)(2)(i):

Guidance is pending and will be updated in future release.

V630
(Rev.)

(ii) Nutritional status.

Interpretive Guidance § 494.110 (a)(2)(ii):

Guidance is pending and will be updated in future release.

V631

(Rev.)

(iii) Mineral metabolism and renal bone disease.

Interpretive Guidance § 494.110 (a)(2)(iii):

Guidance is pending and will be updated in future release.

V632

(Rev.)

(iv) Anemia management.

Interpretive Guidance § 494.110 (a)(2)(iv):

Guidance is pending and will be updated in future release.

V633

(Rev.)

(v) Vascular access.

Interpretive Guidance § 494.110 (a)(2)(v):

Guidance is pending and will be updated in future release.

V634

(Rev.)

(vi) Medical injuries and medical errors identification.

Interpretive Guidance § 494.110 (a)(2)(vi):

Guidance is pending and will be updated in future release.

V635

(Rev.)

(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

Interpretive Guidance § 494.110 (a)(2)(vii):

Guidance is pending and will be updated in future release.

V636

(Rev.)

(viii) Patient satisfaction and grievances.

Interpretive Guidance § 494.110 (a)(2)(viii):

Guidance is pending and will be updated in future release.

V637

(Rev.)

(ix) Infection control; with respect to this component the facility must—

(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;

(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and

(C) Take actions to reduce future incidents.

Interpretive Guidance § 494.110 (a)(2)(ix)(A)(B)(C):

Guidance is pending and will be updated in future release.

V638

(Rev.)

(b) Standard: Monitoring performance improvement. The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

Interpretive Guidance § 494.110 (b):

Guidance is pending and will be updated in future release.

V639

(Rev.)

(c) Standard: Prioritizing improvement activities. The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety.

Interpretive Guidance § 494.110 (c):

Guidance is pending and will be updated in future release.

V640
(Rev.)

The facility must immediately correct any identified problems that threaten the health and safety of patients.

*Interpretive Guidance § 494.110 (c):
Guidance is pending and will be updated in future release.*

V660
(Rev.)

§ 494.120 Condition: Special purpose renal dialysis facilities.

*Interpretive Guidance § 494.120:
Guidance is pending and will be updated in future release.*

V661
(Rev.)

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve ESRD patients while the patients are in a temporary residence) and facilities established to serve ESRD patients under emergency circumstances.

*Interpretive Guidance § 494.120:
Guidance is pending and will be updated in future release.*

V662
(Rev.)

(a) Standard: Approval period. The period of approval for a special purpose renal dialysis facility may not exceed 8 months in any 12- month period.

*Interpretive Guidance § 494.120 (a):
Guidance is pending and will be updated in future release.*

V663
(Rev.)

(b) Standard: Service limitation. Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

Interpretive Guidance § 494.120 (b):

Guidance is pending and will be updated in future release.

No Tag

(c) Standard: Scope of requirements.

(1) Scope of requirements for a vacation camp. A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage–

(i) Infection control at § 494.30;

(ii) Water and dialysate quality at § 494.40 (except as provided in paragraph (c)(1)(viii) of this section);

(iii) Reuse of hemodialyzers at § 494.50 (if reuse is performed);

(iv) Patients' rights and posting of patients' rights § 494.70(a) and § 494.70 (c);

(v) Laboratory services at § 494.130;

(vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and (d);

(vii) Medical records at § 494.170; and

(viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to § 494.100 (c)(1)(v) (home monitoring of water quality) in place of § 494.40 (water quality).

Interpretive Guidance § 494.120 (c)(1):

Guidance is pending and will be updated in future release.

No Tag

(2) Scope of requirements for an emergency circumstance facility. A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must comply with (c)(1) of this section and addition to complying with the following conditions:

(i) Section 494.20 (compliance with Federal, State, and local laws and regulations).

(ii) Section 494.60 (physical environment).

(iii) Section 494.70(a) through section 494.70(c) (patient rights).

- (iv) Section 494.140 (personnel qualifications).*
- (v) Section 494.150 (medical director).*
- (vi) Section 494.180 (governance).*

Interpretive Guidance § 494.120 (c)(2):

This is an informational tag. Sections of the regulations listed here are to be used to survey an emergency circumstance SPRDF. If deficient practices are identified, the appropriate tags under the referenced regulations should be used.

An SPRDF set up for an emergency circumstance will be issued a unique CCN. These facilities may only provide care to those patients who would otherwise be unable to obtain treatment in that geographic area, and are limited to an 8-month period of operation.

V666
(Rev.)

(d) Standard: Physician contact. The facility must contact the patient's physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in § 494.90).

Interpretive Guidance § 494.120 (d):

Guidance is pending and will be updated in future release.

V667
(Rev.)

(e) Standard: Documentation. All patient care provided in the special purpose facility is documented and forwarded to the patient's usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

Interpretive Guidance § 494.120 (e):

Guidance is pending and will be updated in future release.

V675
(Rev.)

§ 494.130 Condition: Laboratory services.

Interpretive Guidance § 494.130:

Guidance is pending and will be updated in future release.

V676
(Rev.)

The dialysis facility must provide or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

Interpretive Guidance § 494.130
Guidance is pending and will be updated in future release.

Subpart D- Administration

V680
(Rev.)

§ 494.140 Condition: Personnel qualifications.

Interpretive Guidance § 494.140:
Guidance is pending and will be updated in future release.

V681
(Rev.)

All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

Interpretive Guidance § 494.130:
Guidance is pending and will be updated in future release.

V682
(Rev.)

(a) Standard: Medical director. (1) The medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12- months of experience providing care to patients receiving dialysis.

Interpretive Guidance § 494.140 (a)(1):

Guidance is pending and will be updated in future release.

V683

(Rev.)

(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility another physician may direct the facility, subject to the approval of the Secretary.

Interpretive Guidance § 494.140 (a)(2):

Guidance is pending and will be updated in future release.

V684

(Rev.)

(b) Standard: Nursing services. (1) Nurse manager. The facility must have a nurse manager responsible for nursing services in the facility who must—

(i) Be a full time employee of the facility;

(ii) Be a registered nurse; and

(iii) Have at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

Interpretive Guidance § 494.140 (b)(1)(i)(ii)(iii):

Guidance is pending and will be updated in future release.

V685

(Rev.)

(2) Self-care and home dialysis training nurse. The nurse responsible for self-care and/or home care training must—

(i) Be a registered nurse; and

(ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

Interpretive Guidance § 494.140 (b)(2)(i)(ii):

Guidance is pending and will be updated in future release.

V686

(Rev.)

- (3) Charge nurse. The charge nurse responsible for each shift must—**
- (i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;**
 - (ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and**

Interpretive Guidance § 494.140 (b)(3)(i)(ii):
Guidance is pending and will be updated in future release.

V687

(Rev.)

- (iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions.**

Interpretive Guidance § 494.140 (b)(3)(iii):
Guidance is pending and will be updated in future release.

V688

(Rev.)

- (4) Staff nurse. Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.**

Interpretive Guidance § 494.140 (b)(4):
Guidance is pending and will be updated in future release.

V689

(Rev.)

- (c) Standard: Dietitian. The facility must have a dietitian who must— (1) Be a registered dietitian with the Commission on Dietetic Registration; and**

Interpretive Guidance § 494.140 (c)(1):
Guidance is pending and will be updated in future release.

V690

(Rev.)

(2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian;

Interpretive Guidance § 494.140 (c)(2):

Guidance is pending and will be updated in future release.

V691

(Rev.)

(d) Standard: Social worker. The facility must have a social worker who—

(1) Holds a master's degree in social work with a specialization in clinical practice

from a school of social work accredited by the Council on Social Work Education; or

(2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140 (d)(1).

Interpretive Guidance § 494.140 (d)(1)(2):

Guidance is pending and will be updated in future release.

V692

(Rev.)

(e) Standard: Patient care dialysis technicians. Patient care dialysis technicians must—

(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and

(2) Have a high school diploma or equivalency;

Interpretive Guidance § 494.140 (e)(1)(2):

Guidance is pending and will be updated in future release.

V693

(Rev.)

(3) Have completed a training program that is approved by the medical director and governing body, under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, including patient sensitivity training and care of difficult patients.

Interpretive Guidance § 494.140 (e)(3):

Guidance is pending and will be updated in future release.

V694

(Rev.)

The training program must include the following subjects:

- (i) Principles of dialysis.*
- (ii) Care of patients with kidney failure, including interpersonal skills.*
- (iii) Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis.*
- (iv) Possible complications of dialysis.*
- (v) Water treatment and dialysate preparation.*
- (vi) Infection control.*
- (vii) Safety.*
- (viii) Dialyzer reprocessing, if applicable*

Interpretive Guidance § 494.140 (e)(3)(i)(ii)(iii)(iv)(v)(vi)(vii)(viii):

Guidance is pending and will be updated in future release.

V695

(Rev.)

(4) Be certified under a State certification program or a national commercially available certification program, as follows—

- (i) For newly employed patient care technicians, within 18 months of being hired as a dialysis patient care technician; or*
- (ii) For patient care technicians employed on October 14, 2008, within 18 months after such date.*

Interpretive Guidance § 494.140 (e)(4)(i)(ii):

Guidance is pending and will be updated in future release.

V696

(Rev.)

(f) Standard: Water treatment system technicians. Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

Interpretive Guidance § 494.140 (f):

Guidance is pending and will be updated in future release.

V710
(Rev.)

§ 494.150 Condition: Responsibilities of the medical director.

Interpretive Guidance § 494.150:
Guidance is pending and will be updated in future release.

V711
(Rev.)

The dialysis facility must have a medical director who meets the qualifications of § 494.140(a) to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients.

Interpretive Guidance § 494.150:
Guidance is pending and will be updated in future release.

V712
(Rev.)

Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.

Interpretive Guidance § 494.150 (a):
Guidance is pending and will be updated in future release.

V713
(Rev.)

(b) Staff education, training, and performance.

Interpretive Guidance § 494.150 (b):
Guidance is pending and will be updated in future release.

V714
(Rev.)

(c) Policies and procedures. The medical director must— (1) Participate in the development, periodic review and approval of a “patient care policies and procedures manual” for the facility; and

Interpretive Guidance § 494.150 (c)(1):

Guidance is pending and will be updated in future release.

V715

(Rev.)

(2) Ensure that— (i) All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and

Interpretive Guidance § 494.150 (c)(2)(i):

Guidance is pending and will be updated in future release.

V716

(Rev.)

(ii) The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180(f).

Interpretive Guidance § 494.150 (c)(2)(ii):

Guidance is pending and will be updated in future release.

V725

(Rev.)

§ 494.170 Condition: Medical records.

Interpretive Guidance § 494.170

Guidance is pending and will be updated in future release.

V726

(Rev.)

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of ESRD services and all other home dialysis patients whose care is under the supervision of the facility.

Interpretive Guidance § 494.170

Guidance is pending and will be updated in future release.

V727

(Rev.)

- (a) Standard: Protection of the patient's record. The dialysis facility must—**
- (1) Safeguard patient records against loss, destruction, or unauthorized use; and**
 - (2) Keep confidential all information contained in the patient's record, except when release is authorized pursuant to one of the following:**
 - (i) The transfer of the patient to another facility.**
 - (ii) Certain exceptions provided for in the law.**
 - (iii) Provisions allowed under third party payment contracts.**
 - (iv) Approval by the patient.**
 - (v) Inspection by authorized agents of the Secretary, as required for the administration of the dialysis program.**

Interpretive Guidance § 494.170 (a)(1)(2)(i)(ii)(iii)(iv)(v)

Guidance is pending and will be updated in future release.

V728

(Rev.)

- (3) Obtaining written authorization from the patient or legal representative before releasing information that is not authorized by law.**

Interpretive Guidance § 494.170 (a)(3)

Guidance is pending and will be updated in future release.

V729

(Rev.)

- (b) Standard: Completion of patient records and centralization of clinical information.**
- (1) Current medical records and those of discharged patients must be completed promptly.**

Interpretive Guidance § 494.170 (b)(1):

Guidance is pending and will be updated in future release.

V730

(Rev.)

(2) All clinical information pertaining to a patient must be centralized in the patient's record, including whether the patient has executed an advance directive. These records must be maintained in a manner such that each member of the interdisciplinary team has access to current information regarding the patient's condition and prescribed treatment.

Interpretive Guidance § 494.170 (b)(2)

Guidance is pending and will be updated in future release.

V731

(Rev.)

(3) The dialysis facility must complete, maintain, and monitor home care patients' records, including the records of patients who receive supplies and equipment from a durable medical equipment supplier.

Interpretive Guidance § 494.170 (b)(3)

Guidance is pending and will be updated in future release.

V732

(Rev.)

(c) Standard: record retention and preservation. In accordance with 45 CFR § 164.530(j)(2), all patient records must be retained for 6 years from the date of the patient's discharge, transfer or death.

Interpretive Guidance § 494.170 (c)

Guidance is pending and will be updated in future release.

V733

(Rev.)

(d) Standard: Transfer of patient record information. When a dialysis patient is transferred, the dialysis facility releasing the patient must send all requested medical record information to the receiving facility within 1 working day of the transfer.

Interpretive Guidance § 494.170 (d):

Guidance is pending and will be updated in future release.

V750

(Rev.)

§ 494.180 Condition: Governance.

Interpretive Guidance § 494.180

Guidance is pending and will be updated in future release.

V751

(Rev.)

The ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility.

Interpretive Guidance § 494.180:

Guidance is pending and will be updated in future release.

V752

(Rev.)

(a) Standard: Designating a chief executive officer or administrator. The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, including, but not limited to—

Interpretive Guidance § 494.180 (a)

Guidance is pending and will be updated in future release.

V753

(Rev.)

(1) Staff appointments;

Interpretive Guidance § 494.180 (a)(1)

Guidance is pending and will be updated in future release.

V754

(Rev.)

(2) Fiscal operations;

Interpretive Guidance § 494.180 (a)(2)

Guidance is pending and will be updated in future release.

V755

(Rev.)

(3) The relationship with the ESRD networks; and

Interpretive Guidance § 494.180 (a)(3)

Guidance is pending and will be updated in future release.

V756

(Rev.)

(4) Allocation of necessary staff and other resources for the facility's quality assessment and performance improvement program as described in § 494.110.

Interpretive Guidance § 494.180 (a)(4):

Guidance is pending and will be updated in future release.

V757

(Rev.)

(b) Standard: Adequate number of qualified and trained staff. The governing body or designated person responsible must ensure that— (1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; and

Interpretive Guidance § 494.180 (b)(1):

Guidance is pending and will be updated in future release.

V758

(Rev.)

The registered nurse, social worker and dietitian members of the interdisciplinary team are available to meet patient clinical needs;

Interpretive Guidance § 494.180 (b)(1):

Guidance is pending and will be updated in future release.

V759

(Rev.)

(2) A registered nurse, who is responsible for the nursing care provided, is present in the facility at all times that in-center dialysis patients are being treated;

Interpretive Guidance § 494.180 (b)(2):

Guidance is pending and will be updated in future release.

V760

(Rev.)

(3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and

Interpretive Guidance § 494.180 (b)(3):

Guidance is pending and will be updated in future release.

V761

(Rev.)

(4) All employees have an opportunity for continuing education and related development activities;

Interpretive Guidance § 494.180 (b)(4):

Guidance is pending and will be updated in future release.

V762

(Rev.)

(c) Standard: Medical staff appointments. The governing body— (1) Is responsible for all medical staff appointments and credentialing in accordance with State law, including attending physicians, physician assistants, nurse practitioners and clinical nurse specialists; and

Interpretive Guidance § 494.180 (c)(1):

Guidance is pending and will be updated in future release.

V763
(Rev.)

- (2) Ensures that all medical staff who provide care in the facility are informed of all facility policies and procedures, including the facility's quality assessment and performance improvement program specified in § 494.110.*
- (3) Communicates expectations to the medical staff regarding staff participation in improving the quality of medical care provided to facility patients*

Interpretive Guidance § 494.180 (c)(2)(3):
Guidance is pending and will be updated in future release.

V764
(Rev.)

- (d) Standard: Furnishing services. The governing body is responsible for ensuring that the dialysis facility furnishes services directly on its main premises or on other premises that are contiguous with the main premises and are under the direction of the same professional staff and governing body as the main premises (except for services provided under § 494.100).*

Interpretive Guidance § 494.180(d)
Guidance is pending and will be updated in future release.

V765
(Rev.)

- (e) Standard: Internal grievance process. The facility's internal grievance process must be implemented so that the patient may file an oral or written grievance with the facility without reprisal or denial of services. The grievance process must include—*
- (1) A clearly explained procedure for the submission of grievances.*
- (2) Timeframes for reviewing the grievance.*
- (3) A description of how the patient or the patient's designated representative will be informed of steps taken to resolve the grievance.*

Interpretive Guidance § 494.180(e)(1)(2)(3)
Guidance is pending and will be updated in future release.

V766
(Rev.)

- (f) Standard: Involuntary discharge and transfer policies and procedures. The governing body must ensure that all staff follow the facility's patient discharge and*

transfer policies and procedures. The medical director ensures that no patient is discharged or transferred from the facility unless –

- (1) The patient or payer no longer reimburses the facility for the ordered services;*
- (2) The facility ceases to operate;*
- (3) The transfer is necessary for the patient’s welfare because the facility can no longer meet the patient’s documented medical needs; or*

Interpretive Guidance § 494.180 (f)(1)(2)(3)
Guidance is pending and will be updated in future release.

V767
(Rev.)

(4) The facility has reassessed the patient and determined that the patient’s behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired, in which case the medical director ensures that the patient’s interdisciplinary team—

- (i) Documents the reassessments, ongoing problems(s), and efforts made to resolve the problem(s), and enters this documentation into the patient’s medical record;*
- (ii) Provides the patient and the local ESRD Network with a 30-day notice of the planned discharge;*
- (iii) Obtains a written physician’s order that must be signed by both the medical director and the patient’s attending physician concurring with the patient’s discharge or transfer from the facility;*
- (iv) Contacts another facility, attempts to place the patient there, and documents that effort; and*
- (v) Notifies the State survey agency of the involuntary transfer or discharge.*

(5) In the case of immediate severe threats to the health and safety of others, the facility may utilize an abbreviated involuntary discharge procedure.

Interpretive Guidance § 494.180 (f)(4)(i)(ii)(iii)(iv)(v)(5)
Guidance is pending and will be updated in future release.

V768
(Rev.)

(g) Standard: Emergency coverage. (1) The governing body is responsible for ensuring that the dialysis facility provides patients and staff with written instructions for obtaining emergency medical care.

Interpretive Guidance § 494.180 (g)(1):
Guidance is pending and will be updated in future release.

V769

(Rev.)

(2) The dialysis facility must have available at the nursing/monitoring station, a roster with the names of physicians to be called for emergencies, when they can be called, and how they can be reached.

Interpretive Guidance § 494.180 (g)(2):

Guidance is pending and will be updated in future release.

V770

(Rev.)

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must:

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

Interpretive Guidance § 494.180 (g)(3)(i)(ii):

Guidance is pending and will be updated in future release.

V771

(Rev.)

(h) Standard: Furnishing data and information for ESRD program administration. Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

(2) Be submitted electronically in the format specified by the Secretary;

(3) Include, but not be limited to—

(i) Cost reports;

(ii) ESRD administrative forms;

(iii) Patient survival information; and

(iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

*Interpretive Guidance § 494.180 (h)(1)(2)(3)(i)(ii)(iii)(iv):
Guidance is pending and will be updated in future release.*

V772
(Rev.)

(i) Standard: Relationship with the ESRD network. The governing body receives and acts upon recommendations from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.

*Interpretive Guidance § 494.180 (i):
Guidance is pending and will be updated in future release.*

V773
(Rev.)

(j) Standard: Disclosure of ownership. In accordance with § 420.200 through § 420.206 of this chapter, the governing body must report ownership interests of 5 percent or more to its State survey agency.

*Interpretive Guidance § 494.180 (j):
Guidance is pending and will be updated in future release.*

Part II - ESRD Core Survey Process

Note: Publication of the ESRD Facility survey process is pending and will be updated in a future release.

State Operations Manual

Appendix K - Guidance for Surveyors: Comprehensive Outpatient Rehabilitation Facilities

(Rev.)

I-602

(Rev.)

§485.66 Condition of Participation: Utilization Review Plan

The facility must have in effect a written utilization review plan that is implemented *annually, without modification*, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

A - General

(I-602) Each facility must have in effect, a written utilization review plan. An established utilization review plan serves to indicate how well policies are functioning, how effective treatment regimens have been, and how well the CORF has adapted its particular program to selected patients.

B - Major Sources of Information

- Clinical records; and
- Written utilization plan

State Operations Manual

Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

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(Rev.)

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Q-0042

(Rev.)

§416.41(b) Standard: Hospitalization

- (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.**
- (2) This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under §482.2 of this chapter.**
- (3) The ASC must *periodically provide the local hospital with written notice of its operations and patient population served.***

Interpretive Guidelines: §416.41(b)(1-3)

Guidance pending and will be updated in future release.

Q-0104

(Rev.)

§416.44(b) Standard: Safety From Fire

(1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

Interpretive Guidelines: §416.44(b)(1)-(3)

Guidance pending and will be updated in future release.

Q-0105

(Rev.)

(4) An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

Interpretive Guidelines: §416.44(b)(4)

Guidance pending and will be updated in future release.

Q-0106

(Rev.)

(5) When a sprinkler system is shut down for more than 10 hours, the ASC must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

Interpretive Guidelines: §416.44(b)(5)

Guidance pending and will be updated in future release.

Q-0107

(Rev.)

(6) Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to hazardous areas.

Interpretive Guidelines: §416.44(b)(6)

Guidance pending and will be updated in future release.

Q-0108

(Rev.)

§416.44(c) Standard: Building Safety.

Except as otherwise provided in this section, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.

(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §416.44(c)

Guidance pending and will be updated in future release.

Q-0109

(Rev.)

§416.44(d) Standard: Emergency Equipment

The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements:

- (1) Be immediately available for use during emergency situations.**
- (2) Be appropriate for the facility's patient population.**
- (3) Be maintained by appropriate personnel.**

Interpretive Guidelines §416.44(d)

Guidance pending and will be updated in future release.

Q-0110

(Rev.)

§416.44(e) Standard: Emergency Personnel

Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

Interpretive Guidelines: §416.44(e)

Guidance pending and will be updated in future release.

Q-0111

(Rev.)

§416.44(f) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

Q-0162

(Rev.)

§416.47(b) Standard: Form and Content of Record

The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

- (1) Patient identification;**
- (2) Significant medical history and results of physical examination (*as applicable*);**
- (3) Pre-operative diagnostic studies (entered before surgery), if performed;**
- (4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body;**
- (5) Any allergies and abnormal drug reactions;**
- (6) Entries related to anesthesia administration;**
- (7) Documentation of properly executed informed patient consent; and**
- (8) Discharge diagnosis.**

Interpretive Guidelines: §416.47(b)

The medical record must contain all of the required elements listed in the regulation. Specifically:

- The identity of the patient must be clear through use of identifiers such as name, date of birth, social security number, etc.
- A medical history and physical assessment (H&P), completed *as applicable* and entered into the medical record in accordance with the requirements at §416.52, as well as the results of the pre-surgical assessments specified at §416.42 and §416.52.

- If pre-operative diagnostic studies were performed, they must be included in the medical record prior to the start of surgery.

- An operative report that describes the surgical techniques and findings. A pathologist's report on all tissues removed during surgery must also be included, unless the governing body has adopted a written policy exempting certain types of removed tissue from this requirement. Depending on the type of surgery performed in the ASC, tissue may or may not routinely be removed during surgery; no pathologist's report is required when no tissue has been removed. The governing body's policy on exemption should provide the clinical rationale supporting the exemption decision. For example, an ASC that performs cataract removal and implantation of an artificial lens might exempt from the pathologist's report requirement the ocular lens removed in routine procedures where there is no indication suggesting the presence of other disease for which a pathology analysis should be required. On the other hand, it generally would not be reasonable to exempt intestinal polyps removed during a colonoscopy, since a pathologist's analysis of the tissue would be required to confirm whether or not the polyp(s) were malignant growths.

- The patient's history of allergies or abnormal drug reactions prior to the surgery, as well as any allergies or abnormal drug reactions that occurred during or after the surgery prior to discharge.

- Information related to the administration of anesthesia during the procedure and the patient's recovery from anesthesia after the procedure.

- Documentation of a properly executed informed patient consent. A well-designed informed consent process would most likely include a discussion of the following elements:
 - A description of the proposed surgery, including the anesthesia to be used;
 - The indications for the proposed surgery;
 - Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but a high degree of severity;
 - Treatment alternatives, including the attendant material risks and benefits;
 - Who will conduct the surgical intervention and administer the anesthesia;
 - Whether physicians other than the operating practitioner will be performing important tasks related to the surgery. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines; and
 - Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia,

and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the ASC.

- Documentation of the patient's discharge diagnosis. The record should also include the patient's disposition, i.e., whether the patient was discharged to home (including to a nursing home for patients already resident in a nursing home at the time of surgery), or transfer to another healthcare facility, including emergent transfers to a hospital.

Survey Procedures: §416.47(b)

- Evaluate the sample of open and closed records selected for review to determine whether they contain all of the required elements. For open records of patients whose surgery has not yet begun, focus on the elements that must be present before surgery, e.g., H&P (*as applicable*), immediate pre-surgical assessment, informed consent, etc. The absence of any required element must be cited as standard-level noncompliance. The absence of a number of elements from a number of medical records might warrant citation of condition-level noncompliance. Likewise the absence of one element from a number of medical records – e.g., lack of informed consent to surgery – should warrant citation of condition-level noncompliance.

Ask the ASC's leadership if the ASC removes tissue during surgery and, if so, does it exempt any or all classes of tissue removed from the requirement for analysis by a pathologist? If yes, ask to see the policy and its rationale, to determine whether it was adopted by the governing body and whether the clinical rationale for the exemption is reasonable.

Q-0261

(Rev.)

§416.52(a): *Standard: Patient assessment and admission.*

(1) The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must--

(i) Include the timeframe for medical history and physical examination to be completed prior to surgery.

(ii) Address, but is not limited to, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.

(iii) Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.

Interpretive Guidelines §416.52(a)(1)

Guidance pending and will be updated in future release.

Q-0262

(Rev.)

§416.52(a) Standard: Admission and Pre-surgical Assessment

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) The pre-surgical assessment must include documentation of any allergies to drugs and biologicals.

Interpretive Guidelines: §416.52(a)(2)-(3)

Guidance pending and will be updated in future release.

Q-0263

(Rev.)

§416.52(a) Standard: Admission and Pre-surgical Assessment

(4) The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure.

Interpretive Guidelines: §416.52(a)(4)

Guidance pending and will be updated in future release.

State Operations Manual
Appendix M - Guidance for Surveyors: Hospice
(Rev.)

L609

(Rev.)

§418.76(a) Standard: Hospice aide qualifications

(1) A qualified hospice aide is a person who has successfully completed one of the following:

- (i) A training program and competency evaluation as specified in paragraphs (b) and (c) of this section respectively.**
- (ii) A competency evaluation program that meets the requirements of**

paragraph (c) of this section.

(iii) A nurse aide training and competency evaluation program approved by the State as meeting the requirements of §483.151 through §483.154 of this chapter, and is currently listed in good standing on the State nurse aide registry.

(iv) *A State licensure program.*

L688

(Rev.)

§418.106(a)(1)

(1) A hospice that provides inpatient care directly in its own facility must provide pharmacy services under the direction of a qualified licensed pharmacist who is an employee of or under contract with the hospice. The provided pharmacist services must include evaluation of a patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

Interpretive Guidelines: §418.106(a)(1)

Guidance pending and will be updated in future release.

L689

(Rev.)

§418.106(a)(2)

[Reserved]

L782

(Rev.)

§418.112(f) Standard: Orientation and training of staff.

Hospice staff, *in coordination with SNF/NF or ICF/IID facility staff*, must assure orientation of *such* staff furnishing care to hospice patients in the hospice philosophy, including hospice policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements.

Interpretive Guidelines §418.112(f)

It is *a shared* responsibility *of the hospice in conjunction with the SNF/NF or ICF/IID* to assess the need for staff training and coordinate the staff training with representatives of the facility, *and* to determine how frequently training needs to be offered in order to ensure that the facility staff furnishing care to hospice patients are oriented to the

philosophy of hospice care. Facility staff turnover rates should be a consideration in determining training frequency.

Procedures and Probes §418.112(f)

If during observations and interviews with the patient/representative and staff, concerns are identified that staff are not following the hospice philosophy, policies and procedures regarding methods of comfort, pain control, symptom management, as well as principles about death and dying, individual responses to death, patient rights, appropriate forms, and record keeping requirements, interview hospice staff on how they have provided education to the facility staff.

How does the hospice assure that the facility staff furnishing care to hospice patients are trained in the hospice philosophy of care?

State Operations Manual
Appendix U - Survey Procedures and Interpretive
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(Rev.)

R150

(Rev.)

§403.736 Condition of Participation: Discharge Planning

The RNHCI must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary. *The RNHCI must assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning.*

Interpretive Guidelines §403.736:

Guidance pending and will be updated in future release.

R151

(Rev.)

§403.736(a) Standard: Discharge Planning Evaluation

(1) Discharge instructions must be provided at the time of discharge to the patient or the patient's caregiver as necessary.

Interpretive Guidelines §403.736(a):

Guidance pending and will be updated in future release.

R153

(Rev.)

(2) If the patient assessment indicates a need for a discharge plan, the discharge plan must include instructions on post-RNHCI care to be used by the patient or the caregiver in the patient's home, as identified in the discharge plan.

Interpretive Guidelines §403.736(a)(1 - 2):

Guidance pending and will be updated in future release

R154

(Rev.)

(3) If the RNHCI's patient assessment does not indicate a need for a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.

Interpretive Guidelines §403.736(a)(3):

Guidance pending and will be updated in future release

R161

(Rev.)

§403.736(b) Standard: Transfer or Referral

The RNHCI must transfer or refer patients in a timely manner to another facility (including a medical facility if requested by the beneficiary, or his or her legal representative) in accordance with [§403.730\(b\)\(2\)](#)

Interpretive Guidelines §403.736(b):

Guidance pending and will be updated in future release

R162

(Rev.)

§403.736(c) Standard: Reassessment

The RNHCI must reassess its discharge planning process on an ongoing basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

Interpretive Guidelines §403.736(c):

Guidance pending and will be updated in future release

R200

(Rev.)

§403.742 Condition of Participation: Physical Environment

A RNHCI must be designed, constructed, and maintained to ensure the safety of the patients, staff, and the public.

§403.742(a) Standard: Buildings

The physical plant and the overall environment must be maintained in a manner that ensures the safety and well-being of the patients. The RNHCI must have the following:

Interpretive Guidelines §403.742:

Guidance pending and will be updated in future release

R202

(Rev.)

(1) Procedures for the proper storage and disposal of trash.

Interpretive Guidelines §403.742(a)(1):

Guidance pending and will be updated in future release

R203

(Rev.)

(2) Proper ventilation and temperature control and appropriate lighting levels to ensure a safe and secure environment.

Interpretive Guidelines §403.742(a)(2):

Guidance pending and will be updated in future release

R206

(Rev.)

(3) An effective pest control program.

Interpretive Guidelines §403.742(a)(3):

Guidance pending and will be updated in future release

R207

(Rev.)

(4) A preventive maintenance program to maintain essential mechanical, electrical, and fire protection equipment operating in an efficient and safe manner.

Interpretive Guidelines §403.742(a)(4):

Guidance pending and will be updated in future release

R208

(Rev.)

(5) A working call system for patients to summon aid or assistance.

Interpretive Guidelines §403.742(a)(5):

Guidance pending and will be updated in future release

R224

(Rev.)

§403.744 Condition of Participation: Life Safety From Fire

§403.744(a) General

An RNHCI must meet the following conditions:

Interpretive Guidelines: §403.744

Guidance pending and will be updated in future release.

R225

(Rev.)

§403.744(a) General. An RNHCI must meet the following conditions:

(1) Except as provided in this section-

- (i) *The RNHCI must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).*

*Interpretive Guidelines: §403.744 (a)(1)(i)
Guidance pending and will be updated in future release.*

R226
(Rev.)

§403.744(a) General. An RNHCI must meet the following conditions:

(1) Except as provided in this section-

- (i) *Notwithstanding paragraph (a)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.*

*Interpretive Guidelines: §403.744 (a)(1)(ii)
Guidance pending and will be updated in future release.*

R227
(Rev.)

§403.744 (a)(2) The RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff, and the public; evacuation; and cooperation with fire fighting authorities.

*Interpretive Guidelines: §403.744 (a)(2)
Guidance pending and will be updated in future release.*

R228
(Rev.)

§403.744 (a)(3) The RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.

Interpretive Guidelines: §403.744 (a)(3)

Guidance pending and will be updated in future release.

R229

(Rev.)

§403.744 (a)(4) *The RNHCI may place alcohol based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.*

Interpretive Guidelines: §403.744 (a)(4)

Guidance pending and will be updated in future release.

R230

(Rev.)

§403.744 (a)(5) *When a sprinkler system is shut down for more than 10 hours the RHNCI must:*

- (i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or*
- (ii) Establish a fire watch until the system is back in service.*

Interpretive Guidelines: §403.744 (a)(5)

Guidance pending and will be updated in future release.

R231

(Rev.)

§403.744 (a)(6) *Building must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.*

Interpretive Guidelines: §403.744 (a)(6)

Guidance pending and will be updated in future release.

R232

(Rev.)

§403.744(b) Exceptions

(1) *In consideration of a recommendation by the State survey agency or Accrediting Organization, or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a RNHCI facility, but only if the waiver will not adversely affect the health and safety of the patients.*

(2) If CMS finds that the fire and safety code imposed by State law adequately protects patients in the institution, the provisions of the Life Safety Code required in paragraph (a)(1) of this section do not apply in that State.

*Interpretive Guidelines: §403.744(b)(1) and (2):
Guidance pending and will be updated in future release.*

R233
(Rev.)

§403.744(c) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/Federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

- (1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.*
 - (i) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;*
 - (ii) TIA 12-1 to NFPA 101, issued August 11, 2011.*
 - (iii) TIA 12-2 to NFPA 101, issued October 30, 2012.*
 - (iv) TIA 12-3 to NFPA 101, issued October 22, 2013.*
 - (v) TIA 12-4 to NFPA 101, issued October 22, 2013.*
- (2) [Reserved]*

R234
(Rev.)

§ 403.745 Condition of participation: Building Safety.

- (a) Standard: Building Safety. Except as otherwise provided in this section the RNHCI must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).*
- (b) Standard: Exceptions. Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a RNHCI.*
- (c) Waiver. If application of the Health Care Facilities Code required under paragraph (a) of this section would result in unreasonable hardship for the RNHCI, CMS may waive specific provisions of the Health Care Facilities Code,*

but only if the waiver does not adversely affect the health and safety of individuals.

(d) Incorporation by reference. The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(2) [Reserved]

Interpretive Guidelines: §403.745

Guidance pending and will be updated in future release.

State Operations Manual

Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

(Rev.)

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Regulations and Interpretive Guidelines for CAHs (Rev.)

C-0800 (Rev.)

§485.601 Basis and Scope

(a) Statutory basis. This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) Scope. This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

C-0802 (Rev.)

§485.603 Rural Health Network

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network when applicable;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

C-0804

(Rev.)

§485.604 Personnel Qualifications

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) Clinical nurse specialist. A clinical nurse specialist must be a person who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and

(2) Holds a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.

(b) Nurse practitioner. A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) Physician assistant. A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that—

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

C-0808
(Rev.)

§485.606 Designation and Certification of CAHs

(a) Criteria for State Designation.

(1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in §482.58 of this chapter.

(b) Criteria for CMS certification. CMS certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this part and all other applicable requirements for participation in part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a CAH by the State under the rules in this subpart.

C-0810

(Rev.)

§485.608 Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

Interpretive Guidelines §485.608

Failure of the CAH to meet a Federal, State or local law may only be cited when the Federal, State or local authority having jurisdiction has made both a determination of noncompliance and has taken a final adverse action as a result.

Refer or report suspected violations to the appropriate Federal, State, or local agency.

C-0812

(Rev.)

§485.608(a) Standard: Compliance with Federal Laws and Regulations

The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

Interpretive Guidelines §485.608(a)

Each CAH must be in compliance with applicable Federal laws and regulations related to the health and safety of patients. This includes other Medicare regulations and Federal laws and regulations not specifically addressed in the CoPs. State Survey Agencies are expected to assess the CAH's compliance with the following Medicare provider

agreement regulation provisions when surveying for compliance with §485.608(a):

Advance Directives

An advance directive is defined at 42 CFR 489.100 as “a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.” In accordance with the provisions of 42 CFR 489.102(a), the advance directives regulations apply to CAHs. The CAH patient (inpatient or outpatient) has the right to formulate advance directives, and to have CAH staff implement and comply with the individual’s advance directive. The regulation at 42 CFR 489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual’s option, advance directives.

In the advance directive, the patient may provide guidance as to his/her wishes concerning provision of care in certain situations; alternatively, the patient may delegate decision-making authority to another individual, as permitted by State law. (In addition, the patient may use the advance directive to designate a “support person,” as specified in §485.635(f), for purposes of exercising the patient’s visitation rights.) When a patient who is incapacitated has executed an advance directive designating a particular individual to make medical decisions for him/her when incapacitated, the CAH must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient’s care. The CAH must also seek the consent of the patient’s representative when informed consent is required for a care decision. The explicit designation of a representative in the patient’s advance directive takes precedence over any non-designated relationship and continues throughout the patient’s inpatient stay or, as applicable, outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.

§489.102 also requires the CAH to:

- Provide written notice of its policies regarding the implementation of patients’ rights to make decisions concerning medical care, such as the right to formulate advance directives. If an individual is incapacitated or otherwise unable to communicate, the CAH may provide the advance directive information required under §489.100 to the individual’s “family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law.” (§489.102(e)) §489.102(b)(1) requires that notice of the CAH’s advance directive policy be provided at the time an individual is admitted as an inpatient. However, the CAH should also consider providing the advance directive notice at the time of registration, to outpatients (or their representatives) who are in the emergency department, who are in an observation status, or who are undergoing same-day surgery.

- The notice must include a clear and precise statement of limitation if the CAH cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should:
 - Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians or other practitioners;
 - Identify the State legal authority permitting such an objection; and
 - Describe the range of medical conditions or procedures affected by the conscience objection.

It should be noted that this provision allowing for certain conscience objections to implementing an advance directive is narrowly focused on the directive's content related to medical conditions or procedures. This provision would not allow a CAH or individual physician or practitioner to refuse to honor those portions of an advance directive that designate an individual as the patient's representative and/or support person, given that such designation does not concern a medical condition or procedure.

Issuance of the written notice of the CAH's advance directive policies to the patient or the patient's representative must be documented in the patient's medical record.

- Document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive;
- Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;
- Assure compliance with requirements of State law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;
- Provide for the education of staff concerning its policies and procedures on advance directives. The right to formulate advance directives includes the right to formulate a psychiatric advance directive (as allowed by State law); and
- Provide community education regarding advance directives and the CAH must document its efforts.

A **psychiatric advance directive** is akin to a traditional advance directive for health care. This type of advance directive might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment. The psychiatric advance directive may cover a range of subjects, and may

name another person who is authorized to make decisions for the individual if he or she is determined to be legally incompetent to make his/her own choices. It may also provide the patient's instructions about hospitalization, alternatives to hospitalization, the use of medications, types of therapies, and the patient's wishes concerning restraint or seclusion. The patient may designate who should be notified upon his/her admission to the CAH, as well as who should not be permitted to visit him or her. State laws regarding the use of psychiatric advance directives vary.

In accordance with State law, a psychiatric advance directive should be accorded the same respect and consideration that a traditional advance directive for health care is given. CAHs should carefully coordinate how the choices of a patient balance with the rights of other patients, staff, and individuals in the event that a dangerous situation arises.

However, even if State law has not explicitly spoken to the use of psychiatric advance directives, consideration should be given to them. When the patient is, for whatever reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight to the CAH's professional staff as they develop a plan of care and treatment for the patient.

Required CAH Disclosures to Patients:

Physician Ownership

- 42 CFR 489.3 defines a "physician-owned hospital" as any participating hospital, including a CAH, in which a physician or immediate family member of a physician (as defined in §411.351) has an ownership or investment interest in the CAH, except for those satisfying an exception found at §411.356(a) or (b). Surveyors are not required to make an independent determination regarding whether a CAH meets the Medicare definition of "physician-owned," but they must ask whether the CAH is physician-owned.
- However, the notice requirement does not apply to any physician-owned CAH that does not have at least one referring physician (as defined at §411.351 of this chapter) who has an ownership or investment interest in the CAH or who has an immediate family member who has an ownership or investment interest in the CAH. In such cases, the CAH must sign an attestation statement that it has no referring physician with an ownership or investment interest or whose immediate family member has an ownership or investment interest in the CAH. The CAH must maintain this attestation in its records.
- 42 CFR 489.20(u)(1) requires that all physician-owned CAHs provide written notice to their patients at the beginning of each patient's CAH inpatient stay or outpatient visit stating that the CAH is physician-owned, in order to assist the patient in making an informed decision about his or her care.

- A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.
- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the CAH is physician-owned and that a list of owners or investors who are physicians or immediate family members of physicians is available upon request. If the patient (or someone on behalf of the patient) requests this list, the CAH must provide it at the time of the request.
- 42 CFR 489.20(u)(2) provides that physician-owned CAHs must require each physician owner who is a member of the hospital's medical staff to agree, as a condition of obtaining/retaining CAH medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the CAH their ownership or investment interest or that of any immediate family member in the CAH. The CAH must require that this disclosure be made at the time of the referral and the requirement should be reflected in the hospital's policies and procedures governing privileges for physician owners.
 - The CAH may exempt from this disclosure requirement any physician owner who does not refer any patients to the CAH.
- 42 CFR 489.12 permits CMS to refuse to enter into a provider agreement with a physician-owned CAH applicant that does not have procedures in place to notify patients of physician ownership in the hospital, as required under §483.20(u).
- 42 CFR 489.53(c) permits CMS to terminate the provider agreement of a physician-owned CAH if the CAH fails to comply with the requirements at §489.20(u).

MD/DO 24/7 On-Site Presence

42 CFR 489.20(w) mandates that if there is no doctor of medicine or osteopathy present in the CAH 24 hours per day, seven days per week the CAH must provide written notice to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of outpatient visits. The purpose of the requirement is to assist the patient in making an informed decision about his/her care. CAHs that have an MD/DO (including residents who are MDs or DOs) on-site 24/7 do not need to issue any disclosure notice about emergency services capability.

- The notice must be provided to all inpatients and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia.
- The notice must be provided at the beginning of the planned or unplanned inpatient

stay, or applicable outpatient visit.

- A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the CAH.
- Individual notices are not required in the CAH's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24(b)), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted notice must state that the CAH does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the CAH will meet the medical needs of any patient with an emergency medical condition, as defined in 42 CFR 489.24(b) [the EMTALA definition], at a time when there is no doctor of medicine or doctor of osteopathy present in the CAH. If an emergency department patient is determined to require admission, then the individual notice provisions of 42 CFR 489.20(w) would apply to that patient.
- Before admitting an inpatient or providing outpatient services requiring notice, the CAH must obtain a signed acknowledgement from the patient stating that he/she understands that a doctor of medicine or doctor of osteopathy may not be present during all hours services are furnished to him/her.
 - In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances the CAH must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.
- For a CAH that participates in Medicare with multiple campuses providing inpatient services (e.g., a main provider campus and a separate remote location for a psychiatric or rehabilitation distinct part unit (DPU) under one CMS Certification Number) a separate determination is made for each campus/location with inpatient services as to whether the disclosure notice is required. For example, if a CAH has a main campus with 25 inpatient beds and a remote location with 10 psychiatric DPU beds and 10 rehabilitation DPU beds, and a physician is present 24/7 on the main campus, but not at the DPU remote location, the CAH is required to provide the disclosure notice at the DPU location. No notice is required for patients coming to the main provider campus. In this same example, if the CAH also has a provider-based, off-campus ambulatory surgery department, no notice is required at that off-campus surgery site, since the CAH's main campus does have an MD/DO present 24/7.

- 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a CAH if the CAH fails to comply with the requirements at §489.20(w) when it does not have an MD or DO on-site 24/7.

Other Federal Requirements

Other Federal requirements also apply to patient health and safety in the CAH. For example, Federal laws and regulations govern both the disposal of medical waste and occupational health. However, surveyors are not expected to be knowledgeable about the requirements of other Federal agencies and therefore do not assess compliance with non-CMS regulations. A surveyor who suspects a CAH may not be in compliance with other Federal requirements may refer the matter to the appropriate Federal agency. If CMS is notified or becomes aware of another Federal agency's final enforcement action, action will be taken only if the final enforcement action remains in effect.

Survey Procedures §485.608(a)

Assessing Compliance with Advance Directives Requirements

- Review the CAH's advance directive notice. Does it advise inpatients or applicable outpatients, or their representatives, of the patient's right to formulate an advance directive and to have CAH staff comply with the advance directive (in accordance with State law)? Does it include a clear, precise, and valid statement of limitation if the CAH cannot implement an advance directive on the basis of conscience?
- Review the records of a sample of patients for evidence of CAH compliance with advance directive notice requirements. Does every inpatient or applicable outpatient record contain documentation that notice of the CAH's advance directives policy was provided at the time of admission or registration? Is there documentation of whether or not each patient has an advance directive? For those patients who have reported an advance directive, has a copy of the patient's advance directive been placed in the medical record?
- What mechanism does the CAH have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the CAH is promoting and protecting each patient's right to formulate an advance directive?
- Determine to what extent the CAH complies, as permitted under State law, with patient advance directives that delegate decisions about the patient's care to a designated individual.
- Determine to what extent the CAH educates its staff regarding advance directives.
- Interview staff to determine their knowledge of the advance directives of the patients

in their care.

- Determine to what extent the CAH provides education for the patient population regarding one's rights under State law to formulate advance directives.

Assessing Required Disclosures

Physician Ownership

- If the CAH indicates that it is physician-owned but is exempt under §489.20(v) from the disclosure requirement of §489.20(u)(2), ask to see the signed attestation that it does not have any referring physicians with an ownership/investment interest or whose immediate family member has an ownership/investment interest in the CAH. (As with any other on-the-spot correction of a deficiency during a survey, creation of an attestation at the time of a survey does not mean that there was no deficiency and that the CAH would not be cited.)
- If the CAH is physician-owned but not exempt from the physician ownership disclosure requirements:
 - Verify that appropriate policies and procedures are in place to assure that written notices are provided to all patients at the beginning of an inpatient or outpatient stay.
 - Review the notice the CAH issues to each patient to verify that it discloses, in a manner reasonably designed to be understood by all patients, that the CAH meets the Federal definition of "physician-owned," that a list of owners and investors who are physicians or immediate family members of physicians is available upon request, and that such list is provided to the patient at the time the request is made by or on behalf of the patient.
 - Determine through staff interviews, observation, and a review of policies and procedures whether the CAH furnishes its list of physician owners and investors at the time a patient or patient's representative requests it.
 - Determine through staff interviews and review of policies, procedures, and staff records whether a physician-owned CAH's medical staff membership and admitting privileging requirements include a requirement that, as a condition of continued membership or admitting privileges, physician owners who refer patients to the CAH agree to provide written disclosure of their own or any immediate family member's ownership or investment interest to all patients at time of the referral to the CAH.

MD/DO 24/7 On-site Presence

- Determine through interviews, observation, and medical record review whether an

MD/DO is present in the CAH 24 hours per day, 7 days per week. For each required location where an MD/DO is not present:

- Verify that appropriate policies and procedures are in place to assure that written notices that a MD/DO is not present at all times are provided at the beginning of a planned or unplanned inpatient stay or outpatient visit to all inpatients and to all outpatients receiving observation services, surgery or another procedure requiring anesthesia.
- Verify that there is a signed acknowledgement by the patient of such disclosure, obtained by the CAH prior to the patient's admission or before applicable outpatient services were provided.
- Ask a sample of inpatients and affected outpatients whether they were provided notice about an MD/DO not being present at all times in the CAH.
- Verify that the CAH's emergency department has signage with the appropriate disclosure information.
- Review the notice the CAH issues to verify that it indicates how the CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present at that CAH, including any remote location.

Other Federal Requirements

Surveyors do not assess compliance with Medicare payment provisions or non-Medicare requirements. However, a surveyor may refer suspected noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., hazardous chemical and waste issues to EPA, blood-borne pathogens and TB control to OSHA, etc.).

C-0814 ***(Rev.)***

§485.608(b) Standard: Compliance With State and Local Laws and Regulations

All patient care services are furnished in accordance with applicable State and local laws and regulations.

Interpretive Guidelines §485.608(b)

There are wide variations in the States' practice acts relative to the extent to which MD/DOs may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a MD/DO, and local situations in which nurse

practitioners, clinical nurse specialists, and physician assistants may function.

Survey Procedures §485.608(b)

Prior to going on the survey, determine what professional specialists provide patient care services at the CAH and review State practice act requirements.

C-0816
(Rev.)

§485.608(c) Standard: Licensure of CAH

The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

Survey Procedures §485.608(c)

Prior to the survey, determine whether the CAH is subject to licensure requirements and verify that the licensing agency has approved the CAH as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing CAHs.

C-0818
(Rev.)

§485.608(d) Standard: Licensure, Certification or Registration of Personnel

Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

Interpretive Guidelines §485.608(d)

All staff required by the State to be licensed must possess a current license. The CAH must ensure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dietitians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory technicians and facility administrators.

All CAH staff must meet all applicable standards required by State or local law for CAH personnel. This would include at a minimum:

- Certification requirements;
- Minimum qualifications; and
- Training/education requirements.

Survey Procedures §485.608(d)

- Verify for those personnel required to be licensed by the State, that the CAH has established, and follows, procedures for determining that personnel providing patient care services are properly licensed.
- Check a sample of personnel files to verify that licensure information is up to date. Verify that appropriate categories of staff and personnel are licensed in accordance with State requirements. Verify state licensure compliance of the direct care personnel, as well as administrators and supervisory personnel, and any contracted personnel.
- Verify that there are procedures in place to guarantee licensure of employees working at the CAH under contract or agreement.
- Review CAH policies regarding certification, licensure, and registration of personnel. Are the CAH policies compliant with State and local laws? Are the personnel in compliance with CAH policy?

C-0822
(Rev.)

§485.610 Condition of Participation: Status and Location

Interpretive Guidelines §485.610

The CAH must meet the location requirements of §485.610(b) and §485.610(c) at the time of the initial survey. Compliance with these location requirements must be reconfirmed at the time of every subsequent recertification (including the recertification of a deemed status CAH whose accreditation has been renewed). If the CAH moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and (c). If a CAH that has been certified on the basis of having been designated by the State as a necessary provider moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and §485.610(d).

C-0824
(Rev.)

§485.610(a) Standard: Status

The facility is--

- (1) A currently participating hospital that meets all conditions of participation set forth in this subpart;**
- (2) A recently closed facility, provided that the facility--**

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that--

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

Interpretive Guidelines §485.610(a)

Confirm that a CAH meets the basic status requirement prior to scheduling the survey. The appropriate RO will reverify the status requirement prior to approving a CAH for Medicare certification.

C-0826
(Rev.)

§485.610(b) Standard: Location in a Rural Area or Treatment as Rural

The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of paragraph (b)(3), (b)(4), or (b)(5) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter and is not among a group of hospitals have been redesignated to an adjacent urban area under §412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.

(3) Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on June 3, 2003.

(4) Effective for October 1, 2009 through September 30, 2011, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2010, was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008.

(5) Effective on or after October 1, 2014, for a period of 2 years beginning with the effective date of the most recent Office of Management and Budget (OMB) standards for delineating statistical areas adopted by CMS, the CAH no longer meets the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, prior to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, was located in a rural area as defined by OMB, but under the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, is located in an urban area.

Interpretive Guidelines §485.610(b)

Among other requirements, pursuant to 42 CFR 485.610(b), all CAH applicants and existing CAHs, including necessary provider CAHs, must either be:

- located in a rural area; or
- treated as rural in accordance with 42 CFR 412.103

in order to be eligible for CAH designation and certification. (The temporary provisions at 42 CFR 485.610(b)(3) and (4) have expired and no longer apply.)

Only the CMS Regional Office makes the determination whether a CAH applicant or existing CAH meets the rural location requirement, following the instructions below. However, State Survey Agencies (SA) may wish to make informal assessments prior to conducting a survey, following the guidance provided in Section 2256A of the SOM. If the SA's informal assessment suggests the CAH applicant or existing CAH is not rural, it should consult with the RO before conducting a survey.

Survey Procedures §485.610(b)

Conduct an informal assessment of the CAH's rural status, following the procedures in

Section 2256A of the SOM, and if it appears the CAH no longer has rural status, confer with the CMS RO prior to scheduling the initial or recertification survey.

C-0830
(Rev.)

[\$485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification]

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

Interpretive Guidelines §485.610(c)

A CAH that has not been designated by a State as a necessary provider prior to December 31, 2005 must be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from any other CAH or hospital. An exception is made for Indian Health Service (IHS) or Tribal CAHs and hospitals that are located less than the 35 or 15 miles from another hospital or CAH. Given that IHS and Tribal CAHs and hospitals serve distinctly different populations, IHS CAHs and hospitals are excluded from consideration when determining the proximity of non-IHS hospitals seeking CAH certification to other CAHs or hospitals. For the same reason, when an IHS or Tribal hospital applies for certification to participate in Medicare as a CAH, CMS will consider only its proximity to other IHS and Tribal CAHs and hospitals in determining whether it meets the location requirement under section 485.610(c).

If a CAH is located on an island and the location meets the following characteristics, the CAH is considered to be in compliance with the distance requirements relative to other hospitals and CAHs under §485.610(c):

- The island is entirely surrounded by water;
- The CAH is the only hospital or CAH on the island; and
- The island is not accessible by any roads.

CAHs located on islands that meet the criteria above are still required to comply with the rural location requirement under §485.610(b).

A CAH that can document that it was designated by a State as a necessary provider CAH prior to January 1, 2006, does not have to meet the location relative to other facilities standard at §485.610(c). As of January 1, 2006, States do not have the authority to designate any new necessary provider CAHs. Necessary provider CAHs that were designated prior to that date are grandfathered by statute, subject to certain conditions if

they relocate (see the discussion related to §485.610(d)). ROs and SAs should have the documentation related to a CAH's original designation as a necessary provider in the file on each CAH. If they do not, they should ask the CAH to supply copies of the original necessary provider designation documents.

For applicants seeking a new CAH provider agreement, or for CAHs that seek to relocate and do not have a grandfathered necessary provider designation, ROs will review the application and make the determination whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in Chapter 2, §2256A of the State Operations Manual. At the conclusion of its review, the RO will notify the SA of its determination. Existing CAHs that are not grandfathered necessary provider CAHs must be periodically evaluated to determine whether there are any more recently certified Medicare-participating hospitals that are not more than a 35-mile drive, or 15-mile drive, as applicable, from the CAH. In the event that an existing CAH that is not a grandfathered necessary provider no longer meets the minimum distance requirement, it is provided the opportunity to avoid termination of its provider agreement by converting to a certified Medicare hospital after demonstrating compliance with the hospital CoPs.

C-0832
(Rev.)

§485.610(d) Standard: Relocation of CAHs With a Necessary Provider Designation

A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

- (1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location--
 - (i) Serves at least 75 percent of the same service area that it served prior to its relocation;
 - (ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and
 - (iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.
- (2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does

not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3).

Interpretive Guidelines §485.610(d)

Renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation. However, as discussed in the adoption of this regulation (70 FR 47472), all newly-constructed, necessary provider CAH facilities, including entirely new replacement facilities constructed on the same site as the existing CAH main campus, are considered relocated facilities. The determination of whether or not CAHs with a necessary provider designation have met the requirements at §485.610(d) will be made by the RO, generally prior to an SA or accreditation survey. The RO will utilize the evaluation criteria set forth in the SOM, Chapter 2, §2256F to make this determination. At the conclusion of its review, the RO will notify the SA of its results.

C-0834
(Rev.)

§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs

Standard: Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:

- (1) If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in §413.65(a)(2) of this chapter, with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement of paragraph (c) of this section only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. A change of ownership of any of the facilities with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement.**
- (3) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, [or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section,] the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.**

Interpretive Guidelines §485.610(e)(1) & (3)

A CAH may not be co-located with another hospital or CAH, because this would violate the minimum distance requirement found at §485.610(c). However, some CAHs that were designated as necessary providers prior to January 1, 2006, and therefore exempted from this distance requirement, also chose to co-locate with another hospital. Co-location occurs when a necessary provider CAH shares the same campus and/or building in which the CAH is currently located with another hospital or necessary provider CAH. For example, a necessary provider CAH shares the same campus with an unrelated psychiatric or rehabilitation hospital.

Effective January 1, 2008, grandfathered necessary provider CAHs may no longer enter into co-location arrangements with another CAH or hospital (72 FR 66878). However, necessary provider CAHs that had co-location arrangements in effect prior to January 1, 2008, are permitted to continue these arrangements as long as the type and scope of services offered by the facility co-located with the CAHs do not change. An example of a change in type of services would be when a hospital that provides only rehabilitation services chooses to provide general hospital acute care services. An example of a change in scope of services would be when a grandfathered necessary provider CAH is currently co-located with a 20 bed psychiatric hospital and the psychiatric hospital now decides to increase the number of beds to 30.

The determination of whether or not CAHs with a grandfathered necessary provider designation have met the requirements at §485.610(e)(1) is made by the RO. If the SA or accreditation organization (AO) becomes aware of a co-location arrangement, the SA or AO must notify the RO. The RO will utilize the co-location guidance in §2256G of the SOM to determine if such CAHs satisfy the co-location requirements at §485.610(e)(1). The RO will notify the CAH as well as the SA (and the AO, if applicable) of its determination.

A CAH found out of compliance with the requirements is subject to termination of its Medicare provider agreement under §489.53(a)(3). In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. If the CAH corrects the situation, by terminating the co-location arrangement that led to the non-compliance during this 90 day period, then the provider agreement is not terminated.

A facility facing termination of its CAH designation as a result of non-compliance with §485.610(e)(1) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CMS Certification Number (CCN) would be assigned accordingly.

C-0836
(Rev.)

[§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:]

(2) If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b) of this chapter, but including a department or remote location, as defined in §413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH.

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State [does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, or] creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

Interpretive Guidelines §485.610(e)(2) & (3)

Section 42 CFR 485.610(e)(2) requires that if a CAH operates an off-campus provider-based facility as defined in §413.65(a)(2) (except for a rural health clinic (RHC)) or off-campus rehabilitation or psychiatric distinct part unit as defined at §485.647, that was created or acquired on or after January 1, 2008, then the off-campus facility must meet the requirement at 42 CFR 485.610(c) to be more than a 35 mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from any other CAH or hospital. Off-campus CAH facilities that were in existence prior to January 1, 2008, are not subject to this requirement.

If a non-IHS or non-Tribal CAH operates an off-campus provider-based facility, its proximity to an IHS or Tribal CAH or hospital is not considered when assessing compliance with the requirements of this section. Similarly, if an IHS or Tribal CAH operates an off-campus provider-based facility, its proximity to a non-IHS or non-Tribal CAH or hospital is not considered when assessing compliance.

The drive to another hospital or CAH is to be calculated from the provider-based facility's location to the main campus of the other hospital or CAH.

The distance to another hospital or CAH requirement does not apply to the following types of facilities/services, because such facilities or services are not eligible for provider-based status in accordance with §413.65(a)(1)(ii):

- Ambulatory surgical centers (ASCs);
- Comprehensive outpatient rehabilitation facilities (CORFs);
- Home Health Agencies (HHAs);
- Skilled nursing facilities (SNFs);
- Hospices;
- Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services;
- ESRD facilities;
- Departments of providers that perform functions necessary for the successful operation of the CAH, but for which separate CAH payment may not be claimed under Medicare or Medicaid, e.g., laundry, or medical records department; and
- Ambulances.

In the case of Federally Qualified Health Centers (FQHCs), although CMS rules permit them to be provider-based departments of a hospital or CAH, it is unlikely that there are new FQHCs that meet the provider-based criteria, since the Health Resources and Services Administration (HRSA) requirements for separate FQHC governance make it unlikely an FQHC could meet provider-based governance requirements. However, there are grandfathered FQHCs that were in operation prior to April 7, 2000 which are permitted to retain their provider-based status.

Those CAHs seeking a provider-based determination for newly created or acquired provider-based departments, remote locations and/or psychiatric or rehabilitation units located off-campus must submit an attestation to the Regional Office (RO), as specified in §2254H of the SOM, who makes the determination of whether it satisfies the CAH provider-based criteria at §485.610(e)(2), and the provider-based rules at §413.65. At the conclusion of its review, the RO will notify the CAH and the SA (and accreditation organization (AO), if applicable) of its determination.

If the SA or AO becomes aware of a provider-based off-campus facility that appears not to comply with the provider-based location requirements, the SA or AO must notify the RO. The RO will utilize the guidance in §2254H of the SOM to determine if the CAH

satisfies the provider-based location requirements at §485.610(e)(2). The RO will notify the CAH as well as the SA (and the AO, if applicable) of its determination.

A CAH found out of compliance with the off-campus location requirements at §485.610(e)(2) is subject to termination of its Medicare provider agreement. In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. If the CAH corrects the situation, by terminating the off-campus provider-based arrangement that led to the non-compliance during this 90 day period, then the provider agreement is not terminated.

A facility facing termination of its CAH status as a result of non-compliance with §485.610(e)(2) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CCN number would be assigned accordingly.

C-0840
(Rev.)

§485.612 Condition of Participation: Compliance With CAH Requirements at the Time of Application

Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

Interpretive Guidelines §485.612

This COP only applies to initial surveys. All facilities that apply to become a CAH are surveyed using the CAH CoP to determine compliance, whether they are:

- A currently operating CAH; or
- A re-opened CAH; or
- A CAH that down-sized to become a clinic.

If a facility has never been a Medicare participating hospital and wishes to be a CAH, the facility is a new provider to Medicare and must first meet the certification as a hospital and then put in a change of status request to be a CAH. In these cases, the facility must be surveyed twice. They must be initially surveyed using the hospital CoP and, when the change request is received, they must be surveyed again using the CAH CoP. In addition, these facilities are to be treated as new providers to Medicare necessitating completion of an application package as a new Medicare provider.

C-0860
(Rev.)

§485.616 Condition of Participation: Agreements

C-0862
(Rev.)

§485.616(a) Standard: Agreements With Network Hospitals

In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for:

Interpretive Guidelines §485.616(a)

Section 485.603 defines a rural health network as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services.

Survey Procedures §485.616(a)

- If the CAH is a member of a rural health network having a communications system, ask to see the agreement.
- How does the CAH participate with other hospitals and facilities in the network communications system?
 - Is a communications log kept at the facility?
 - Ask staff if there have been difficulties in contacting network members. If so, ask how the CAH deals with communication delays.
- How does the network's communications system compare with any available communications equipment in the CAH?
- When the network communications system is not in operation, how does the CAH communicate and share patient data with other network members?
- Review any policies and procedures related to the operation of any communications system.
- How is the CAH staff educated on the use of any communication system utilized in the facility?
- Review any written agreements with the local EMS service.

C-0864
(Rev.)

§485.616(a)(1) Patient referral and transfer;

C-0866
(Rev.)

§485.616(a)(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

C-0868
(Rev.)

§485.616(a)(3) The provision of emergency and non-emergency transportation between the facility and the hospital.

C-0870
(Rev.)

§485.616(b) Standard: Agreements for Credentialing and Quality Assurance

Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least--

- (1) One hospital that is a member of the network;**
- (2) One QIO or equivalent entity; or**
- (3) One other appropriate and qualified entity identified in the State rural health care plan.**

Interpretive Guidelines §485.616(b)

Other qualified entities could include another CAH or any licensed firms, businesses, or agencies that provide credentialing and QA services. The location for these other qualified entities is not limited to local entities.

Agreements for QA need to include medical record review as part of the determination of the quality and medical necessity of medical care at the CAH.

Survey Procedures §485.616(b)

- Review any agreements related to credentialing or quality assurance to determine

the level of assistance to be provided and the responsibilities of the CAH.

- Review policies and procedures to determine how information is to be obtained, utilized, and how confidentiality of information will be maintained.

C-0872
(Rev.)

§485.616(c) Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners.

(1) The governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the following requirements with regard to its physicians or practitioners providing telemedicine services:

(i) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(ii) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

(iii) Assure that the medical staff has bylaws.

(iv) Approve medical staff bylaws and other medical staff rules and regulations.

(v) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

(vi) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

(vii) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

(2) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site hospital, that the following provisions are met:

(i) The distant-site hospital providing telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges;

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH is located; and

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the individual distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

Interpretive Guidelines §485.616(c) §485.616(c)(1)&(2)

“Telemedicine,” as the term is used in this regulation, means the provision of clinical services to patients by physicians and practitioners from a distance via electronic communications. The distant-site telemedicine physician or practitioner provides clinical services to the CAH patient either simultaneously, as is often the case with teleICU services, for example, or non-simultaneously, as may be the case with many teleradiology services. “Simultaneously” means that the clinical services (for example, assessment of the patient with a clinical plan for treatment, including any medical orders needed) are provided to the patient in “real time” by the telemedicine physician or practitioner, similar to the actions of an on-site practitioner when called in by a patient's attending physician to see the patient. “Non-simultaneously” means that, while the telemedicine physician or practitioner still provides clinical services to the patient, such services may involve after-the-fact interpretation of diagnostic tests in order to provide an assessment of the patient's condition and do not necessarily require the telemedicine practitioner to directly assess the patient in “real time.” This would be similar to the services provided by an on-site radiologist who interprets a patient's x-ray or CT scan and then communicates his or her assessment to the patient's attending physician who then bases his or her diagnosis and treatment plan on these findings. . (See 76 FR 25552, May 5, 2011)

A CAH may make arrangements with a distant-site Medicare-participating hospital for the provision of telemedicine services to the CAH's patients by physicians or practitioners granted privileges by the distant-site hospital.

If a CAH enters into an agreement for telemedicine services with a distant-site hospital, the agreement must be in writing. Furthermore, the written agreement must specify that it is the responsibility of the distant-site hospital to conduct its credentialing and privileging process for those of its physicians and practitioners providing telemedicine services such that the distant-site hospital:

- Determines, in accordance with State law, which categories of practitioners are eligible candidates for privileges or membership on the distant-site hospital's medical staff.
- Appoints members and grants medical staff privileges after considering the recommendations of the existing members of the distant-site hospital's medical staff.
- Assures that the distant-site hospital's medical staff has bylaws.
- Approves the distant-site hospital's medical staff bylaws and other medical staff rules and regulations.
- Ensures that the medical staff is accountable to the distant-site hospital's governing body for the quality of care provided to patients.
- Ensures the criteria for granting medical staff membership/privileges to an individual are the individual's character, competence, training, experience, and judgment.
- Ensures that under no circumstances is the accordance of distant-site hospital medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society.

Since the distant-site hospital must also participate in Medicare, it has an independent obligation to comply with these same requirements for all of its medical staff under §§482.12(a)(1) through (a) (7). Nevertheless, the written telemedicine services agreement between the CAH and the distant-site hospital must explicitly include a provision addressing the distant-site hospital's obligation to comply with these provisions.

The CAH's governing body (or the individual responsible for the CAH if it has no governing body) has the option, when considering granting privileges to telemedicine physicians and practitioners, to rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners. In order to exercise this alternative credentialing and privileging option, the CAH's governing body must ensure that its written agreement with the distant-site hospital addresses all of the following:

- That the distant-site hospital participates in the Medicare program. If the distant-site hospital's participation in Medicare is terminated, either voluntarily or

involuntarily, at any time during the agreement, then as of the effective date of the termination, the CAH may no longer receive telemedicine services under the agreement;

- That the distant-site hospital provides a list to the CAH of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site hospital. The list may not include any physician or practitioner who does not hold privileges at the distant-site hospital. The list must be current, so the agreement must address how the distant-site hospital will keep the list current;
- That each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the State where the CAH is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the CAH whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be; and
- That the CAH has evidence that it reviews the telemedicine services provided to its patients and provides feedback based on this review to the distant-site hospital for the latter's use in its periodic appraisal of each physician and practitioner providing telemedicine services under the agreement. At a minimum, the CAH must review and send information to the distant-site hospital on all adverse events that result from a physician or practitioner's provision of telemedicine services and on all complaints the CAH has received about a telemedicine physician or practitioner.

If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site hospital, then it must for each physician or practitioner providing telemedicine services under an agreement follow the CAH's standard process for review of credentials and granting of privileges to physicians and practitioners.

Survey Procedures §485.616(c)(1)&(2)

- Ask the CAH's leadership whether it uses telemedicine services. If yes,
 - Ask to see a copy of the written agreement(s) with the distant-site hospital(s). Does each agreement include the required elements concerning credentialing and privileging of the telemedicine physicians and practitioners by the distant-site hospital?
 - Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner?
- Does the documentation indicate that the CAH's governing body or responsible

individual made the privileging decision based on the privileging decisions of the distant-site hospital? If yes:

- Does the agreement address the required elements concerning the distant-site hospital's Medicare participation, appropriate licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges, and review by the CAH of the telemedicine physicians' and practitioners' services?
- Ask to see the list provided by the distant-site hospital of the telemedicine physicians and practitioners, including their privileges and pertinent licensure information.
- Ask for evidence that the CAH conducts the required review of the telemedicine services provided by the telemedicine physicians and practitioners, including any associated adverse events and complaints, and that it provides the required feedback to the distant-site hospital.

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(Rev.)

§485.616(c)(3) The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, in accordance with §485.635(c)(4)(ii), furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services.

§485.616(c)(4) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the following provisions are met:

- (i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at (c)(1)(i) through (c)(1)(vii).**
- (ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides a current list to the CAH**

of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

- (iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH whose patients are receiving the telemedicine services is located.**
- (iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such information for use in periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.**

Interpretive Guidelines §485.616(c)(3)&(4)

For the purposes of this rule, a distant-site telemedicine entity is defined as an entity that -- (1) provides telemedicine services; (2) is not a Medicare-participating hospital; and (3) provides contracted services in a manner that enables a CAH using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of physicians and practitioners providing telemedicine services to the patients of a CAH. A distant-site telemedicine entity would include a distant-site hospital that does not participate in the Medicare program that is providing telemedicine services to a Medicare-participating CAH. (See 76 FR 25553, May 5, 2011)

A CAH may have an agreement with a distant-site telemedicine entity for the provision of telemedicine services to the CAH's patients by physicians or practitioners granted privileges by the distant-site telemedicine entity.

If a CAH enters into an agreement for telemedicine services with a distant-site telemedicine entity, the agreement must be in writing. Furthermore, the written agreement must specify that under the agreement the distant-site telemedicine entity is a contractor providing services to the CAH, and that, in accordance with the requirements of §485.635(c)(4)(ii), the distant-site telemedicine entity furnishes its telemedicine services in a manner that enables the CAH to comply with all applicable CAH Conditions of Participation (CoPs), including, but not limited to, the specific requirements governing telemedicine services. Under §485.635(c)(4)(ii), the CAH's governing body or responsible individual is obligated to ensure that all contractors of services furnish those services in a manner that enables the CAH to comply with all applicable CoPs.

The CAH's governing body (or the individual responsible for the CAH if it has no governing body) has the option, when considering granting privileges to telemedicine physicians and practitioners, to rely upon the credentialing and privileging decisions of the distant-site telemedicine entity for these physicians and practitioners. In order to exercise this alternative credentialing and privileging option, the CAH's governing body must ensure through its written agreement with the distant-site telemedicine entity that all of the following requirements are included in the agreement and that the contractor fulfills these requirements:

- The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meets the standards at §485.616(c)(1)(i) through (c)(1)(vii). In other words, the distant-site telemedicine entity must at a minimum:
 - Determine, in accordance with State law, which categories of practitioners are eligible candidates for medical staff privileges or membership at the telemedicine entity;
 - Appoint members and grant medical staff privileges after considering the recommendations of the existing members of its medical staff;
 - Assure that its medical staff has bylaws;
 - Approve its medical staff's bylaws and other medical staff rules and regulations;
 - Ensure that the medical staff is accountable to the distant-site telemedicine entity's governing body for the quality of care provided to patients;
 - Ensure the criteria for granting distant-site telemedicine medical staff membership/privileges to an individual are the individual's character, competence, training, experience, and judgment; and
 - Ensure that under no circumstances is the accordance of medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society.
- The distant-site telemedicine entity provides to the CAH a list of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site telemedicine entity. The list may not include any physician or practitioner who does not hold privileges at the distant-site telemedicine entity. The list must be current, so the agreement must address how the distant-site telemedicine entity will keep the list current;
- Each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the State where the CAH is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and

they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the hospital whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be; and

- The CAH reviews the performance of the physicians and practitioners providing telemedicine services to its patients and provides a written review to the distant-site telemedicine entity for the latter's use in its periodic appraisal of each physician and practitioner providing telemedicine services under the agreement. At a minimum, the CAH must review and send information to the distant-site telemedicine entity on all adverse events that result from a physician's or practitioner's provision of telemedicine services and on all complaints the CAH has received about a telemedicine physician or practitioner.

If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site telemedicine entity, then it must for each practitioner providing telemedicine services under an agreement follow the CAH's standard process for review of credentials and granting of privileges to physicians and practitioners.

Survey Procedures §485.616(c)(3)&(4)

- Ask the CAH's leadership whether it uses telemedicine services. If yes,
 - Ask to see a copy of the written agreement(s) with the distant-site telemedicine entity(ies). Does each agreement explicitly state that the distant-site telemedicine entity will provide telemedicine services in a manner that enables the CAH to comply with all applicable CoPs?
 - Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner?
 - Does the documentation indicate that the CAH's governing body or responsible individual made the privileging decision based on the privileging decisions of the distant-site telemedicine entity? If yes:
 - Does the written agreement with the distant-site telemedicine entity address the required elements concerning the distant-site telemedicine entity's utilization of a medical staff credentialing and privileging process that meets the requirements of the hospital CoPs, licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges at the distant-site telemedicine entity, and written review by the CAH of the telemedicine physicians' and practitioners' services?
 - Is there a list provided by the distant-site telemedicine entity of the telemedicine physicians and practitioners covered by the agreement, including their privileges and pertinent licensure information?

- Is there evidence that the CAH reviews the services provided by the telemedicine physicians and practitioners, including any adverse events and complaints, and provides written feedback to the distant-site telemedicine entity?
- Ask the CAH how it verifies that the telemedicine entity fulfills the terms of the agreement with respect to its credentialing and privileging process and otherwise assures that services are provided in a manner that enables the CAH to meet all applicable CAH requirements? (Surveyors do not attempt to independently verify whether or not the distant-site telemedicine entity's credentialing and privileging process fulfills the regulatory requirements. Surveyors focus only on what actions the CAH takes to ensure that the distant-site telemedicine entity complies with the terms of the agreement.)

C-0880
(Rev.)

§485.618 Condition of Participation: Emergency Services

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

Interpretive Guidelines §485.618

All emergency services must be provided as a direct service in the CAH. The ED cannot be a provider-based off-site location. Emergency needs of patients must be met in accordance with acceptable standards of practice.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations, and guidelines governing all services provided in the CAH'S emergency department, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations such as the American Medical Association, American Association for Respiratory Care, American Society of Emergency Medicine, American College of Surgeons, American Nursing Association, etc.

The CAH'S emergency services must be under the direction of a qualified member of the CAH'S medical staff. The CAH'S medical staff establishes criteria for the qualifications for the director of the CAH'S emergency services in accordance with State law and acceptable standards of practice.

The CAH'S medical staff must establish policies and procedures governing the medical care provided in the emergency services or emergency department. Emergency services or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QA activities. The CAH'S emergency services must be integrated into the

CAH-wide QA program.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the provision of emergency care services. Qualifications include necessary education, experience and specialized training, consistent with State law and acceptable standards of practice.

The CAH must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility. There must be sufficient medical and nursing personnel to respond to the emergency medical needs and care of the patient population being served.

The CAH must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the CAH needed to meet its anticipated emergency needs. The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

The CAH must conduct ongoing assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Emergency care necessary to meet the needs of its inpatients and outpatients would include the provision of respiratory services as needed by the CAH'S emergency patients. When respiratory services are provided those services must be provided in accordance with acceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the CAH should be defined in writing, and approved by the medical staff.

The CAH must provide the appropriate equipment and qualified personnel necessary to furnish all services offered in a safe manner in accordance with acceptable standards of practice.

There should be written policies for the delivery of any services provided. The policies and procedures must be developed and approved by the medical staff and include the participation of any mid-level practitioners working in the ED. The written policies should address the following services, as appropriate:

- Each type of service provided by the CAH;
- The qualifications, including job title, licensure requirements, education, training and experience of personnel authorized to perform each type of respiratory care

service and whether they may perform it without supervision;

- Equipment assembly and operation;
- Safety practices, including infection control measures;
- Handling, storage, and dispensing of therapeutic gases;
- Cardiopulmonary resuscitation;
- Procedures to follow in the advent of adverse reactions to treatments or interventions;
- Pulmonary function testing;
- Therapeutic percussion and vibration;
- Bronchopulmonary drainage;
- Mechanical ventilatory and oxygenation support;
- Aerosol, humidification, and therapeutic gas administration;
- Administration of medications; and
- Procedures for obtaining and analyzing blood samples (arterial blood gases).

Survey Procedures §485.618

- Verify that emergency services are organized under the direction of a qualified member of the medical staff.
- Verify that procedures and policies for emergency medical services (including triage of patients and any respiratory services provided) are established, evaluated, and updated on an ongoing basis.
- Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility and that there are specific assigned duties for emergency care
- Review any policies and procedures for emergency services in the CAH. What evidence indicates that the CAH is capable of providing necessary emergency care for its inpatients and outpatients?
- Review a sample of patient records for patients treated in the emergency services department to see if the CAH followed its own policies and procedures.

- Verify that emergency services are provided in accordance with acceptable standards of practice.
- Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:
 - Parenteral administration of electrolytes, fluids, blood and blood components;
 - Care and management of injuries to extremities and central nervous system;
 - Prevention of contamination and cross infection; and
 - Provision of emergency respiratory services.
- Determine if the CAH provides any degree of respiratory care services and that the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.
- Review the CAH policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.
- Review staffing schedules to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished.
- If blood gases or other laboratory tests are performed as part of the delivery of respiratory services, verify that there is a current CLIA certificate.

C-0882
(Rev.)

§485.618(a) Standard: Availability

Emergency services are available on a 24-hours a day basis.

Interpretive Guidelines §485.618(a)

The CAH “makes available 24-hour emergency services.” This does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, (or 1 hour in certain frontier areas), 24 hours a day.

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by state and local law and in accordance with accepted standards of practice.

Survey Procedures §485.618(a)

Ascertain by record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observations that ED services were made available to patients presenting on a 24-hour a day basis. How does the CAH ensure that emergency services are made available on a 24-hour a day basis?

C-0884
(Rev.)

§485.618(b) Standard: Equipment, Supplies, and Medication

Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

Interpretive Guidance §485.618(b)

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by State and local law and in accordance with accepted standards of practice.

Survey Procedures §485.618(b)

- How does the CAH ensure that the required equipment, supplies and medications are always readily available in the CAH?
- Interview staff and tour the ER to ascertain compliance and ability to provide emergency services.

C-0886
(Rev.)

§485.618(b)(1) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

Survey Procedures §485.618(b)(1)

- How does the CAH ensure that staff knows where drugs and biologicals are kept?

- How is the inventory maintained?
- Who is responsible for monitoring drugs and biologicals?
- How are drugs and biologicals replaced?

C-0888
(Rev.)

§485.618(b)(2) Equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

Survey Procedures §485.618(b)(2)

- How does the CAH ensure that required equipment and supplies are readily available to staff?
- How does the CAH ensure that staff knows where emergency equipment and supplies are kept?
- How is the supply inventory maintained?
- Who is responsible for monitoring supplies?
- How are supplies replaced?
- When was the last time emergency supplies were used?
- Is there an equipment maintenance schedule (e.g., for the defibrillator)?
- Ask staff if equipment has ever failed to work when needed.
- Examine sterilized equipment (e.g., tracheostomy sets) for expiration dates when applicable.
- Examine the oxygen supply system to determine functional capabilities.
- Check the force of the vacuum (suction) equipment to see that it is in operating condition.

C-0890
(Rev.)

§485.618(c) Standard: Blood and Blood Products

The facility provides, either directly or under arrangements, the following--

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

Interpretive Guidelines §485.618(c)(1)

This requirement can be met at a CAH by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement in the regulation for a CAH to store blood on site, although it may choose to do so. In some cases, it may be more practical to transport a patient to the source of the blood supply than to bring blood to the patient at the CAH. A facility that has the capability of providing blood services on site would be in compliance even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa.

A CAH that performs CLIA tests on blood on-site must have a CLIA certificate and is subject to survey under CLIA. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory, is not performing testing as defined by CLIA. However, under this regulation, the CAH must ensure that blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures. The provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration.

“**Availability**” in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients at the CAH. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been utilized) of making blood products available to its emergency patients 24 hours a day.

If a CAH performs type and compatibility testing it must have the necessary equipment, (i.e., serofuge and heat block), as well as typing and cross matching reagents, some of which have a 30-day expiration date. Another way for a CAH to meet this requirement would be to properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only. CAHs that choose to store O negative packed red blood cells for emergency release of uncross matched blood will require a release form to be signed by a doctor, prior to transfusion, acknowledging that the blood has not been cross matched for the patient. Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells.

C-0892

(Rev.)

§485.618(c)(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

Survey Procedures §485.618(c)(2)

- If blood banking services are provided on site, what evidence shows that the blood facility is under the control and supervision of a pathologist or other qualified MD/DO?
- For blood banking services provided under arrangement, what evidence shows that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?

C-0894

(Rev.)

§485.618(d) Standard: Personnel

(1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner or a clinical nurse specialist with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if—

(i) The registered nurse is on site and immediately available at the CAH when a patient requests medical care; and

(ii) The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.

(3) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if--

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural health care plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(4) The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

Interpretive Guidance § 485.618(d)

When State laws are more stringent and require more stringent staffing or expanded operational hours, the CAH must staff its emergency department in accordance with state laws. For example, if State law requires the CAH emergency department be open and be staffed with a MD/DO 24/7 then the CAH must comply.

Survey Procedures §485.618(d)

- Review on-call schedules to determine how the CAH ensures that a qualified staff member is on call 24 hours a day and available on site at the CAH within 30 minutes, or 60 minutes in certain frontier areas.
- Interview staff to determine how the CAH staff knows who is on call.
- What documentation demonstrates that a MD/DO, nurse practitioner, physician assistant, clinical nurse specialist or registered nurse (as allowed under (d)(3)) with emergency training or experience has been on call and available on site at the CAH within 30 or 60 minutes, as appropriate?

C-0898
(Rev.)

§485.618(e) Standard: Coordination With Emergency Response Systems

The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

Interpretive Guidelines §485.618(e)

The CAH, not the local ambulance service, is responsible for ensuring that an effective procedure is in place to meet this requirement.

Survey Procedures §485.618(e)

- Verify that the CAH has policies and procedures in place to ensure an MD/DO is available by telephone or radio, on a 24-hour a day basis to receive emergency calls and provide medical direction in emergency situations?
- What evidence demonstrates that the procedures are followed and evaluated for effectiveness?
- Interview staff to see how an MD/DO is contacted when emergency instructions are needed.

C-0900
(Rev.)

§485.620 Condition of Participation: Number of Beds and Length of Stay

C-0902
(Rev.)

§485.620(a) Standard: Number of Beds

Except as permitted for CAHs having distinct part units under §485.647, the CAH maintains no more than 25 inpatient beds. Inpatient beds may be used for either inpatient or swing-bed services.

Interpretive Guidelines §485.620(a)

Section 1820(c)(2)(B)(iii) of the Social Security Act limits a CAH to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to provide inpatient acute care limited, on an annual average basis, to 96 hours per patient (see interpretive guidelines for §485.620(b)).

Section 1820(c)(2)(E) of the Act also permits a CAH to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU, without counting these beds toward the 25-bed inpatient limit.

The limit applies to the number of inpatient beds; not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds. Any bed used for inpatient services at any time must be counted when assessing compliance with the 25 inpatient bed limit. Beds used for outpatient services, such as observation services, sleep studies, emergency services, etc. do not count towards the CAH's 25-bed limit only if they are never used for inpatient services.

Beds Used for Observation Services

Beds used solely for patients receiving observation services are not included in the 25-bed maximum, nor in the calculation of the average annual acute care patient length of stay. This makes it essential for surveyors to determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits.

Inappropriate use of observation services also subjects Medicare beneficiaries to an increased beneficiary coinsurance liability that could have been avoided, had the beneficiary been properly admitted as an inpatient. This is the case because, as CAHs are

not paid under the hospital Outpatient Prospective Payment System (OPPS), the beneficiary in an observation status will be liable for a coinsurance charge equal to 20 percent of the CAH's customary charges for the services. Further, as CAHs are also not subject to the preadmission payment window, a Medicare beneficiary would be liable for the coinsurance charges for the observation status services even when subsequently admitted. Depending on the terms of their health insurance coverage, other CAH patients may also face similar increased and avoidable costs when inappropriately placed in an observation status.

Observation care is a well-defined set of specific, clinically appropriate services that include ongoing short-term treatment, assessment, and reassessment, that are provided before a decision can be made regarding whether a patient will require further treatment as an inpatient, or may be safely discharged. Observation status is commonly assigned to patients with unexpectedly prolonged recovery after outpatient surgery, and to patients who present to the emergency department and who then require a significant period of treatment or monitoring before a clinical decision is made concerning their next placement. The CAH should ensure that once there is sufficient information to render this clinical decision, the patient should be expeditiously admitted, appropriately transferred, or discharged.

A patient may be in an observation status even though the CAH furnishes the patient overnight accommodation, food, and nursing care.

Observation services are **NOT** appropriate:

- As a substitute for an inpatient admission;
- For continuous monitoring;
- For medically stable patients who need diagnostic testing or outpatient procedures (e.g., blood transfusion, chemotherapy, dialysis) that are routinely provided in an outpatient setting;
- For patients awaiting nursing home placement;
- To be used as a convenience to the patient, his or her family, the CAH, or the CAH's staff;
- For routine prep or recovery prior to or following diagnostic or surgical services; or
- As a routine "stop" between the emergency department and an inpatient admission.

Observation services **BEGIN** and **END** with an order by a physician or other qualified licensed practitioner of the CAH.

- The order for observation services must be written prior to initiation of the service, as

documented by a dated and timed order in the patient's medical record. The order may not be backdated. Orders should be clear for the level of care intended, such as "admit to inpatient" or "place in observation." (**NOTE:** It is not uncommon for hospitals and practitioners to refer to "admitting" a patient for observation. Technically, only inpatients are "admitted," while patients receiving observation services are in an outpatient status. However, usage of the term "admit" in an order placing a patient in observation status does not violate any CAH CoP and is not cited.)

- Observation services end when the physician or other qualified licensed practitioner orders an inpatient admission, a transfer to another health care facility, or discharge. The inpatient stay begins on the date and time of the new order.
- Standing orders for observation services are not acceptable, since it is not necessary to employ observation services for every patient in a given category, e.g., every emergency department patient, in order to reach a clinical decision about the appropriate next step in the patient's care.

Medicare generally will not pay for observation services lasting more than 48 hours. However, some States may have more stringent limits in their licensure or other regulatory requirements on the length of observation services, e.g., 24 hours. In such cases the State's more stringent limit on the length of an observation stay applies to Medicare beneficiaries as well, but is not enforced through the Federal survey process, unless the State has taken a final enforcement action.

The CAHs must provide appropriate documentation upon surveyor request to show that an observation bed is not an inpatient bed. The CAH must be able to document that it has specific clinical criteria for placing a patient in and discharging from, the observation service, and that these criteria are clearly distinguishable from those used for inpatient admission and discharge. CMS expects a CAH to employ the same type of clinical criteria for observation versus inpatient status for all patients, regardless of their payer status. For example, if a CAH were routinely placing only Medicare beneficiaries in its dedicated observation unit, then this could suggest that non-clinical criteria were being used in the decision to admit versus place in observation status. This would not only call the observation bed status into question, but could also violate the CAH's provider agreement requirement that prohibits differential treatment of Medicare beneficiaries. (See 42 CFR 489.53(a)(2)).

If a CAH maintains beds that are dedicated to observation services, the CAH must be able to provide evidence, such as the clinical criteria for admission to that unit and how patients in the unit meet those criteria, to demonstrate that its observation beds are not being used for inpatient services. CMS expects there to be a reasonable relationship between the size of the CAH's inpatient and observation operations. For example, a 10-bed observation unit in a 25-bed CAH might be disproportionately large, and the surveyor must determine whether the observation unit is actually functioning as an inpatient overflow unit. A CAH observation unit that routinely operates at a high occupancy rate could also be an indicator of the need to probe further.

Other Types of Beds

Other bed types that do not count toward the 25 inpatient bed limit include, but are not limited to:

- Examination or procedure tables;
- Stretchers;
- Operating room tables;
- Beds in a surgical recovery room used exclusively for surgical patients during recovery from anesthesia;
- Beds in an obstetric delivery room used exclusively for OB patients in labor or recovery after delivery of newborn infants;
- Newborn bassinets and isolettes used for well-baby boarders (**NOTE:** If the baby is being held for treatment at the CAH, his or her bassinet or isolette **does** count towards the CAHs 25-bed limit);
- Stretchers in emergency departments; and
- Inpatient beds in Medicare-certified distinct part rehabilitation or psychiatric units.

Beds Used for Hospice Services

A CAH can dedicate beds to a hospice under arrangement, but the beds must count as part of the maximum bed count. The computation contributing to the 96 hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

Survey Procedures §485.620(a)

- Count the number of inpatient beds the CAH maintains, excluding any DPU beds.
- Ask the CAH how frequently it uses observation services, and for its policies and procedures governing use of observation services.
- Verify that patients are never pre-registered for observation services; there should be

no scheduled observation stays.

- Check to see if the CAH has specific clinical criteria for placement in and discharge from observation status, and that these clinical criteria are clearly distinguishable from those used for inpatient admission and discharge.
- If there is a separate unit of observation beds, ask the CAH for evidence of how its criteria for placement in the observation unit differ from admission criteria for an inpatient bed. Count the number of beds in the observation unit and compare them to the number of inpatient beds. The higher the proportion of observation beds, the greater is the CAH's burden to prove these are not being used as inpatient beds. Ask for the occupancy rates for the observation unit; the higher the occupancy rate, particularly if there are more than a couple of beds, the greater is the CAH's burden to prove these are not being used as inpatient beds.
- Review the medical records for patients who are in observation status at the time of survey. Verify that the medical record includes an order to place the patient in observation status, including the clinical reason for observation, e.g., as "Place patient in observation to rule out possible myocardial infarction (MI)."
- Select a sample of closed medical records for patients who were in an observation status. Verify that the medical record includes an order to place the patient in observation status, as well as a later order to admit, discharge, or transfer the patient.
- Verify through medical record review that observation services are not ordered as a standing order following outpatient surgery or prior to admission from the emergency department.

C-0904
(Rev.)

§485.620(b) Standard: Length of Stay

The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

Interpretive Guidelines §485.620(b)

The Fiscal Intermediary (FI) will determine compliance with this CoP. The FI will calculate the CAH'S length of stay based on patient census data. If a CAH exceeds the length of stay limit, the FI will send a report to the CMS-RO as well as a copy of the report to the SA. The CAH will be required to develop and implement a plan of correction (POC) acceptable to the CMS Regional Office or provide adequate information to demonstrate compliance.

C-0910

(Rev.)

§485.623 Condition of Participation: Physical Plant and Environment

Interpretive Guidelines §485.623

This CoP applies to all locations of the CAH, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations.

The CAH'S departments or services responsible for the CAH'S building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH'S QA program and be in compliance with the QA requirements.

C-0912

(Rev.)

§485.623(a) Standard: Construction

The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

Interpretive Guidelines §485.623(a)

The CAH's physical facilities must be constructed, designed and maintained such that patients are always accessible and the safety of patients is assured. The CAH's construction must be in accordance with applicable Federal, State and local law, as determined by the authorities having jurisdiction to enforce such law.

The CAH's physical plant must provide sufficient space to support those services the CAH provides on-site. There must also be adequate space to support all additional services the CAH offers.

Survey Procedures §485.623(a)

- Verify through observation that the physical facilities are large enough for the scope of services the CAH is required to provide on-site, as well as any additional services it offers on-site or at a provider-based, off-site location. The adequacy of the space depends on both the nature of the services provided and the number of patients to whom the CAH typically provides those services.
- Verify through observation that the CAH's building(s) is/are maintained in a manner to ensure the safety and well being of patients (e.g., condition of ceilings, walls, and floors, presence of patient hazards, etc.).
- Verify through observation that the design of the CAH assures that staff can reach patients readily.

C-0914
(Rev.)

§485.623(b) Standard: Maintenance

The CAH has housekeeping and preventive maintenance programs to ensure that--

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

Interpretive Guidelines §485.623(b)(1)

In order to ensure all essential mechanical, electrical and patient-care equipment is maintained in safe operating condition, the CAH must identify the essential equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the CAH must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the CAH (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, electrical systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the CAH (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades. Equipment to be used for the first time should be inspected and tested for performance and safety in accordance with manufacturer recommendations, unless a sufficient amount of maintenance history has been acquired, either based on its contractor's records or available publicly from nationally recognized sources, to determine whether the alteration of initial inspection and testing activities and frequencies would be safe.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using CAH personnel, contracted services, or through a combination of CAH personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The CAH maintains records of CAH personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the CAH's clinical maintenance personnel, safety department personnel or other personnel

who have been assigned responsibility for equipment maintenance by CAH leadership.

CAHs comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. CAHs may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the CAH must maintain documentation of those recommendations and the CAH's associated maintenance activity for the affected equipment.

Alternate Equipment Management (AEM) Program

A CAH may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. CAHs that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the CAH associated with the use of facility or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance. An example of guidelines for a medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/ (R) 2013, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which CAHs might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are CAH employees or contractors. CAHs must be able to verify that qualified personnel, employees or contractors, are making the decisions to place equipment in the AEM program, performing the risk-based assessments, establishing the alternate equipment maintenance requirements, managing the AEM program, and performing the maintenance in accordance with the AEM policies and procedures.

In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (e.g., facility manager, director of facilities, vice president of facilities) would be considered

qualified.

The CAH must maintain records of the qualifications of CAH personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the CAH must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the CAH where it is used.

A CAH is expected to identify any equipment in its AEM program which is critical equipment, i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a CAH's AEM program on critical equipment in that program and the CAH's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a CAH to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

- How the equipment is used and the likely consequences of equipment failure or malfunction: would failure or malfunction of the equipment CAH-wide or in a particular setting be likely to cause harm to a patient or a staff person?
 - How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.
 - How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.
- Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale for the manufacturer's recommendations;
- Maintenance requirements of the equipment:
 - Are they simple or complex?
 - Are the manufacturer's instructions and procedures available in the CAH, and if so can the CAH explain how and why it is modifying the manufacturer's instructions?
 - If the manufacturer's instructions are not available in the CAH, how does the

- CAH assess whether the AEM uses appropriate maintenance strategies?
- How readily can the CAH validate the effectiveness of AEM methods for particular equipment? For example, can the CAH explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?
 - The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and
 - Incident history of identical or very similar equipment – is there documented evidence, based on the experience of the CAH (or its third party contractor), or on evidence publicly reported by credible sources outside the CAH, which:
 - Provides the number, frequency and nature of previous failures and service requests?
 - Indicates use of an AEM strategy does not result in degraded performance of the equipment?

Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The CAH is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.

Equipment not Eligible for Placement in the AEM Program:

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

- Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements. In these instances, the CAH must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the CAH Conditions of Participation (CoPs).
- Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:
 - The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 485.623(d) have provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §485.623(d)(7)(v) requires CAHs to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is

assessed on Federal surveys.

- Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, must be maintained per manufacturer's recommendations.
- The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.
- New equipment for which sufficient maintenance history, either based on the CAH's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination must not be immediately included in the AEM program. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a CAH later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the CAH must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A CAH may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.

In developing AEM maintenance strategies, CAHs may rely upon information from a variety of sources, including, but not limited to: manufacturer recommendations and other materials, nationally recognized expert associations, and/or the CAH's (or its third party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The CAH is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

- **Preventive Maintenance (Time-based Maintenance)** – a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance.

Most preventive maintenance is “interval-based maintenance” performed at fixed time intervals (e.g., annual or semi-annual), but may also be “metered maintenance” performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.

- **Predictive Maintenance (Condition-based Maintenance)** – a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer’s recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.
- **Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance)** – a maintenance strategy based upon a “run it until it breaks” philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.
- **Reliability-Centered Maintenance** – a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation

indicating:

- The pertinent types and level of risks to patient or staff health and safety;
- Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the CAH is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;
- Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 – 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.
- The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and
- Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual. (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the CAH's required tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)

When the CAH has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The CAH must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program, the CAH is expected to address factors including, but not limited to:

- How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment, e.g., miscalibration.
- How incidents of equipment malfunction are investigated, including:
 - whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and

- how a determination is made whether or not the malfunction resulted from the use of an AEM strategy;
- The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and
- The use of performance data to determine if modifications in the AEM program procedures are required.

Equipment Inventory

All CAH facility and medical equipment essential to the operation of the CAH, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk essential equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the CAH, e.g., “15 vacuum cleaners for cleaning patient rooms and common areas.”

If the CAH is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, CAHs have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.

- A unique identification number;
- The equipment manufacturer;
- The equipment model number;
- The equipment serial number;
- A description of the equipment;
- The location of the equipment (for equipment generally kept in a fixed location);
- The identity of the department considered to “own” the equipment;
- Identification of the service provider;
- The acceptance date; and

- Any additional information the CAH believes may be useful for proper management of the equipment.

Survey Procedures §485.623(b)(1)

Interview personnel in charge of equipment maintenance:

- Determine if the CAH has identified equipment that is essential for both regular operations and in an emergency situation.
- Determine if the CAH has made adequate provisions to ensure the availability of those and equipment when needed.

Concerning facility and medical equipment:

- Interview equipment users when surveying the various units/departments of the CAH to determine if equipment failures are occurring and causing problems for patient health or safety.
- Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.
 - Is critical equipment readily identified?
 - If the CAH employs an AEM program, is equipment in this program readily identified?
- Determine if the CAH has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of CAH personnel responsible for the AEM program (if one is being used by the CAH) as well as for those performing maintenance.
- Determine if the CAH is able to demonstrate how it assures contractors use qualified personnel.

If the CAH is following the manufacturer-recommended equipment maintenance activities and frequencies:

In addition to reviewing maintenance records on equipment observed while inspecting various CAH locations for multiple compliance assessment purposes, select a sample of equipment from the CAH's equipment inventory to determine whether the CAH is following the manufacturer's recommendations. Critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. should make up the sample majority.

For the sample selected, determine if:

- The CAH has available manufacturer's recommendations (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.);
- Maintenance is being performed in accordance with manufacturer's recommendations

If a CAH is using an AEM for some equipment:

- Does the CAH's inventory include equipment which is not eligible for AEM, for example, any diagnostic imaging or therapeutic radiologic equipment?
- Determine if the CAH's development of alternate maintenance activities and frequencies for equipment in the AEM program as well as AEM activities are being performed by qualified personnel.
- Verify the CAH has documented maintenance activities and frequencies for all equipment included in the AEM program;
- Verify the CAH is evaluating the safety and effectiveness of the AEM program.
- If there is equipment on the inventory the CAH has identified as having such a very low level of risk that it has determined it can use a broad interval range or departmental "sweeps," ask the CAH for the evidence used to make this determination. Does it seem reasonable?

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. For the sample selected:

- Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?
- Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?
- Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.

Verify the CAH is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.

C-0920
(Rev.)

§485.623(b)(2) There is proper routine storage and prompt disposal of trash;

Interpretive Guidelines §485.623(b)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(b)(2)

Survey Procedures are pending and will be updated in future release.

C-0922
(Rev.)

§485.623(b)(3) Drugs and biologicals are appropriately stored;

Survey Procedures §485.623(b)(3)

What standards, guidelines, State and Federal law is the CAH following to ensure that drugs and biologicals are appropriately stored (e.g., properly locked) in all storage areas?

C-0924
(Rev.)

§485.623(b)(4) The premises are clean and orderly; and

Interpretive Guidelines §485.623(b)(4)

“**Clean and orderly**” means an uncluttered physical environment where patients and staff can function safely. Equipment and supplies are stored in proper spaces, not in corridors. Spills are not left unattended. There are no floor obstructions. The area is neat and well kept. There is no evidence of peeling paint, visible water leaks, or plumbing problems.

C-0926
(Rev.)

§485.623(b)(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

Interpretive Guidelines §485.623(b)(5)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(b)(5)

Survey Procedures are pending and will be updated in future release.

C-0930

(Rev.)

§485.623(c) Standard: Life Safety From Fire

(1) Except as otherwise provided in this section,

- (i) the CAH must meet the applicable provisions *and must proceed in accordance with* the Life Safety Code (*NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.*)**
- (ii) *Notwithstanding paragraph (d)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.***

Interpretive Guidelines §485.623(c)(1)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(1)

Survey procedures are pending and will be updated in future release.

C-0932

(Rev.)

§485.623(c)(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §485.623(c)(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(3)

Survey procedures are pending and will be updated in future release.

C-0934

(Rev.)

§485.623(c)(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

Interpretive Guidelines §485.623(c)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(4)

Survey procedures are pending and will be updated in future release.

C-0936

(Rev.)

§485.623(c)(5) A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

Interpretive Guidelines §485.623(c)(5)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(5)

Survey Procedures are pending and will be updated in future release.

C-0938

(Rev.)

§485.623(c)(6) When a sprinkler system is shut down for more than 10 hours, the CAH must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

Interpretive Guidelines §485.623(c)(6)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(6)

Survey Procedures are pending and will be updated in future release.

C-0940
(Rev.)

§485.623(c)(7) *Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.*

(i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.

(ii) Special nursing care areas of new occupancies shall not exceed 60 inches.

Interpretive Guidelines §485.623(c)(7)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(7)

Survey Procedures are pending and will be updated in future release.

C-0942
(Rev.)

§485.623(c)(2) *In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a CAH, but only if the waiver will not adversely affect the health and safety of the patients.*

Interpretive Guidelines §485.623(c)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(2)

Survey Procedures are pending and will be updated in future release.

C-0944
(Rev.)

§485.623(d) Standard: Building safety. *Except as otherwise provided in this section, the CAH must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).*

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a CAH.

(2) If application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for the CAH, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guidelines §485.623(d)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(d)

Survey Procedures are pending and will be updated in future release.

Please refer to Appendix Z of the State Operations Manual to cite the specific Emergency Preparedness E-Tags, interpretive guidelines, and survey procedures.

C-0950

(Rev.)

§485.625 Condition of Participation: Emergency Preparedness

The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) Emergency plan. The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) Policies and procedures. The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to—

(i) Food, water, medical, and pharmaceutical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the CAH's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the CAH must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to CAH patients.

(8) The role of the CAH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The CAH must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CAHs and hospitals.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CAH's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CAH's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CAH's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The CAH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) Training program. The CAH must do all of the following:

(i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of the training.

(iii) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.

(2) Testing. The CAH must conduct exercises to test the emergency plan at least twice per year. The CAH must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or,

(B) If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from

engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an annual additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

(e) Emergency and standby power systems. The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) Emergency generator location. The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) Emergency generator inspection and testing. The CAH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) Emergency generator fuel. CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) Integrated healthcare systems. If a CAH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the CAH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include—

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__location.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11,

2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

C-0960

(Rev.)

§485.627 Condition of Participation: Organizational Structure

C-0962

(Rev.)

§485.627(a) Standard: Governing Body or Responsible Individual

The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH'S total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

Interpretive Guidelines §485.627(a)

The CAH must have only one governing body (or responsible individual) and this governing body (or responsible individual) is responsible for the conduct of the CAH as

an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations.

The governing body (or responsible individual) must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

It is the responsibility of the governing body (or responsible individual) to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering medical staff recommendations, and in accordance with established CAH medical staff criteria and State and Federal laws and regulations, the governing body (or responsible individual) decides whether or not to appoint new medical staff members or to continue current members of the medical staff.

The governing body (or responsible individual) must ensure that the medical staff has bylaws that comply with State and Federal law and the requirements of the CAH CoP.

The governing body (or responsible individual) decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body (or responsible individual) before they are considered effective.

The governing body (or responsible individual) must ensure that the medical staff is accountable to the governing body (or responsible individual) for the quality of care provided to patients. The governing body (or responsible individual) is responsible for the conduct of the CAH and this conduct would include the quality of care provided to patients.

All CAH patients must be under the care of a member of the medical staff or under the care of a practitioner who is under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner granted privileges to provide or order that care and is in accordance with State law.

Criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on:

- Individual character;
- Individual competence;
- Individual training;
- Individual experience; and
- Individual judgment

Survey Procedures §485.627(a)

- Verify that the CAH has an organized governing body or has written documentation that identifies the individual that is responsible for the conduct of the CAH operations.
- Review documentation and verify that the governing body (or responsible individual) has determined and stated the categories of practitioners that are eligible candidates for appointment to the medical staff.
- Have the facility's operating policies been updated to fully reflect its responsibilities as a CAH (e.g., PA responsibilities, provision of required CAH direct services)?
- What evidence (e.g., minutes of board meetings) demonstrates that the governing body or the individual who assumes responsibility for CAH operation is involved in the day-to-day operation of the CAH and is fully responsible for its operations?
- Evaluate records of medical staff appointments to substantiate the governing body's (or responsible individual's) involvement in appointments of medical staff members.
- Confirm that the governing body (or responsible individual) appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.
- Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations.
- Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body (or responsible individual).
- Verify that any revisions or modifications in the medical staff bylaws, rules, and policies, have been approved by the medical staff and the governing body (or responsible individual). For example, look at the bylaws and check for date of last review and initials by the person(s) responsible.
- Verify that the governing body (or responsible individual) is periodically apprised of the medical staff evaluation of patient care services provided in the CAH, at every patient care location of the CAH.
- Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the

- governing body (or responsible individual) for the quality of services provided.
- Verify that there are written criteria for staff appointments to the medical staff.
 - Verify that selection of medical staff for membership, both new and renewal, is based upon an individual practitioner's compliance with the medical staff's membership criteria.
 - Verify that at a minimum, criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

C-0964
(Rev.)

§485.627(b) Standard: Disclosure

§485.627(b)(1) The person principally responsible for the operation of the CAH; and

Survey Procedures §485.627(b)(1)

How does the CAH implement its policy or procedure for reporting changes in operating officials to the State agency?

C-0966
(Rev.)

§485.627(b)(2) The person responsible for medical direction

Survey Procedures §485.627(b)(2)

How does the CAH implement its policy or procedure for reporting changes in medical director to the State agency?

C-0970
(Rev.)

§485.631 Condition of Participation: Staffing and Staff Responsibilities

C-0971
(Rev.)

§485.631(a) Standard: Staffing

(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

Interpretive Guidelines §485.631(a)(1)

A CAH may operate with a MD/DO on staff as well as with any combination of mid-level practitioners.

Survey Procedures §485.631(a)(1)

- Review listings or organizational charts showing the names of all staff MD/DOs, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff.
- Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.

C-0972

(Rev.)

§485.631(a)(2) Any ancillary personnel are supervised by the professional staff.

Survey Procedures §485.631(a)(2)

Use organizational charts and staff interviews to determine how the CAH ensures that the professional staff supervises all ancillary personnel.

C-0974

(Rev.)

§485.631(a)(3) The staff is sufficient to provide the services essential to the operation of the CAH.

Survey Procedures §485.631(a)(3)

- How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services, direct services, and nursing services)?
- Review staffing schedules and daily census records.

C-0976

(Rev.)

§485.631(a)(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

Interpretive Guidelines §485.631(a)(4)

Section 485.635(b)(1) requires CAHs to provide “those diagnostic and therapeutic services and supplies that are commonly furnished in “a physician’s office” such as low intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation. This requirement does not mean the CAH must have a practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients.

Survey Procedures §485.631(a)(4)

- If the CAH does not have regular announced hours of operation, ask the individual who is principally responsible for the operation of the CAH, when is the CAH is open to the public to provide outpatient services.
- What kinds of arrangements have been made by the CAH to ensure that a practitioner is available on site at all times the CAH operates to furnish patient care services?

C-0978 ***(Rev.)***

§485.631(a)(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

Survey Procedures §485.631(a)(5)

Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

C-0980 ***(Rev.)***

§485.631(b) Standard: Responsibilities of the Doctor of Medicine or Osteopathy

C-0981 ***(Rev.)***

485.631(b)(1) The doctor of medicine or osteopathy--

- (i) Provides medical direction for the CAH’S health care activities and consultation for, and medical supervision of, the health care staff;**

Interpretive Guidelines §485.631(b)(1)(i)

A CAH must have a MD/DO on its staff. That individual must perform all of the medical oversight functions.

Survey Procedures §485.631(b)(1)(i)

What evidence demonstrates that an MD/DO provides medical direction for the CAH'S health care activities and is available for consultation and supervision of the CAH health care staff?

C-0982
(Rev.)

§485.631(b)(1)(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH'S written policies governing the services it furnishes.

Survey Procedures §485.631(b)(1)(ii)

- What evidence demonstrates that an MD/DO has participated in the development of policies governing CAH services?
- How does the CAH ensure that an MD/DO periodically reviews these policies?

C-0984
(Rev.)

§485.631(b)(1)(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH'S patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

Survey Procedures §485.631(b)(1)(iii)

- How does the CAH ensure that an MD/DO periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides medical care to CAH patients?
- What evidence demonstrates that there is a periodic review of patient records by the CAH MD/DO(s)?

C-0986
(Rev.)

§485.631(b)(1)

[The doctor of medicine or osteopathy-]

(iv) Periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(v) Periodically reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician.

Interpretive Guidelines §485.631(b)(1)(iv) & (v)

All inpatient records for patients whose treatment is/was managed by a nonphysician practitioner in the CAH, i.e., nurse practitioners, clinical nurse specialists, or physician assistants, must be reviewed periodically by a CAH MD/DO who must sign the records after the review has been completed. The MD/DO review is expected to cover all applicable inpatient records open at the time of the review, as well as all applicable inpatient records closed since the last review.

In the case of inpatients whose care is/was managed by an MD/DO, as evidenced by an admission order, progress notes, and/or medical orders, etc., but who also receive services from a non-physician practitioner, a subsequent MD/DO review of the inpatient record is not required.

In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, i.e., a nurse practitioner, a clinical nurse specialist, a certified nurse midwife, or a physician assistant, a CAH MD/DO must review and sign a sample of outpatient records. The outpatient medical record sample reviewed must be representative of all non-physician practitioners providing care to patients of the CAH. The CAH determines by policy the size of the sample reviewed and signed; however, CMS recommends, but does not require, a sample size of 25% of the records of all outpatient encounters managed by a non-physician practitioner since the prior MD/DO review. If State law requires MD/DO review or signature of a larger percentage of the outpatient records, the CAH must comply with State law.

In States where no physician record review or physician co-signature is required for patients managed by a non-physician practitioner, an MD/DO is not required to review or sign outpatient records of such patients.

Neither the regulation nor the preamble to the final rule adopting this regulation (79 Fed. Reg. 27105, May 12, 2014) specify a particular timeframe to satisfy the requirement for “periodic” review, but the CAH must specify a maximum interval between inpatient record reviews in its policies and procedures. The CAH is expected to take into account the volume and types of services it offers in developing its policy. For example, a CAH that has only four certified beds and one MD/DO on staff and which does not always

have an inpatient in house would likely establish a different requirement for inpatient record review than a CAH with 25 certified beds, multiple MDs/DOs on staff and a high inpatient occupancy rate. Further, there is no regulatory requirement for the review of records to be performed on site and in person. Thus, if the CAH has electronic medical records that can be accessed and digitally signed remotely by the MD or DO, this method of review is acceptable. Therefore, CAHs with and without the capability for electronic record review and signature might also develop different policies for the maximum interval between reviews.

Survey Procedures §485.631(b)(1)(iv) & (v)

Select a sample of inpatient and outpatient records, including both open and closed records.

- For inpatient records of patients whose care is/was managed by a non-physician practitioner, verify that:
 - An MD/DO has reviewed and signed all records that were open at the time of the review, and all inpatient records that were closed since the MD/DO's last review; and
 - That reviews take place within the timeframe specified by the CAH's policy.
 - If State law requires a physician to review or co-sign (or both) any outpatient records of patients whose care is/was managed by non-physician practitioner, determine whether an MD or DO has reviewed and/or co-signed a representative sample of these records within the timeframe specified in the CAH's policies.
 - Ask the CAH how many outpatient encounters are managed by non-physician practitioners, what sample size its policy requires to have an MD/DO review, and what timeframe its policy specifies for reviews.
 - Ask the CAH to explain how it ensures the sample is representative of the various non-physician practitioners as well as of the various types of outpatient services they provide.
 - Ask the CAH to describe the method it uses to make sure that reviews are performed in a timely manner on a sample that complies with the CAH's policy.
 - Review selected records from the CAH's outpatient sample to verify that there is evidence of an MD or DO review and/or signature.

C-0988
(Rev.)

§485.631(b)(2) A doctor of medicine or osteopathy is present for sufficient periods of

time to provide medical direction, consultation, and supervision for the services provided in the CAH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

Interpretive Guidelines §485.631(b)(2)

An MD/DO must be present in the CAH for sufficient periods of time to provide overall medical direction, consultation and supervision of the healthcare services the CAH furnishes. Being “present” in the CAH means being physically on-site in the CAH. The regulation does not specify a minimum amount of time an MD/DO must spend on-site that applies to all CAHs. Instead, CAHs have the flexibility to develop policies appropriate for their circumstances. With the development of technology such as telemedicine, a CAH may use a variety of ways and timeframes for MDs/DOs to provide the necessary medical direction and oversight. For CAHs that offer a range of more complex services, have more than one MD/DO on staff, and have busy emergency departments and/or extensive outpatient services, an on-site visit by an MD/DO only once every week or every two weeks, for example, would be grossly inadequate. On the other hand, a bi-weekly on-site visit could be unduly burdensome as well as unnecessary for a small CAH in a remote rural area that offers very limited services and has a low patient volume.

CAHs are expected to have adequate staffing to provide the services they have chosen to furnish, including staffing or supervision by MDs/DOs as applicable. CMS expects each CAH to evaluate its services and adjust its MD/DO on-site schedule accordingly, as an appropriate MD/DO schedule must reflect the volume and nature of services offered.

Note that §485.618(d) also establishes a maximum timeframe for an MD, DO, PA, NP, or clinical nurse specialist to be on-call and available to be on-site to provide emergency care, and that §489.20(r)(2) requires the CAH to maintain an on-call list of MDs/DOs who are available to be on-site as part of the CAH’s Emergency Medical Treatment and Labor Act obligations. The CAH must consider all pertinent requirements when developing its policies for MD/DO presence on site.

In addition to requiring an MD or DO to be on-site for sufficient periods of time, consistent with the requirement at §485.618(e), the CAH must also ensure an MD/DO is available through direct radio, telephone or other form of electronic communication, such as video conferencing, for consultation, assistance in handling patient medical emergencies and referral of patients to other healthcare facilities. An MD/DO providing telemedicine services to the CAH may be used to fulfill the requirement for availability via telecommunications. Further, consistent with the requirements for CAH provision of emergency services at §485.618(d), unless a PA, NP, or clinical nurse specialist with training in emergency care is immediately available via one of these telecommunication methods and available on site within the timeframe specified at §485.618(d)(1), an MD or DO must fulfill these requirements.

Survey Procedures §485.631(b)(2)

- Does the CAH have policies and procedures that address the minimum amount of time and frequency of MD or DO presence on-site at the CAH? Can the CAH demonstrate how its policy reflects the volume and type of services the CAH provides such that there is sufficient MD/DO presence on-site to support the services provided?
- Is there documentation showing that an MD or DO is on-site for the frequency and duration specified in the CAH's policies?
- Can the CAH demonstrate that an MD or DO is always available by telecommunications contact for consultation, assistance and/or patient referral?

C-0990

(Rev.)

§485.631(c) Standard: Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist Responsibilities

C-0991

(Rev.)

§485.631(c)(1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH'S staff--

- (i) **Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and**

Survey Procedures §485.631(c)(1)(i)

- Interview any mid-level professional staff to ascertain their level of involvement in CAH policy development, execution, and periodic review.
- Does the CAH ensure that policies are updated to remain consistent with State standards of practice requirements for mid-level practitioners?

C-0993

(Rev.)

485.631(c)(1)(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

Survey Procedures §485.631(c)(1)(ii)

How does the CAH ensure that mid-level practitioners at the CAH participate with an MD/DO in the review of their patients' health records?

C-0995
(Rev.)

§485.631(c)(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH'S policies.

Survey Procedures §485.631(c)(2)(i)

- Review policies and procedures.
- Interview mid-level practitioners to gauge their knowledge and application of CAH policies.

C-0997
(Rev.)

§485.631(c)(2)(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

Survey Procedures §485.631(c)(2)(ii)

Verify that there are policies and procedures for transferring patients to other facilities.

C-0998
(Rev.)

§485.631(c)(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

Interpretive Guidelines §485.631(c)(3)

The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as

allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

Survey Procedures §485.631(c)(3)

- Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.
- Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body (or responsible individual) in accordance with State laws and medical staff bylaws.
- Verify that an MD/DO is responsible for and is monitoring the care of each Medicare or Medicaid patient for all medical problems during the hospitalization.
- If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.

C-0999
(Rev.)

§485.631(d) Standard: Periodic review of clinical privileges and performance. The CAH requires that—

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialist, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

(i) One hospital that is a member of the network, when applicable;

(ii) One Quality Improvement Organization (QIO) or equivalent entity;

(iii) One other appropriate and qualified entity identified in the State rural health care plan;

(iv) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patient under an agreement between the CAH and a distant-site hospital, the distant-site hospital; or

(v) In the case of distant-site physicians and practitioners providing telemedicine

services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (d)(2)(i) through (iii) of this section.

(3) The CAH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

Interpretive Guidelines §485.631(d)(1),(2)(i)(ii)(iii)(iv)(v),(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.631(d)(1),(2)(i)(ii)(iii)(iv)(v),(3)

Survey Procedures are pending and will be updated in future release.

C-1004

(Rev.)

§485.635 Condition of Participation: Provision of Services

Interpretive Guidelines §485.635

This condition establishes requirements related to patient care policies, required CAH services, and CAH services provided through agreements or arrangements. Assessment of the manner and degree of noncompliance with any one of the following standards in this condition is required in order to determine whether there is noncompliance with this condition.

C-1006

(Rev.)

§485.635(a) Standard: Patient Care Policies

(1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

Interpretive Guidelines §485.635(a)(1)

The CAH must have written policies governing the health care services the CAH furnishes and these policies must be consistent with applicable State law. As discussed in relation to the requirements at §485.608, CMS does not interpret or enforce local law; that is the responsibility of State or local government. If surveyors identify practices related to delivery of health care services that they believe are not consistent with State law, they should refer the matter to the appropriate State authorities.

The regulation requires the CAH to furnish its health care services in accordance with its

written policies. In other words, the CAH must not only have written policies, but must actually adhere to them in delivering services.

Survey Procedures §485.635(a)(1)

- Verify that the CAH has written policies covering the health care services that are furnished in the CAH.
- Observe staff delivering health care services to patients. Is the actual provision of services consistent with the CAH's written policies?

C-1008 ***(Rev.)***

§485.635(a)(2) The policies are developed with the advice of members of the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1).

§485.635(a)(4) These policies are reviewed at least *biennially* by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

Interpretive Guidelines §485.635(a)(2) & (4)

The CAH's written policies governing patient care services must be developed with the advice of members of the CAH's professional healthcare staff. This advisory group must include:

- At least one MD or DO; and
- One or more physician assistants, nurse practitioners, or clinical nurse specialists, at least one of these non-physician practitioners if these professionals are included in the CAH's healthcare staff, as permitted at §485.631(a)(1). A CAH with no non-physician practitioners on staff is not required to obtain the services of an outside non-physician practitioner to serve on the advisory group.

The advisory group not only makes recommendations for new CAH patient care policies, but is also expected to review the existing patient care policies at least *every 2 years* and, if it concludes that changes are needed, recommend those changes. Policies must be reviewed and, as applicable, revised more frequently when required, for example, in response to a change in Federal or State regulations to which the CAH is subject.

The CAH must maintain documentation that provides evidence that the advisory group has conducted its reviews and made recommendations concerning patient care policies. Although a CAH's patient care policies are developed and periodically reviewed with the advice of members of the CAH's professional healthcare staff, the final decision on the

content of the written policies is made by the CAH's governing body or individual responsible for the CAH, consistent with the requirement at §485.627(a). If recommendations of the advisory group are rejected, the governing body must include in the record of its adoption of the final written policies its rationale for adopting a different policy than that which was recommended.

Survey Procedures §485.635(a)(2) & (4)

- Review any meeting minutes for the group of healthcare professionals that advises the CAH's governing body or responsible individual on patient care policies to determine if the group's composition meets the regulatory requirements.
- Interview all staff listed as part of the policy development advisory group to determine if they had the opportunity to express opinions and make recommendations to the group, for the group's consideration as a group recommendation.
- Can the CAH provide documentation that the advisory group developed written recommendations on the CAH's patient care policies for consideration by the CAH's governing body/responsible individual?
- Is there evidence that the group reviewed the CAH's existing policies at least *every 2 years* and indicated whether or not it recommended any changes?

C-1010 ***(Rev.)***

§485.635(a)(3) The policies include the following:

(i) A description of the services the CAH furnishes, including those furnished through agreement or arrangement.

Interpretive Guidelines §485.635(a)(3)(i)

The CAH's written patient care policies must describe the types of health care services that are available at the CAH, including whether those services are furnished by CAH staff or through agreements or arrangements. The types of health services described must include services provided both on-site and off-site.

Healthcare services provided through agreement or under arrangement include those provided through formal contracts, informal agreements, or lease arrangements. Services furnished under arrangement or by agreement may include both healthcare services provided on-site at the CAH by a contractor, as well as healthcare services provided to the CAH's patients outside the CAH. For example, the CAH may contract with a laboratory to provide certain laboratory services on-site, and others at an off-site laboratory; or it may contract with an imaging center for provision of certain advanced radiologic diagnostic services, such as MRI, to CAH inpatients who are temporarily moved to the center for the test and then returned to the CAH.

The descriptions of the services provided may be brief but informative, for example, statements like “taking complete medical histories, providing complete physical examinations, laboratory tests including” (with a list of tests provided), radiologic tests and their interpretation, surgery (with a list of the types of surgery available) would satisfy this requirement.

Survey Procedures §485.635(a)(3)(i)

Verify that the CAH’s healthcare policies identify and describe all healthcare services offered by the CAH, including services provided under arrangement or by agreement.

C-1012
(Rev.)

§485.635(a)(3) [The policies include the following:]

(ii) Policies and procedures for emergency medical services.

Interpretive Guidelines §485.635(a)(3)(ii)

The CAH’s written patient care policies must include its policies and procedures for providing emergency services, addressing all of the requirements at 42 CFR 485.618. See the interpretive guidelines for §485.618.

Survey Procedures §485.635(a)(3)(ii)

Verify that written policies and procedures detail how the CAH plans to comply with the requirements of 42 CFR 485.618. Do the written policies and procedures address the following:

- How the CAH provides 24 hour emergency care to its patients?
- What equipment, supplies, medications, blood and blood products are maintained onsite and which are readily available for treating emergency cases by agreement at other facilities?
- What types of personnel are available to provide emergency services and what are their required onsite response times?

Do they address how the CAH coordinates with local emergency response systems?

C-1014
(Rev.)

§485.635(a)(3) [The policies include the following:]

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

Interpretive Guidelines §485.635(a)(3)(iii)

The written policies for the CAH's healthcare services must include guidelines, such as general instructions and protocols, for the medical management of patients' health problems. The guidelines may include directly or reference protocols that are documented elsewhere for the treatment of medical conditions that are commonly presented in the CAH.

Because nurse practitioners, clinical nurse specialists, and physician assistants may play a large role in patient care at a CAH, the CAH's policies must address the circumstances under which consultation with an MD or DO should occur and which situations require them to consult with or refer to an MD/DO for advice on how to treat a patient. The CAH's policies must also address the circumstances under which patient referral outside the CAH should occur.

The policies must also address maintenance of medical records, consistent with the requirements at §485.638. See interpretive guidelines for §485.638.

The policies must also address the CAH's procedures for periodical review and evaluation of its services, consistent with the requirements of §485.641. See interpretive guidelines for §485.641.

Survey Procedures §485.635(a)(3)(iii)

Verify that the CAH's written patient care policies:

- Address the circumstances under which consultation with other CAH professional healthcare staff, or referral outside the CAH should occur;
- Address maintenance of medical records, in a manner consistent with the requirements at §485.638; and
- Address periodic evaluation of the CAH's healthcare services, in a manner consistent with the requirements at §485.641.

C-1016
(Rev.)

§485.635(a)(3) [The policies include the following:]

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

Interpretive Guidelines §485.635(a)(3)(iv)

The CAH must ensure that drugs and biologicals are managed in a manner that is safe and appropriate, and that its pharmacy system provides all drugs and biologicals prescribed by the CAH's practitioners in a timely manner for administration to its patients.

The CAH's written patient care policies must include rules governing pharmacy services within the CAH. The CAH's rules may be in the form of pharmacy services policies and procedures. These CAH rules must address storage, handling, dispensing, and administration of drugs and biologicals within the CAH. The rules must be in accordance with accepted professional principles of pharmacy and medication administration practices. Accepted professional principles include compliance with applicable Federal and State law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (www.usp.org), the American Society of Health-System Pharmacists (<http://www.ashp.org/>), the Institute for Safe Medication Practices (<http://www.ismp.org/default.asp>), the National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (<http://www.ihl.org/ihl>); or the Infusion Nurses Society (<http://www.insl.org>).

The CAH's rules must address the following:

- **Responsibility for pharmacy services**

The CAH must identify the qualifications for and designate an individual who has overall responsibility for the CAH's pharmacy services, including development of the rules governing pharmacy services. The CAH and the responsible individual must ensure adherence to State law requirements governing who may perform pharmacy services as well as requirements for supervision of pharmacy staff. The CAH and responsible individual are also responsible for assuring that pharmacy practices adhere to accepted professional principles. The CAH is expected to be able to identify the sources of accepted professional pharmacy practices that it relies upon in developing the CAH's pharmacy rules, policies and procedures.

- **Storage of drugs and biologicals, including the location of storage areas, medication carts, and dispensing machines**

Consistent with accepted professional principles, CAHs must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

- **Proper environmental conditions**

Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the CAH is expected to follow the labeled conditions. CAHs must exercise caution in dispensing or using any drug or biological that is not labeled to indicate proper storage conditions or that may have been stored under inadequate conditions.

- **Security**

The CAH must have policies and procedures that are consistent with State and Federal law to address who is authorized access to the pharmacy or drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, ambulatory infusion), they are generally considered secure. Areas restricted to authorized personnel only would generally be considered "secure areas."

CAHs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked.

Medication carts, anesthesia carts, epidural carts and other non-automated medication carts containing drugs or biologicals (hereafter, all referred to as "carts") must be secured when not in use. A CAH's policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety.

If a cart containing drugs or biologicals is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and CAH policy is authorized access to the drugs and biologicals in the cart. That individual must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

- **Handling drugs and biologicals**

“Handling” includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug’s manufacturer. “Handling” also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either CAH staff or a contracted pharmacy service. CAHs use many medications that need to be reconstituted, mixed or compounded. Whether furnishing the services via CAH staff or a contractor, the CAH is responsible for proper handling of drugs and biologicals.

Except in emergencies or when not feasible (for example, when the product’s stability is short), only the pharmacy performs reconstituting, mixing, admixing or compounding.

- **Compounding**

All compounding of medications used or dispensed by the CAH must be performed consistent with accepted professional principles applicable to both sterile and non-sterile compounding.

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

A CAH pharmacy must be administered in accordance with accepted professional principles, and therefore must be able to demonstrate how it assures that all sterile and non-sterile compounded preparations dispensed and/or administered to the CAH’s patients are being compounded consistent with accepted professional standards to ensure safety. The CAH must be able to provide evidence that the CAH’s standard operating procedures for compounding, if performed in-house, and for quality oversight of compounding, regardless of source, are consistent with accepted professional principles.

Compounding may take place in the CAH’s pharmacy on-site and/or the CAH may obtain some or all of its compounded medications from external sources. Regardless of the source, if accepted standards for safe compounding are not met, compounded medications may contain less or more than the intended dose and/or may be chemically or microbiologically contaminated, with potentially serious adverse consequences for the patients who receive them.

- **Use of Outside Compounders (also known as Outsourcing Facilities)**

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The

DQSA created a new section 503B in the FDCA under which a compounder may elect to become an “outsourcing facility.” The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities:

- Must comply with the FDA’s Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA’s publishes the most current versions of its draft and final regulations and guidance related to compounding on its website:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm> ;
- Will be inspected by FDA according to a risk-based schedule; and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

In a January 2014 letter to purchasers of compounded medications (available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm>), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that, “[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling.”

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at:
<http://www.fda.gov/drugs/guidancecomplianceinformation/pharmacycompounding/ucm378645.htm>

Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.”

- **Use of Compounding Pharmacies**

If a CAH obtains compounded medications from a compounding pharmacy rather

than a manufacturer or a registered outsourcing facility, then the CAH must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

Note that these types of compounding pharmacies are also popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board.

For Information – Not Required/Not to be Cited

ASHP Research and Education Foundation™ “Outsourcing Sterile Products Preparation: Contractor Assessment Tool”

The ASHP Research and Education Foundation™ offers a tool that CAHs may find useful for assessing vendors that provide compounded sterile preparations. <http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx> and click on "Start using Sterile Products Outsourcing Tool now."

- **Dispensing drugs and biologicals**

CAHs must comply with applicable State law that governs the qualifications, certification, or licensure of staff who dispense drugs and biologicals. There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery.

Medications must be dispensed in a timely manner. The CAH must have a system that ensures medication orders get to the pharmacy promptly and medications are available for administration to patients when needed, including when the pharmacy is not open. Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following: automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.

Concerns, issues or questions pharmacy staff have about any medication order must be clarified with the prescribing practitioner or another practitioner responsible for the care of the patient before dispensing.

A CAH may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored.

- Automated Dispensing Cabinets (ADCs) for medications are a secure option for medication storage since they ensure locked storage of medications and allow for electronic tracking of controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification so that they can only be accessed by authorized personnel.
- Policies and procedures must address who can access medications during after-hours.

For Information Only – Not Required/Not to be Cited

In addition to the required pharmacy policies and procedures above, a well-designed pharmacy service would have policies and procedures addressing medication safety practices such as:

- Implementation of a do-not-use abbreviation list. CAHs may wish to refer to lists offered by the Institute for Safe Medication Practices (<http://www.ismp.org/tools/errorproneabbreviations.pdf>) or The Joint Commission (http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf);
- A high alert drug list. CAHs may wish to refer to a high alert drug list offered by the Institute for Safe Medication Practices (<https://www.ismp.org/tools/institutionalhighAlert.asp>);
- For specific high alert medications designated by the CAH, having two health professionals independently check doses. CAHs may wish to refer to guidance from the Institute for Safe Medication Practices concerning appropriate use of double-checks (<http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=51>);
- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;
- Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit doses that have been repackaged by the pharmacy;
- The CAH consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system; and
- The American Society of Health-System Pharmacists (ASHP) recommends

that floor stocks of medications should be limited to medications for emergency use and routinely used safe items (e.g. mouthwash, antiseptic solutions).

When utilizing automated dispensing cabinets (ADCs), the Institute for Safe Medication Practices recommendations include the following: (See: <http://www.ismp.org/Newsletters/acutecare/articles/20090212.asp> and http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf) Security processes are established to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs.

- Utilize biometric user identification or, at a minimum, change user passwords quarterly.
- Link the ADC to the pharmacy computer to allow for patient “profiling,” so that a pharmacist can review each medication order and screen it for safety before the drug is dispensed or accessed by the nurse or other healthcare professional.
- Limiting the availability of overrides to the ADC system.
- Limiting access to drugs based on the patients profile so to decrease medication selection errors.
- Store each medication and strength in an individual lidded ADC compartment that opens only when the specific medication is selected.
- Document the destruction of medication waste at the time of removal of the medication whenever possible. Record this waste via the ADC, and match the administered dose with ordered dose. Have a process to routinely review/reconcile the documented medication waste.
- Return all medications to a common secure one-way return bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC.

- **Administration of drugs and biologicals to patients**

CAHs must comply with applicable State law that governs the qualifications, certification, or licensure of staff who administer drugs and biologicals and must adhere to accepted standards of practice for medication administration. See the guidance for §485.635(d)(3) concerning medication administration by CAH nursing staff.

- **Record keeping for the receipt and disposition of all scheduled drugs**

The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five “schedules”, ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. The CAH is required to accurately track the receipt and disposition of all scheduled drugs used in the CAH. Components of a record system for scheduled drugs would include:

- Locked storage of scheduled drugs when not in use.
 - Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
 - The record system tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
 - Any discrepancies in count are reconciled promptly. The CAH is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.
- **Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used for patient care**

The CAH must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use. This would include drugs that are the subject of a manufacturer’s recall.

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer’s approved labeling.

A drug or biological is also outdated after its “beyond-use date”-(BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a

compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available. The CAH must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer

For individual drug containers: each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date. and/or, if applicable, a BUD.

For Information Only

Certain provisions of the FDCA address the labeling of prescription drugs generally (e.g., section 503(b)(2) of the FDCA). Section 503B of the FDCA includes labeling requirements for drugs compounded by registered outsourcing facilities (see section 503B(a)(10)). Although CAHs are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other Federal law.

- **Assessing Adverse Drug Reactions & Medication Administration Errors**

In accordance with §485.635(a)(3)(v) the CAH must have a system for staff to report adverse drug reactions and medication administration errors. The pharmacy services is expected to assess all such reports to determine if problems or errors in pharmacy services caused or contributed to the adverse reaction or medication administration error. Where such problems or errors are identified, the CAH is expected to take effective action to address the identified issues.

Survey Procedures §485.635(a)(3)(iv)

- Has the CAH adopted pharmacy rules that were developed with the advice of the CAH's professional healthcare staff?
- Has the CAH identified the qualifications of and designated an individual who is responsible for developing and implementing the rules for the CAH's pharmacy services, consistent as applicable with State and Federal law?

- Review the qualifications of the responsible individual to verify that they satisfy the CAH's written criteria.
- Ask CAH practitioners, nursing and pharmacy staff whether the CAH's pharmacy service dispenses prescribed drugs and biologicals in a timely manner. If there is evidence in medical records reviewed of late administration of prescribed medications, probe to determine whether delays are due to pharmacy dispensing delays.
- Ask the individual responsible for CAH pharmacy services what sources of accepted professional principles of pharmacy practice the CAH relies upon in developing and implementing its CAH pharmacy rules, policies and procedures. Is the source(s) a nationally recognized source?
- Are drugs and biologicals stored in a secure manner?
 - Are drugs stored in areas not accessible to unauthorized personnel?
 - When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked up?
- Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.
- Determine if the CAH has a system that tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacturer.
 - Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs?
 - Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the CAH to reconcile and address the discrepancies?
- Interview the person responsible for pharmacy services as well as other CAH staff to determine their understanding of the CAH's controlled drug policies.
- Verify that only a pharmacist or other personnel authorized in accordance with State and Federal law compound, label and dispense drugs or biologicals, regardless of whether the services are provided by CAH staff or under arrangement.
 - Interview pharmacy and CAH staff to determine how drugs and biologicals are dispensed;

- o Observe on-site dispensing operations;
- Review records to see if drugs and biologicals are removed from the pharmacy by unauthorized personnel;
- Do the CAH's pharmacy rules address ADCs, if used within the CAH? Are the ADCs being used in the manner prescribed by the CAH's rules?
- Can the CAH demonstrate that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices?
 - Does the individual responsible for the pharmacy service, including compounding policies, practices and quality assurance within the CAH, and selecting and overseeing any external sources of compounded medications, have the expertise to conduct effective quality oversight?
 - Can the individual responsible for the pharmacy services explain the risk level(s) of the CSPs being produced in-house and/or obtained from external sources?
 - If any CSPs are produced in the CAH:
 - Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the CAH and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the CAH's rules, policies and procedures?
 - Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices?
 - Ask the individual responsible for pharmacy services to demonstrate how the following are accomplished to ensure that sterile compounding practices are consistent with standards for the risk level(s) of CSPs being produced for/dispensed to CAH patients:
 - Verification of compounding accuracy and sterility.
 - Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;
 - Personnel training and competency assessment, including but not limited to accuracy/precision in identifying and measuring ingredients; cleansing and garbing; aseptic manipulation skills; environmental quality and disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and

post-production quality checks.

- Review the CAH's procedures for maintaining the quality of CSPs during storage, transport and dispensing. Are CSPs packaged in a manner to protect package integrity and sterility? How are CSP-specific requirements with respect to motion, light exposure, temperature and potentially hazardous contents addressed? How does the CAH ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable?
- Review the pharmacy rules, policies and procedures for determining BUDs (for medications compounded in-house as well as from external sources).
 - Can the CAH demonstrate that the policies and procedures are consistent with or more stringent than the applicable *nationally accepted* standards?
 - Can it demonstrate that the pharmacy personnel assigned to determining BUDs when a manufacturer's instructions are not available have the expertise and technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and hospital policies?
- Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the CAH and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the CAH's rules, policies and procedures?
- If the CAH obtains compounded products from an external source that is not an FDA registered outsourcing facility, can it demonstrate that it systematically evaluates and monitors whether these sources adhere to accepted professional principles for safe compounding?
- Does the CAH have a process for following up on adverse drug reactions and errors in medication administration reported by CAH staff in accordance with §485.635(a)(3)(v)? If any have been reported, did the CAH thoroughly assess and analyze them? Has the CAH taken effective preventive action to address identified issues?
- Spot-check the labels of individual drug containers to verify that they contain the following minimal information:
 - Each patient's individual drug container bears his/her full name and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date, and, when applicable, a BUD.

- o Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date, and, when applicable, a BUD.
- If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, expiration date, and, when applicable, a BUD.
- Spot-check patient-specific and floor stock medications to identify expired, mislabeled or unusable medications, including medications that are past their BUD.

C-1018
(Rev.)

§485.635(a)(3) [The policies include the following:]

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

Interpretive Guidelines §485.635(a)(3)(v)

CAH staff must report all drug (medication) administration errors and all adverse drug reactions. This required reporting includes two distinct steps in the reporting of drug (medication) administration errors and adverse drug reactions. The first and highest priority reporting relates to the care of the patient, at time of occurrence. The second reporting step is related to the CAH-wide Quality Assurance review as addressed in §485.641(b).

- Medication administration error:

The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is “Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.” A medication administration error is one that occurs in the phase of the medication process where the drug actually enters the patient by one of various possible routes, e.g., orally, intravenously, etc.

- Adverse drug reaction:

The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as “Any unexpected, unintended, undesired, or excessive response to a drug that:

1. Requires discontinuing the drug (therapeutic or diagnostic)
2. Requires changing the drug therapy
3. Requires modifying the dose (except for minor dosage adjustments)
4. Necessitates admission to a hospital
5. Prolongs stay in a health care facility
6. Necessitates supportive treatment
7. Significantly complicates diagnosis
8. Negatively affects prognosis, or
9. Results in temporary or permanent harm, disability, or death.

Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.”

Patient Care

In the case of ADRs or medication administration errors that are not caught before they reach the patient, a “report” must be made to a practitioner responsible for the care of the patient.

For example, if a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, then the medication administration error has reached the patient and must be reported to the responsible practitioner.

If, on the other hand the wrong dose of a drug is prepared for a patient, but a nurse catches this and does not give that dose to the patient, then a medication administration error has occurred, but the error has not reached the patient, and thus does not need to be reported to the responsible practitioner.

Not every medication administration error that reaches the patient causes harm or has the potential to cause harm; it depends both on the drug and on the patient’s condition.

In the case of all ADRs and any medication administration error that has harmed or has reached the patient and could potentially cause harm, the report to a practitioner must be made immediately after the staff identify the adverse reaction or (potentially) harmful error, to enable a timely assessment and intervention. The report must be made directly in a manner that confirms a practitioner received the report, for example, via a phone call. If the impact of the medication error that reached a patient is unknown, the error must be reported to a practitioner immediately. Documentation of the error or reaction, including notification to the practitioner, must be in the patient’s medical record.

Medication administration errors that have reached the patient but result in no harm and do not have the potential to cause harm can be reported to a practitioner during usual

working hours. For example, if an over-the counter analgesic dose is missed during the night shift, it can be reported first thing in the morning as no further intervention would be required by the practitioner. CAHs should provide clinical staff with expected guidance on how to respond to these situations.

Quality Assurance/Improvement Reporting:

Reduction of medication administration errors and ADRs may be facilitated by effective internal CAH reporting that can be used to assess vulnerabilities in the medication process and implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the CAH must educate staff on medication administration errors and ADRs including the criteria for those errors and ADRs that are to be reported for quality assurance/improvement purposes, and how, to whom and when they should be reported.

Reporting for quality assurance/improvement purposes covers all identified medication errors, regardless of whether or not they reach the patient, and those ADRs meeting the criteria specified in the CAH's policies.

For Information Only - Not Required/Not to be Cited

To improve staff willingness to report medication errors and ADR incidents, CAHs are encouraged to adopt a non-punitive approach that focuses on system issues rather than individual health care professionals. A non-punitive approach is likely to encourage reporting by those who otherwise may fear retribution or CAH disciplinary action.

In addition to internal staff reporting, the CAH is expected to take other steps to identify medication administration errors and ADRs. Reliance solely on staff-generated incident reporting fails to identify the majority of adverse drug events. Proactive identification includes observation of medication passes, concurrent and retrospective review of patient's clinical records, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event.

The CAH must assess the effectiveness of its internal reporting system to determine whether or not it is identifying as many medication errors and ADRs that would be expected for the size and scope of services provided by the CAH. In making such assessments the CAH could refer to established benchmarks or studies on error or ADR rates published in peer-reviewed journals.

For Information Only – Not Required/Not to be Cited

CAHs are encouraged to participate in state-wide and national patient safety organizations for reporting of drug administration errors, ADRs, and drug incompatibilities. National organizations include, but are not limited to, the FDA MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. These organizations, along with other patient safety organizations, collect and analyze data, identify trends, and provide feedback and recommendations to health care organizations to reduce the risk of medication related errors and events.

Survey Procedures §485.635(a)(3)(v)

- Assess whether the CAH ensures that medication administration errors and ADRs are reported to practitioners in a timely manner.
 - Are nursing staff familiar with the concepts of medication errors that do and do not reach the patient, as well as ADRs?
 - Ask nursing staff what they would do in the case of a medication administration error that reaches the patient or an adverse drug event.
 - Ask nursing staff if they can provide examples of cases where they needed to report an ADR. Is the report to the practitioner documented in the medical record?
 - Review records of medication errors and ADRs to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.
- Can the CAH demonstrate that it has a system for reporting/identifying ADRs and medication administration errors for quality assurance/improvement purposes?
 - Interview CAH staff (nursing, pharmacy and medicine) to ascertain awareness of the CAH's policy on reporting medication administration errors and ADRs for quality improvement purposes
 - Does the CAH have evidence of training staff on reporting expectations?
 - Does the CAH rely only upon internal staff incident reporting or does it use other methods to identify potential/actual medication errors and ADRs, as well?

Ask the individual responsible for the QA program to demonstrate how the CAH determines if the number of medication administration errors and ADRs reported is

consistent with the size and scope of services provided by the CAH.

- Review QA activities for medication administration errors and ADRs to determine if, upon analyses of the reports, potential corrective actions are identified and implemented, if appropriate.

C-1020
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§485.635(a)(3) [The policies include the following:]

(vi) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices. *All patient diets, including therapeutic diets, must be ordered by the practitioner responsible for the care of the patients or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals and that the requirement of § 483.25(i) of this chapter is met with respect to inpatients receiving post CAH SNF care.*

Interpretive Guidelines §485.635(a)(3)(vi)

Guidance is pending and will be updated in future release.

Survey Procedures §485.635(a)(3)(vi)

Survey Procedures are pending and will be updated in future release.

C-1022
(Rev.)

§485.635(a)(4) *These policies are reviewed at least biennially by the group of professional personnel required under paragraph (a)(2) of this section and updated as necessary by the CAH.*

Interpretive Guidelines §485.635(a)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.635(a)(4)

Survey Procedures are pending and will be updated in future release.

C-1024
(Rev.)

§485.635(b) Standard: Patient Services

(1) General

- (i) The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.**

Interpretive Guidelines §485.635(b)(1)(i)

This regulation addresses the minimum level of outpatient services (with the exception of emergency services – see §485.635(b)(4)) which a CAH must provide. Such services must be provided on-site at the CAH, but may be provided either by CAH staff or under an arrangement or contract. At a minimum, the CAH must provide those diagnostic and therapeutic services and supplies which are typically found in an ambulatory healthcare setting where patients first come into contact with the healthcare delivery system. The services required to be provided must, at a minimum, reflect the scope and complexity of services provided in a physician's office or in a hospital outpatient or emergency department that furnishes low intensity (i.e., less complex) services. Such services include, but are not limited to: taking a patient's medical history; conducting a physical examination of the patient; specimen collection, assessment of health status, and treatment for a variety of medical conditions. The extent of the CAH's outpatient services is expected to be sufficient to meet the needs of the patients it services for basic ambulatory care services. Further, the CAH's outpatient services must be integrated with its inpatient services.

For those outpatient services that fall only within the scope of practice of a physician or non-physician practitioner, in order to demonstrate compliance, a CAH physician or non-physician practitioner must be available to treat patients at the CAH when such outpatient services are provided. This requirement does not mean the CAH must have a practitioner physically present in the CAH 24 hours per day, seven days per week. See the discussion of required emergency services at §485.618(d) concerning required response times for a physician or non-physician practitioner to come to the CAH to provide medical care.

Survey Procedures §485.635(b)(1)(i)

- Does the CAH provide on-site outpatient services that are typical of those provided in a physician office or low intensity hospital outpatient or emergency department, including medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions?
- Determine that the outpatient services are integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided.

- Verify that the types and number of qualified personnel are appropriate for the scope and complexity of the outpatient services offered. Review personnel files or contracts to verify current licensure, certifications and training of staff consistent with applicable State laws.
- Verify that equipment, staff and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.

C-1026
(Rev.)

§485.635(b) [Standard: Patient Services

(1) General]

(ii) The CAH furnishes acute care inpatient services.

Interpretive Guidelines §485.635(b)(1)(ii)

In accordance with §485.620(b), CAHs are required to have an average annual per acute inpatient length of stay that does not exceed 96 hours. Accordingly, CAHs are expected to provide less complex inpatient services in order to comply with the length of stay requirement. Furthermore, for each Medicare beneficiary, the CAH is required in accordance with Medicare payment law and regulations to have the practitioner who admits the beneficiary as an inpatient certify that the beneficiary may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH. However, while it may be true that CAHs generally are not expected to handle patients requiring complex, specialized inpatient services, such as those services provided by trauma centers, or cardiac surgery centers, CAHs should be able to handle a range of patient needs requiring inpatient admission. CMS does not believe it is in the best interest of patients for them to routinely be transferred to a more distant hospital if instead their care can be provided locally without compromising quality or the length of stay requirements (78 FR 50749). Accordingly, acute inpatient services must be furnished to patients who present to the CAH for treatment so long as the CAH has an available inpatient bed and the treatment required to appropriately care for the patient is within the scope of services offered by the CAH.

Given the resources of the CAH, the needs of the community it serves, and the variable nature of a CAH's inpatient census, a CAH may not be actively treating inpatients at all times. CAHs may experience significant seasonal variations in the inpatient occupancy rates as well as variations that are a function of the size of the community in which the CAH is located.

A CAH is not required to maintain a minimum average daily census of patients receiving inpatient acute care services or maintain a minimum number of beds that are to be used

for inpatient services. However, in determining compliance with this requirement factors to be considered include, but are not limited to, the following:

- What is the volume of emergency services the CAH provides on average quarterly and annually?
- What is the number of certified inpatient beds in the CAH?
- Are there dedicated observation beds in the CAH? If so, how many compared to the number of inpatient beds?
- What is the average acute care occupancy rate for the CAH's inpatient beds quarterly and annually?
- What is the volume of acute inpatient admissions in the CAH quarterly and annually?
- What is the volume of patients placed in observation status in the CAH quarterly and annually?
- What is the percentage of emergency department patients admitted to the CAH as an inpatient versus transferred to a hospital quarterly and annually?
- What is the range, volume and complexity of outpatient services the CAH provides?

While there is no specific formula for determining the number of patients a CAH is expected to admit, surveyors must be alert to disproportionate relationships among the CAH's various services. For example, if a CAH has only 4 certified beds and an average of 3 acute care inpatients per month, but has 18 observation beds that have an annual occupancy rate of 85%, has an ED staffed by physicians 24/7 and sees 9,000 ED patients/year, offers extensive and complex outpatient services, such as chemotherapy, advanced diagnostic imaging, sleep lab services, and same day surgery, but transfers to another hospital from the ED almost all patients who need inpatient admission, then these inpatient services would not be reasonably proportional to the overall mix and volume of services offered by the CAH. Based on data published by the Agency for Healthcare Research and Quality (AHRQ), in 2008 approximately 8.3 percent of emergency department (ED) visits in a rural "hospital" resulted in an inpatient admission, compared to 16 percent for non-rural hospital ED visits. Also, a higher percentage of rural ED patients were likely to be discharged – 91.7% compared to 84% for non-rural hospitals. The AHRQ rural hospital data included both hospitals and CAHs, with CAHs accounting

for 51 percent of rural EDs.⁶ Other published AHRQ data indicates that, in 2009, 3 percent of patients who lived in a rural area were transferred from the ED where they presented to a hospital, compared to 1.5 percent of all patients nationally who presented to an ED.⁷

Given that a CAH may offer fewer services than even the average rural hospital and is expected to achieve a 96-hour average length of stay or less, there is no expectation that every CAH is expected to admit 8 percent of its ED patients. This benchmark can, however, provide a useful starting point for assessing compliance.

- Generally, if a CAH admits at least 8 percent of its ED patients annually, it would be considered compliant with the requirement to provide inpatient services and surveyors do not have to investigate further.
- If a CAH admits less than 8 percent of its ED patients annually, this is **not** in and of itself evidence of noncompliance. More investigation is needed to assess compliance by determining whether the volume of activity and number of staff the CAH has for its ED, other outpatient, and inpatient services are reasonably related to each other. There can be great variation among CAHs in their volume and types of activities, despite their relative similarity in size, making a “one size fits all” formula inappropriate. Researchers in one State with 79 CAHs found that they averaged 3,851 ED visits annually, but that visits for individual CAHs ranged from a low of 389, or a little more than one patient per day, to a high of 14,425, or about 40 patients per day. CAHs in this State averaged 19,705 other types of outpatient visits annually, but again the range was very large, from a low of 89 to a high of 86,367 per year. For inpatient admissions the annual average was 836, ranging from a low of 100 to a high of 3,838⁸. Presentation of the data found in this State is not intended to provide benchmarks for CAHs in other States, but rather to emphasize the tremendous range in the volume of activity among CAHs, even within one State.
- A couple of extreme but illustrative examples are presented below to indicate the types of factors to be considered when assessing whether the CAH satisfies the requirement to provide inpatient services:
 - Example #1: A CAH has a very low volume of ED visits, such as 2 or fewer patients per day on average, discharges over 90% of its annual ED patients, has a total professional health care staff that consists of one physician who spends a limited amount of time on-site, and one nurse practitioner who works days five

⁶ Hines, A.L., Frazee, T., and Stocks, C. *Emergency Department Visits in Rural and Non-Rural Community Hospitals*, 2008. HCUP Statistical Brief #116. June 2011. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb116.pdf>

⁷ Kindermann, D, Mutter, R. and Pines, J.M. *Emergency Department Transfers to Acute Care Facilities*, 2009. HCUP Statistical Brief #155. May 2013. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb155.pdf>

⁸ Moscovice, I. and Casey, M. *Rural-relevant Quality Measures for Critical Access Hospitals*. June 27, 2011 PowerPoint presentation to the Minnesota Rural Health Conference. <http://www.health.state.mn.us/divs/orhpc/conf/2011/presentations/2b.pdf>

days per week. In this case it would not be unreasonable for the CAH to admit a patient for acute inpatient services only occasionally and transfer a majority of those ED patients who require inpatient services to a hospital.

- Example #2: A CAH has 50 ED visits per day on average, 4 certified inpatient beds, 2 inpatient admissions per month on average (all elective surgery patients who started as outpatient cases), 10 dedicated observation beds and places about 2 ED patients per day in observation; transfers out to a neighboring hospital an average of 15 ED patients per week who require admission, has twenty physicians on staff, is performing an average of three thousand outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 40,000 outpatient visits per year, not counting ED visits. This CAH's services are very skewed toward outpatient services, and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH might arguably have the staff to provide a larger volume of inpatient services to many of the ED patients who require admission. The CAH would be expected to demonstrate to the surveyor why it could be reasonable for its inpatient capacity and admissions to be so disproportionately small compared to its outpatient services volume and capabilities, and in view of the needs of its ED patients for inpatient services. The surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers. See Appendix V)
- Example #3: A CAH has 25 ED visits per day, 25 certified beds, 23 of which, on average, are used for swing-bed services and are occupied by nursing home or skilled nursing facility residents. The CAH transfers out to a neighboring hospital an average of eight ED patients per week who require admission, and admits an average of one patient per month for acute inpatient services. The CAH has fifteen physicians on staff, is performing an average of 800 outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 20,000 outpatient visits per year, not counting ED visits. In this situation the CAH's services are skewed towards outpatient and long-term care services and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH would be expected to demonstrate to the surveyor why it could be reasonable for its inpatient acute care capacity and admissions to be so disproportionately small compared to its outpatient and long term care services and to the needs of its ED patients for inpatient services. The surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers. See Appendix V)

Survey Procedures §485.635(b)(1)(ii)

- Verify that the CAH is furnishing acute care inpatient services by reviewing data on the number of patients admitted over the prior year.
- Determine the percentage of ED visits that result in an admission to the CAH. If fewer than eight percent of ED visits lead to an inpatient admission, review data on transfers of ED patients, overall staffing, the volume and type of outpatient services offered, including observation services, and swing bed services to determine whether there is a reasonably proportionate relationship among the various services the CAH provides.
- Review a sample of records of the patients the CAH transferred and determine if the transfers were appropriate based on the services available at the CAH.

C-1028
(Rev.)

§485.635(b)(2) Laboratory Services

The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following:

- (i) Chemical examination of urine by stick or tablet method or both (including urine ketones).**
- (ii) Hemoglobin or hematocrit.**
- (iii) Blood glucose.**
- (iv) Examination of stool specimens for occult blood.**
- (v) Pregnancy tests.**
- (vi) Primary culturing for transmittal to a certified laboratory.**

Interpretive Guidelines §485.635(b)(2)

Laboratory services that must be provided on-site at the CAH's main campus are the tests specified in the regulation, which would be considered the minimum necessary for diagnosis and treatment of a patient:

- Chemical examination of urine by stick or tablet method or both (including urine ketones);

- Hemoglobin or hematocrit;
- Blood glucose;
- Examination of stool specimens for occult blood;
- Pregnancy tests; and
- Primary culturing for transmittal to a certified laboratory.

These services may be provided by CAH staff or under arrangement or agreement with a laboratory, or through a combination of CAH staff and a laboratory under arrangement. Laboratory services, whether provided directly by the CAH or under an arrangement with a laboratory contractor, must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. Compliance with Part 493 is not assessed by CAH surveyors evaluating compliance with the CAH conditions of participation, but surveyors are expected to refer potential issues they may identify to the program responsible for CLIA certification.

Given that the CAH must provide emergency services 24 hours a day, 7 days a week, the CAH must determine which laboratory services are to be immediately available to meet the emergency needs of patients and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH's emergency services operations.

The provision of laboratory services that exceed the minimum tests specified is optional. The scope and complexity of the CAH's laboratory service must be adequate to support the clinical services the CAH offers to patients. Additional laboratory services may be offered directly or through arrangement. The CAH should have a written description of all the laboratory services that it provides, including those delivered on routine and stat basis.

The laboratory must have written policies and procedures for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the CAH must comply with the requirements of the clinical records CoP at §485.638(a)(4)(ii).

Survey Procedures §485.635(b)(2)

- Ask the CAH to identify which laboratory services it offers. Are the required lab services provided at the CAH's main campus?
- Does the CAH have a CLIA certificate or waiver, as applicable, for all laboratory

tests performed in CAH facilities?

- Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.
- If the CAH refers specimens to another laboratory for testing, does the CAH have documentation that the referral laboratory is CLIA certified for the appropriate tests?
- Has the CAH identified laboratory services that must be available to support the emergency services the CAH provides? Ask the staff who furnish emergency services whether these laboratory services are available whenever they provide emergency services.

C-1030
(Rev.)

§485.635(b)(3) Radiology services. Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

Interpretive Guidelines §485.635(b)(3)

Radiologic services encompass many different modalities used for the purpose of medical imaging. Each type of technology gives different information about the area of the body being studied or treated, related to possible disease, injury, or the effectiveness of medical treatment. All the modalities use some form of radiation, such as ionizing radiation (radiography, computed tomography, fluoroscopy), which has enough energy to potentially cause damage to DNA, and other forms of radiation (ultrasound, magnetic resonance imaging) to view the human body in order to diagnose, monitor, or treat medical conditions.

Radiological services furnished by the CAH may be provided by CAH staff or under arrangement. The CAH must maintain and have available diagnostic radiological services to support the services the CAH provides to meet the needs of its patients. These services must be available at all times the CAH provides services, including emergency services. The CAH has the flexibility to choose the types and complexity of radiologic services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine).

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the governing body (or responsible individual).

Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, Radiological Society of North America, Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, American College of Cardiology, American College of Neurology, American College of Physicians, American College of Radiology, etc.

Qualified Radiologic Personnel

There must be written policies that are developed and approved by the governing body or responsible individual and are consistent with State law, that designate which personnel are qualified to use the radiological equipment and administer procedures.

When telemedicine is used to provide teleradiology services, radiologists who interpret radiological tests must satisfy the telemedicine privileging requirements §485.616(c)(3).

In addition to radiologists, there are other types of healthcare personnel who, depending on State law and the scope and complexity of the CAH's radiologic services, may be involved in the delivery of radiologic services in the CAH, including radiologic technologists and medical physicists. Radiologic technologists perform diagnostic imaging examinations and administer radiation therapy treatments. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection and basic patient care.

For Information Only – Not Required/Not to be Cited

Well-designed radiologic services include a medical physicist, who, in conjunction with the person responsible for radiologic services, performs or supervises the pertinent procedures necessary to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result. The responsibilities of the medical physicist include: protection of the patient and others from potentially harmful or excessive radiation; establishment of adequate protocols to ensure accurate patient dosimetry; the measurement and characterization of radiation; the determination of delivered dose; advancement of procedures necessary to ensure image quality; development and direction of quality assurance programs; and assistance to other health care professionals in optimizing the balance between the beneficial and deleterious effects of radiation (www.aapm.org). CAHs are encouraged to involve a medical physicist in the calibration of the imaging equipment and monitoring of radiation dosage exposures.

Safety from Radiation Hazards

The CAH must adopt and implement policies and procedures that ensure safety from

radiation hazards for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies must address at least the following:

- Adequate radiation shielding for patients, personnel and facilities, which includes:
 - Shielding built into the CAH's physical plant, as appropriate;
 - Types of personal protective shielding to be used, under what circumstances, for patients, including high risk patients as identified in radiologic services policies and procedures, and CAH personnel;
 - Types of containers to be used for various radioactive materials, if applicable, when stored, in transport, in use, and when disposed;
 - Clear signage identifying hazardous radiation areas;
- Labeling of all radioactive materials, including waste, with clear identification of all material(s);
- Transportation of radioactive materials between locations within the CAH;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Periodic testing of equipment for radiation hazards;
- Periodic checking of staff regularly exposed to radiation for the level of radiation exposure, via exposure meters or badge tests;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

Radiologic Equipment Maintenance

The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. The CAH must ensure that equipment is inspected and maintained in accordance with Federal and State laws and regulations, as applicable, and the manufacturer's recommendations. The CAH must have a system in place to correct identified problems. The CAH must have evidence of its inspections and corrective actions.

Radiology Records

The CAH radiology records are to be treated in the same manner as any other part of a medical record. The medical records CoP at §485.638(a)(4)(ii) requires that the CAH maintain reports of physical examinations, diagnostic and laboratory test results, and consultative findings.

Survey Procedures §485.635(b)(3)

- Interview the person responsible for radiologic services.
 - Ask what radiologic services the CAH offers at its main campus. At off-site locations ask how the CAH ensures patient needs for radiologic services are met, if applicable.
 - Ask how the CAH ensures that radiologic services are provided consistent with acceptable standards of practice.
- Safety:
 - Determine if the radiologic services staff is familiar with the policies and procedures related to safety.
 - Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the CAH.
 - Observe areas where radiologic testing is done and check for safety problems.
 - Verify that hazardous materials are clearly labeled. Review records to verify that they are tracked, handled and stored properly in a safe manner with the requisite containers.
 - Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.
- Equipment maintenance:
 - Review the inspection records to verify that periodic inspections and maintenance are conducted in accordance with the manufacturer's recommendations.
 - Determine whether any problems identified are properly corrected in a timely manner and the correction is maintained over time.
- Qualified Personnel:
 - Are studies interpreted only by qualified staff approved to do so by the CAH's

governing body or responsible individual?

- Determine which staff are using various pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine if they meet the qualifications for tasks they perform, as established in the CAH's policies and consistent with state law.
- Ask staff to explain the protocol for the procedures/studies they administer. Ask to see the CAH's written protocols and verify that the staff is adhering to them.

C-1032
(Rev.)

§485.635(b)(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness.

Interpretive Guidelines §485.635(b)(4)

Emergency services must be provided by the CAH at the CAH campus either by CAH staff or by individuals providing services under arrangement or agreement. The individuals providing the services must have the ability to recognize a patient's need for emergency care at all times. The CAH must provide medically appropriate initial interventions, treatment and stabilization of any patient who requires emergency services.

Survey Procedures §485.635(b)(4)

The survey procedures for §485.618 apply.

C-1034
(Rev.)

§485.635(c) Standard: Services Provided Through Agreements or Arrangements

(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including

(5) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the distant-site telemedicine entity is not required to be a Medicare-participating provider or supplier.

Interpretive Guidelines §485.635(c)(1)&(c)(5)

All agreements for providing health care services to the CAH's patients must be with a provider or supplier that participates in the Medicare program, except in the case of an agreement with a distant-site telemedicine entity for the provision of telemedicine services. The agreements should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body (or responsible individual) is responsible for these services provided under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed.

The governing body (or responsible individual) has the responsibility for ensuring that CAH services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by CAH employees or indirectly by agreement or arrangement. The governing body must take actions through the CAH'S QA program to: assess the services furnished directly by CAH staff and those services provided under agreement or arrangement, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities.

Survey Procedures §485.635(c)(1)&(c)(5)

- Determine whether the CAH verifies that every entity providing health care services to the CAH's patients under an agreement participates in Medicare, with the exception of a distant-site telemedicine entity providing telemedicine services under an agreement or arrangement.

C-1036 ***(Rev.)***

§485.635(c)(1) [The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

(i) Services of doctors of medicine or osteopathy;

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guidelines §485.635(c)(1)(i) & §485.635(c)(2)

In accordance with §485.631(a)(1), the CAH is required to have at least one doctor of medicine or osteopathy (MD or DO) on its staff who is responsible for the functions described in §485.631(b). CAHs are free to have additional MDs or DOs on staff, part- or full-time. MDs and DOs who have been credentialed and privileged to provide services on-site at the CAH are part of the CAH's professional healthcare staff, even if they are not at the CAH full-time; they would not be considered to be providing services

under an arrangement and would not be covered by these regulatory provisions. These regulations also do not apply to MDs and DOs who provide telemedicine services to the CAH's patients, even when they are provided under arrangement. (See §485.616(c) and §485.635(c)(5) concerning telemedicine requirements.)

Under §485.635(c)(1)(i) & §485.635(c)(2), the CAH must have policies and procedures for referring patients it discharges who need additional specialized MD or DO services not available at the CAH. The policies and procedures must at a minimum identify the services for which the CAH has referral arrangements or agreements, as well as the information to be provided to referred patients. MDs and DOs to whom the CAH refers its patients must participate in Medicare.

The CAH is not required to have referral arrangements in writing, but if it does not, then it must be able to document that patients it has referred to an outside MD or DO have been offered appointments and treatment.

Survey Procedures §485.635(c)(1)(i) & §485.635(c)(2)

- Verify that the CAH has arrangements with one or more MDs or DOs for referral of discharged CAH patients who need medical services not available at the CAH.
- Are the referral arrangements in writing? If not, can the CAH document that patients referred to an outside MD or DO have been offered appointments and treatment?
- Does the CAH have policies and procedures addressing referral of discharged patients? Are the CAH's practitioners and staff who handle the discharge of patients familiar with these policies and procedures?

C-1038 ***(Rev.)***

§485.635(c)(1) [The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

(ii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guidelines §485.635(c)(1)(ii) & §485.635(c)(2)

In accordance with §485.635(b)(2), the CAH is required to furnish, either directly by the

CAH staff, under arrangement or agreement, or through a combination of CAH staff and a laboratory under arrangement basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). These services must be provided on-site at the CAH and may be provided either by CAH staff or under an arrangement with a laboratory. The CAH is also free to provide additional laboratory services on-site, beyond the minimum required services. The provision at §485.635(c)(1)(ii) does not apply to laboratory services provided on-site.

Instead, this provision addresses the requirement for the CAH to have an arrangement or agreement, as appropriate, with a laboratory that can provide additional or specialized clinical laboratory services that are not available at the CAH. The arrangement or agreement may provide either for the CAH to draw the specimens to be examined and send them to the outside laboratory. The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside laboratory to which it sends specimens provides the CAH with test results.

Laboratories that provide additional diagnostic and clinical laboratory services to a CAH under agreement or arrangement must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. The CAH is expected to have evidence of the outside laboratory to which it refers patients holding a current CLIA certificate or waiver.

The CAH must have policies and procedures for additional or specialized laboratory services provided under arrangement or agreement which address at least the following: the specific laboratory services provided under arrangement; and the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Likewise, although the CAH is expected to provide radiology services in accordance with §485.635(b)(3), it is also expected to have an arrangement or agreement, as appropriate, with other providers or suppliers of diagnostic imaging services, including advanced diagnostic imaging services, such as magnetic resonance imaging, computed tomography, etc. The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside diagnostic imaging facility to which it sends patients provides the CAH with the resulting studies and reports.

Patient diagnostic imaging studies and reports, laboratory results and all other laboratory clinical patient records must be included in the patient's medical record and meet all requirements at §485.638(a)(4)(ii).

Survey Procedures §485.635(c)(1)(ii) & §485.635(c)(2)

- Verify that the CAH has an agreement or arrangement with an outside laboratory and an outside diagnostic imaging facility for services not provided in the CAH.

- Ask the CAH how it ensures that the laboratory with which it has an agreement or arrangement holds the necessary CLIA certification.
- If the agreement or arrangement is not in writing, can the CAH document that it is sending specimens to an outside laboratory and patients to an outside diagnostic imaging facility when needed, and that it is receiving test results?
- Do policies and procedures address which imaging and lab services are provided under arrangement, as well as, for lab services, collection, preservation, transportation, receipt, and reporting of tissue specimen results?

C-1040
(Rev.)

§485.635(c)(1) [The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

(iii) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

Interpretive Guidelines §485.635(c)(1)(iii)

If the CAH does not provide all food and other services required to meet the nutritional needs of the CAH's inpatients using CAH staff, then the CAH must provide these services under an agreement or arrangement.

The CAH must assure that dietary services provided under an agreement or arrangement are provided in accordance with the CAH's policies adopted as required by §485.635(a)(3)(vii). Unless the CAH is a grandfathered co-located CAH (see §485.610(e)(1)) that has an arrangement with the co-located facility to provide food services to the CAH's inpatients, it is expected that the CAH's vendor provides dietary services on-site at the CAH in order to meet the needs of the CAH's inpatients. Surveyors assess compliance with the requirements of §485.635(a)(3)(vii) in the same manner, regardless of whether the services are provided by CAH staff or a vendor. In the case of a grandfathered co-located CAH that obtains food services from the co-located facility, surveyors must assess the food service operations in the co-located facility as part of the CAH survey.

Survey Procedures §485.635(c)(1)(iii)

- Verify that the CAH has an agreement or arrangement with a vendor to provide dietary services to inpatients if the CAH does not use its own staff to provide these services.

C-1042

(Rev.)

§485.635(c)(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

Interpretive Guidelines §485.635(c)(3)

The CAH must maintain a list of all patient care services furnished by the CAH through arrangements or agreements. The list must be updated each time a contracted service is added or removed. For each service the list must include, at a minimum, the following information:

- The service(s) being offered;
- The individual(s) or entity providing the service(s);
- Whether the services are offered on- or off-site;
- Whether there is any limit on the volume or frequency of the services provided; and
- When the service(s) are available.

Survey Procedures §485.635(c)(3)

- Review the list of contracted services and verify that it contains all required information.
- Ask the CAH for evidence that the list is updated whenever there are changes.
- Ask various CAH staff during the course of the survey whether they work directly for the CAH or some other entity; check that services provided by staff employed by outside entities are on the list of contracted services.

C-1044

(Rev.)

§485.635(c)(4) The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following:

- (i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.**
- (ii) Ensuring that a contractor of services (including one for shared services and**

joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

Interpretive Guidelines §485.635(c)(4)

The person principally responsible for the operation of the CAH, in accordance with §485.627(b)(2), i.e., the CAH's Chief Executive Officer (CEO), is responsible for the operation of all patient care services furnished at the CAH. This includes services provided directly by CAH staff and services provided by the CAH under arrangement or agreement. It includes not only care provided directly to patients, but also services related to patient care, such as environmental cleaning, instrument cleaning and sterilization, laundry, pharmacy services, laboratory services, etc. (This requirement for the CEO to be responsible does not relieve the CAH's governing body of its ultimate responsibility for the CAH's total operation in those CAHs where there are both a governing body and a CEO.)

The CEO must take actions to assure that all services furnished by the CAH through a contractor comply with the applicable requirements of the CAH's CoPs. When assessing compliance of a service provided by a contractor with the CoPs, deficiencies cited under other CoPs warrant a citation of this requirement, because the CEO has failed to assure that the contractor provides services in a manner that allows the CAH to comply with the CoPs.

Survey Procedures §485.635(c)(4)(i)

- Ask the CAH's CEO to demonstrate how he or she provides oversight of all contracted services related to patient care.
- Ask for specific examples of how the CEO assures that services furnished in the CAH comply with the CoPs (e.g., policies and procedures, by-laws, etc.) that the individual responsible for its operations is responsible for all services provided through arrangements or agreements.

C-1046
(Rev.)

§485.635(d) Standard: Nursing Services

Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

Interpretive Guidelines §485.635(d) & (d)(1)

In order to meet the needs of patients, nursing services must be a well-organized service of the CAH. The CAH designates an individual who is responsible for nursing services, including development of policies and procedures for nursing services. The designated individual is generally expected to be a registered nurse. Various titles may be used for the responsible nurse leader may have (e.g., director of nursing services, nurse executive, chief nursing officer, or nurse manager). The nurse leader is responsible for the overall management and evaluation of nursing care in the CAH, including, but not limited to:

- Development and maintenance of nursing policies and procedures;
- Supervision of nursing staff, either directly, or, depending on the size of the CAH, indirectly through other nursing managers; and
- Ongoing review and analysis of the quality of nursing care.

As required at §485.631(a)(5), the CAH must have a registered nurse, clinical nurse specialist, or licensed practical nurse on duty whenever the CAH has one or more inpatients (including patients in a swing bed receiving long term care services).

The CAH must also ensure that, for outpatient nursing services, appropriate nursing staff are available in accordance with State law and CAH policy.

For both inpatient and outpatient services there must be sufficient numbers of supervisory and non-supervisory nursing personnel with the appropriate education, experience, licensure (as applicable), competence and specialized qualifications to respond to the nursing needs of the patient population of each CAH department or nursing unit. Staffing schedules must be reviewed and revised as necessary to meet patient care needs and to make adjustments for nursing staff absenteeism.

The CAH must have a procedure for assigning and coordinating the nursing care for every CAH patient. A registered nurse must either provide directly, or assign to other staff, the required nursing care for each CAH patient, including patients receiving swing bed services. The RN making the assignment must consider the specialized qualifications and competence of the CAH's available nursing staff in order to meet patients' nursing care needs. Nursing care duties may be assigned to appropriate personnel, such as a licensed practical nurse, nursing assistant or nurse's aide, so long as such assignment is consistent with state law and the individual has the qualifications and competence to perform the assigned tasks.

The CAH must ensure that all CAH nursing staff are adequately trained and oriented, aware of CAH nursing policies and procedures, supervised, and that their clinical activities are evaluated. If temporary outside agency nurses are employed to address temporary nurse staffing needs, determine how are these nurses oriented and supervised. **(NOTE:** Regular nursing services may be provided under arrangement instead of using CAH employees, but in this case the CAH is responsible for the ongoing training and

supervision of these regular nursing staff.)

Survey Procedures §485.635(d)(1)

- Determine whether an RN has been designated responsible for nursing services at the CAH.
- Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Sources of information to use in the evaluation of the nursing services are: staffing schedules, nursing care plans for inpatients, credentialing and training files (including contracted staff), and QA activities and reports.
- Interview the registered nurse responsible for nursing services and ask the following--
 - How are the nursing needs of patients determined? Who makes this determination?
 - How are staff assigned to provide nursing care to patients?
 - How does the CAH ensure that care provided meets the needs of each patient?
 - How are staff trained and oriented? If temporary outside agency nurses are used, how are they oriented and supervised?
- Review nursing assignments in one or more inpatient units, the emergency department, and one other outpatient department. Did an RN make the assignments? Was the complexity of patient care needs and the competence and specialized qualifications of the nursing staff taken into consideration?
- Review written staffing schedules; do they adhere to the CAH's policies and procedures for staffing levels and types of nursing personnel?
- Verify that there is supervision of personnel performance and nursing care for each nursing unit.
- If there are temporary agency nurses providing services, interview one or more to determine if they are familiar with the nursing policies and procedures of the unit or department where they are working.
- Review personnel files to determine that nursing staff have required licenses and competencies.

§485.635(d)(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

Interpretive Guidelines §485.635(d)(2)

The nursing care of each patient of the CAH must be supervised by a registered nurse or a physician assistant where permitted by State law. Even where permitted under State law, a CAH is not required to have nursing care supervised by a physician assistant. This is simply an option for the CAH.

For inpatients, including patients receiving long term care services in swing beds, evaluation of their nursing care includes evaluating the care for each patient upon admission and, when appropriate, on an ongoing basis in accordance with accepted standards of nursing practice and CAH policy. Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions.

Nursing care plans are not developed for outpatients, so the focus of the evaluation would be on adherence to generally acceptable standards of nursing care practice, including requirements at §485.635(d)(3) for medication administration.

Survey Procedures §485.635(d)(2)

- Determine that a registered nurse (or physician assistant where permitted by State law and CAH policy) supervises and evaluates the nursing care for each patient.
- Interview one or more registered nurses (or physician assistants, if applicable) who supervise and evaluate the nursing care for CAH patients.

C-1049 ***(Rev.)***

§485.635(d)(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

Interpretive Guidelines §485.635(d)(3)

As required at §485.635(a)(3)(iv), the CAH must have written policies and procedures for the administration of all drugs and biologicals that adhere to accepted standards of practice and Federal and State laws. In accordance with §485.635(d)(3), all medication administration must be consistent with accepted standards of practice, as well as Federal

and State laws. Examples of nationally recognized organizations with expertise in medication administration include, but are not limited to:

- National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org);
- Institute for Healthcare Improvement (<http://www.ihl.org/ihl>);
- U.S. Pharmacopeia (www.usp.org);
- Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: www.ismp.org/Newsletters/acutecare/articles/20110113.asp;
- Infusion Nurses Society (<http://www.ins1.org>).

In addition, the Centers for Disease Control and Prevention (CDC) publishes evidenced-based practice guidelines and recommendations on medication preparation and administration practices, designed to reduce the risk of infection associated with these activities.

Who May Administer Medications?

Drugs and biologicals, including intravenous (IV) medications, must be administered by, or under the supervision of, an MD or DO; an RN, or, where permitted by State law, a PA. Other personnel, such as LPN's, may administer medications when permitted by State law and CAH policy, so long as they are supervised by an MD, DO, RN or, where permitted by State law, a PA. The CAH's written policies must delineate the categories of clinical staff authorized to administer medication at the CAH.

Medication Orders

Drugs and biologicals, including intravenous (IV) medications, may only be administered in accordance with orders written and signed by a practitioner who is authorized by CAH policy, and in accordance with State law, to write orders and who is responsible for the care of the patient as specified under §485.631(b)(1)(iii).

Accepted standards of practice

Based on accepted standards of practice for medication administration, the CAH must assure compliance with the following requirements concerning:

- Minimum content of medication orders;
- Policies and procedures for verbal and standing orders;

- Self-administration of medications, if the CAH permits this;
- Training;
- Basic Safe Practices;
- Timing of Medication Administration;
- Assessment/Monitoring of Patients Receiving Medications;
- Intravenous (IV) medications; and
- Documentation

Content of the medication order

In accordance with accepted standards of practice, the minimum elements that must be present in orders for all drugs and biologicals to ensure safe preparation and administration include:

- Name of patient;
- Age and weight of patient, to facilitate dose calculation when applicable. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the CAH's policies. (**NOTE:** Dose calculations are based on metric weight (kg, or g for newborns). If a CAH permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, CAHs must specify a uniform approach to be used by prescribing practitioners. For example, a CAH could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric);
- Date and time of the order;
- Drug name;
- Exact strength or concentration, when applicable;
- Dose, frequency, and route;
- Dose calculation requirements, when applicable;
- Quantity and/or duration, when applicable;
- Specific instructions for use, when applicable; and

- Name of the prescriber.

Verbal and Standing Orders

Although the regulation requires medication administration be based on a written, signed order, this does not preclude the CAH from using:

- Verbal orders; or
- Standing orders.

In the case of both verbal and standing orders, a practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact. The CAH must adopt policies and procedures regarding verbal and standing orders. (**NOTE:** CAHs that have a distinct part psychiatric and/or rehabilitation unit must follow the hospital CoPs for all services provided in those units, including the hospital requirements for verbal and standing orders.)

For verbal orders, CAH policies must, at a minimum, address the following:

- Describe situations in which verbal orders may be used, as well as limitations or prohibitions on their use;
- Provide a mechanism to establish the identity and authority of the practitioner issuing a verbal order;
- List the elements required for inclusion in the verbal order process;
- Establish protocols for clear and effective communication and verification of verbal orders. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order;
- Identify the categories of clinical staff who are authorized to receive and act upon a verbal order; and
- Provide for prompt documentation in the medical record of the receipt of a verbal order.

For standing orders, CAH policies must, at a minimum, address the following:

- The process by which a standing order is developed; approved; monitored; evaluated and updated when needed;
- For each standing order, which staff may initiate it and under what circumstances; (under no circumstances may a CAH use standing orders in a manner that requires

any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders); and

- The requirements for subsequent authentication by a practitioner responsible for the care of the patient.

For Information Only – Not Required/Not to Be Cited

Verbal Orders

CAHs are encouraged to minimize the use of verbal orders as much as possible and not permit their use merely as a convenience to practitioners. Verbal orders carry a higher risk of miscommunication and error and thus should only be used when necessary. With the increasing use of Electronic Health Records and Computerized Physician Order Entry systems, the need for verbal orders is expected to decline.

Standing Orders

There is no standard definition of a “standing order” in the healthcare community, but the terms “pre-printed standing orders,” “electronic standing orders,” “order sets,” and “protocols for patient orders” are various ways in which the term “standing orders” has been applied. The lack of a standard definition for these terms and their interchangeable and indistinct use by health care facilities professionals may result in confusion

CAHs are encouraged to focus on those situations where their use of “standing orders” permits treatment that is outside the scope of practice of a non-practitioner, such as a nurse, to be initiated by the non-practitioner without a prior specific order from a practitioner responsible for the care of the patient. Such treatment is typically initiated when a patient’s condition meets certain pre-defined clinical criteria. For example, standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order from a practitioner prior to the provision of care.

Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence. Much of the evidence on the effectiveness of standing orders has been narrowly focused on aspects of their use by Rapid Response Teams addressing inpatient emergencies. However, standing orders may also be appropriate in other clinical circumstances, including, but not limited to:

- Protocols for triaging and initiating required screening examinations and stabilizing treatment for emergency department patients presenting with symptoms suggestive of acute asthma, myocardial infarction, stroke, etc. (This

does not relieve a CAH of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, provide stabilizing treatment in a timely manner.)

- Post-operative recovery areas.
- Timely provision of immunizations, such as certain immunizations for newborns, for which there are clearly established and nationally recognized guidelines.

CAHs are encouraged to address at least the following in their standing orders policies and procedures:

- Review and approval of each standing order by a multi-disciplinary team that includes the following individuals or their designees: the MD/DO providing medical direction and the individuals designated responsible for nursing and pharmacy services.
 - The CAH should be able to document that the standing order is consistent with nationally recognized and evidence-based guidelines. This does not mean that there must be a template standing order available in national guidelines which the CAH copies, but rather that the content of each standing order the CAH uses is consistent with nationally recognized, evidence-based guidelines for providing care.
- Clear, specific criteria in the protocol for the order for authorized non-practitioners to initiate the execution of the order, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified.
- Instructions that the clinical staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders.
- At least annual review of each standing order as well as a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions based on changes in nationally recognized, evidence-based guidelines. Among other things, reviews should consider:
 - Whether there have been any preventable adverse patient events resulting from the use of the standing order, and if so, whether changes in the order would reduce the likelihood of future similar adverse events. The review would not be expected to address adverse events that are a likely outcome of the course of patient's disease or injury, even if the order was applied to that patient, unless there is concern that use of the standing order

exacerbated the patient's condition; and

- Whether a standing order has been initiated and executed in a manner consistent with the order's protocol, and if not, whether the protocol needs revision and/or staff need more training in the correct procedures.

Self-Administration of Medications

The CAH may choose to allow practitioners to write orders allowing patients to self-administer CAH-issued drugs and biologicals or drugs the patient has brought from home into the CAH for use during their stay, e.g., an insulin pen for a diabetic patient. If the CAH does permit this, it must develop policies and procedures for self-administration of drugs by patients or their informal caregivers.

Training

Medication administration education and training is typically included in the CAH's orientation or other continuing education programs for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication administration may include but are not limited to the following:

- Safe handling and preparation of drugs, biologicals, and IV medications;
- Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications; and
- Equipment, devices, special procedures, and/or techniques required for medication administration.

Policies and procedures must address the required components of the training and if the training provided during CAH orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

Basic safe practices for medication administration

The CAH's policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (often referred to as the "five rights" of medication administration practice):

- Right patient: the patient's identity— acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the CAH; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the CAH's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication

labeling prior to medication administration to ensure that the medication is being given to the correct patient.

- Right medication: the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;
- Right dose: the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);
- Right route: the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and
- Right time: the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

NOTE: The “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error. CAHs are also expected to comply with requirements for pharmacy services at §485.635(a)(3)(iv), using a systems approach to all components of the medication process.

For Information – Not Required/Not to be Cited

Recent literature* identifies up to nine “rights” of medication administration including:

- Right patient
- Right drug
- Right route
- Right time
- Right dose
- Right documentation
- Right action (appropriate reason)
- Right form
- Right response

However, other sources refer to 8 or 10 “rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 “rights.”

*Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.

CAHs are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly.

Timing of Medication Administration

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them. The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration. Consequently, the application of a uniform required window of time before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately. This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, CAH policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration. The policies and procedures must address at least the following:

- Medications **not eligible** for scheduled dosing times;
- Medications **eligible for** scheduled dosing times;
- Administration of eligible medications outside of their scheduled dosing times and windows; and
- Evaluation of medication administration timing policies, including adherence to them.

Medications or categories of medication not eligible for scheduled dosing times

The policies and procedures must identify medications or categories of medication which are not eligible for scheduled dosing times, either in general or in specific clinical applications. These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals.

The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors. Examples of medications that CAHs may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

- Stat doses (immediate);
- First time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);
- One-time doses; doses specifically timed for procedures;
- Time-sequenced doses; doses timed for serum drug levels;
- Investigational drugs; or
- Drugs prescribed on an as needed basis (PRN doses).

The policies and procedures must ensure timely administration of such medications. In addition they must specify if the policy for the administration of these medications will be applied throughout the CAH or only for specific CAH units or specific clinical situations or types of diagnoses.

Medications eligible for scheduled dosing times

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc. The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time.

Medication administration policies and procedures typically establish standardized dosing times for the administration of all ‘scheduled’ medications. For example, medications prescribed for BID (twice a day) administration might, under a given CAH’s policies and procedures, be scheduled to be administered at 8am and 8pm. Another CAH might choose to schedule BID medications at 7:30 am and 7:30 pm. Use of these standardized times facilitates the medication administration process, e.g., by providing to the CAH’s pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration. For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address: first dose medications, including parameters within which nursing staff are allowed to use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times; retiming of missed or omitted doses;

medications that will not follow scheduled dosing times; and patient units that are not subject to following the scheduled dosing times.

Time-critical scheduled medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. Accordingly, scheduled medications identified under the CAH's policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of one hour.

It is possible for a given medication to be time-critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients. Therefore, CAH policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical. Examples of time-critical scheduled medications/medication types may include, but are not limited to:

- Antibiotics;
- Anticoagulants;
- Insulin;
- Anticonvulsants;
- Immunosuppressive agents;
- Pain medication (non-IV);
- Medications prescribed for administration within a specified period of time of the medication order;
- Medications that must be administered apart from other medications for optimal therapeutic effect; or
- Medications prescribed more frequently than every 4 hours.

Non-time-critical scheduled medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm. For such medications greater flexibility in the timing of their administration is permissible. Specifically:

- Medications prescribed for daily, weekly or monthly administration may be within two hours before or after the scheduled dosing time, for a total window that does not exceed four hours.
- Medications prescribed more frequently than daily but no more frequently than every four hours may be administered within one hour before or after the scheduled dosing time, for a total window that does not exceed two hours.

Missed or late administration of medications

The CAH's policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time. This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration. Likewise, policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff are allowed to use their own judgment regarding the rescheduling of missed or late doses and when notification of the practitioner responsible for the care of the patient is required prior doing so. In either case, errors in the administration of medication must be reported internally as required at §485.635(a)(1)(v).

Evaluation of medication administration timing policies

CAHs must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration. Medication errors related to the timing of medication administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the CAH must consider whether there is a need to revise the policies and procedures governing medication administration timing.

Assessment/Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to

anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;

- Physical signs and clinical symptoms relevant to the patient’s medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.

Certain types of medications – “high alert medications” - are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients

For Information – Not Required/Not to be Cited

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. The current list may be found at:

<http://www.ismp.org/Tools/highAlertMedicationLists.asp>

In addition, certain factors place some patients at greater risk for adverse effects of medication. Factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea, patient weight (obesity may increase apnea or smaller patients may be more sensitive to dose levels of medications), asthma, history of smoking, drug-drug interactions, and first-time medication use may contribute to increased risk.

Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients’ medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are moved from a nursing for tests, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established CAH protocols.

An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient who is receiving pain medication via a patient controlled analgesia (PCA) pump. Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or

arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all parts of the CAH in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. (See also the discussion below for intravenous medications.)

As part of the monitoring process, staff are expected to include the patient's reports of his/her experience of the medication's effects. Further, when monitoring requires awakening the patient in order to assess effects of the medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. In addition, CAHs are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

CAH policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the CAH's requirements for the method(s) of communication.

IV Medications & Blood Transfusions

Many of the medications included in the high-alert categories are administered intravenously. CAH policies and procedures for IV medications must address at least the following:

Vascular Access Route

Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan. Safe administration of blood transfusions and IV medications includes the correct choice of vascular access. IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication's chemical properties or safety concerns. Hospital policies and procedures must address which medications can be given intravenously via what type of access.

Other Patient Safety Practices

In addition to the basic safe practices that apply to all medication administration, there are additional safe practices specific to IV medication administration that require consideration, including but not limited to, the following:

- Tracing invasive lines and tubes prior to administration to ensure the medication is to be administered via the proper route (for example, peripheral catheter versus epidural catheter connections);
- Avoiding forcing connections when the equipment offers clear resistance;

- Verifying proper programming of infusion devices (concentrations, flow rate, dose rate).

Monitoring patients receiving IV medications

To the extent that IV medications have a more rapid effect on the body, it is important that staff administering medications via IV understand each medication and its monitoring requirements. Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements, including assessment of patients for risk factors that would influence the type and frequency of monitoring.

For example: a 50 year old patient with a history of renal failure is receiving IV vancomycin to treat a wound infection. The CAH policy for IV antibiotics, including vancomycin, requires the patient's kidney function to be monitored daily with blood draws. Based on review of the lab results, a practitioner responsible for the care of the patient would be expected to determine on a timely basis whether or not the antibiotic dose needs to be adjusted to protect kidney function or prevent drug toxicity while achieving the desired therapeutic effects. Staff administering the medication would be expected to review the lab results as well, and to raise with a practitioner responsible for the care of the patient any concerns they might have about whether an adjustment in the medication is needed.

CAH policies and procedures related to monitoring patients receiving IV medications are expected to address, but are not limited to, the following:

- **Monitoring for Fluid & Electrolyte Balance**

Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance. Policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications.

- **Monitoring Patients Receiving High-alert Medications, Including IV Opioids**

Policies and procedures related to IV medication administration must address those medications the CAH has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously.

At a minimum, if the CAH provides surgical services, it is expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients.

Opioids are a class of medication used frequently to treat pain. The sedating effects of opioids make it difficult at times to properly assess the patient's level of sedation. It can be erroneously assumed that patients are asleep when

they are actually exhibiting progressive symptoms of respiratory compromise - somnolence, decreased respiratory rate, and decrease in oxygen levels. These symptoms, if unrecognized, can progress to respiratory depression and even death.

In addition to those patient characteristics that affect risk of adverse effects from medication discussed above, other factors placing patients receiving IV opioids at higher risk for oversedation and respiratory depression include, but are not limited to⁹:

- Snoring or history of sleep apnea
- No recent opioid use or first-time use of IV opioids
- Increased opioid dose requirement or opioid habituation
- Longer length of time receiving general anesthesia during surgery
- Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other central nervous system depressants
- Preexisting pulmonary or cardiac disease
- Thoracic or other surgical incisions that may impair breathing

Of particular concern are patients receiving IV opioids post-operatively.

The effects of IV opioids in post-operative patients must be monitored vigilantly via serial assessments of pain, respiratory status, and sedation levels.

CAHs that provide surgical services must have policies and procedures related to the use of high-alert medications, including IV opioids for post-operative patients. Policies and procedures must address, at a minimum, the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods. The policies and procedures must also address whether and under what circumstances practitioners prescribing IV opioids are allowed to establish protocols for IV opioid administration and monitoring that differ from the CAH's policies and procedures.

The frequency of the serial assessments and duration of the monitoring timeframe for post-operative patients receiving IV opioids must be determined based on at least the following considerations:

⁹ Jarzyna D., Junquist C., Pasero C., et al. American Society for Pain Management Nursing - Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression. *Pain Management Nursing*, Vol 12, No. 3 (September), 2011; pp 118-145

- Patient risk for adverse events;
- Opioid dosing frequency and IV delivery method. (push or patient-controlled analgesia (PCA));
- Duration of IV opioid therapy.

Regardless of the above factors, at a minimum monitoring must include the following:

- Vital signs (blood pressure, temperature, pulse, respiratory rate);
- Pain level;
- Respiratory status;
- Sedation level; sedation levels are important indicators for the clinical effects of opioids. Sedation is a useful assessment parameter to observe the effects of opioids since sedation typically precedes respiratory depression¹⁰. See the blue box below for information on sedation assessment methods.

For Information – Not Required/Not to be Cited

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

In addition to vigilant nursing assessment at appropriate intervals, CAHs may choose to use technology to support effective monitoring of patients' respiratory rate and oxygen levels.

For additional information regarding recommendations of expert organizations on post-operative opioid monitoring, including technology-supported monitoring, see blue boxes below. The practices described in the blue boxes below are not required under the regulations.

¹⁰ *Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013*

The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient in order to assess effects of the medications. In addition, CAHs are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

For Information – Not Required/Not to be Cited Institute for Safe Medication Practices Guidelines for PCA Monitoring						
Assessment of Opioid Tolerance	Vital Signs	Pain	Sedation	Respiratory		
				Rate	Quality	SPO₂* &/or ETCO₂**
Baseline Assessment before PCA	X	X	X	X	X	X
PCA Initiation or Change in Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
PCA Dose Change or Bolus Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Adverse Event or Patient Deterioration (e.g., adverse change in sedation score) Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours	X	X	X	X	X	X
Hand-offs/Shift Change	X	X	X	X	X	X
Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council * SPO ₂ : Saturation of peripheral oxygen via pulse oximetry ** ETCO ₂ : End-tidal carbon dioxide via capnography						

***For Information – Not Required/Not to be Cited
Anesthesia Patient Safety Foundation***

- *APSF calls for every patient receiving postoperative opioid analgesics to be managed based on the following clinical considerations*:*
 - *Individualize the dose and infusion rate of opioid while considering the unique aspects of each patient's history and physical status.*
 - *Make continuous monitoring of oxygenation (pulse oximetry) the routine rather than the exception.*
 - *Assess the need for supplemental oxygen, especially if pulse oximetry or intermittent nurse assessment are the only methods of identifying progressive hypoventilation.*
 - *When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.*

*APSF also has issued a video on opioid induced ventilatory impairment:
http://apsf.org/resources_video4.php*

**Stoelting, RK., Weinger MB. Dangers of postoperative opioids: Is there a Cure? APSF Newsletter 2009;24:2.*

***For Information – Not Required/Not to be Cited
The Patient Safety Movement Foundation***

PSMF recommends all patients receiving IV opioids have continuous measure-through motion and low perfusion pulse oximetry, and that patients on supplemental oxygen also have continuous respiration rate monitoring. It also calls for the monitoring system to be linked with a notification system to clinical staff who can respond immediately. It calls for an escalation protocol so that if a staff person does not acknowledge the alert in 60 seconds a second person will be notified.

The Patient Safety Movement Foundation - Actionable Patient Safety Solution (APSS) #1: Failure to Rescue: Post-Operative Respiratory Depression. January 13, 2013

Adverse patient reactions to IV medications require timely and appropriate intervention, per established protocols.

IV Blood Administration Procedures

According to the U.S. Department of Health and Human Services, 13,785,000 units of whole blood and red blood cells were transfused in the United States in 2011¹¹. The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. Blood transfusions can be life-saving. However, they are not without risk of harm to patients. Transfusion reactions and/or errors can be fatal.

In addition to the safe practices and other safety considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

- Confirming the following prior to each blood transfusion:
 - the patient's identity
 - verification of the right blood product for the right patient

The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.

- Requirements for patient monitoring, including frequency and documentation of monitoring
- How to identify, treat, and report any adverse reactions the patient may experience during or related to transfusion.

Documentation

Note that documentation of medication administration is addressed in the Medical Records CoP at §485.638(a)(4)(iii). This regulation requires that the record contain: "All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment...." Documentation is expected to occur after actual administration of the drugs or biologicals to the patient; advance documentation is not only inappropriate, but may result in medication errors. Proper documentation of medication administration actions taken and their outcomes is essential for planning and delivering future care of the patient. See the guidance for the various parts of §485.638 concerning documentation in the medical record. Deficiencies in documentation would be cited under the Clinical Records regulation.

¹¹ *The 2011 National Blood Collection and Utilization Survey Report. Retrieved September 27, 2013 from <http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf>*

Survey Procedures §485.635(d)(3)

- Ask the person responsible for nursing services what type of personnel administer drugs and biologicals, including IVs. Are they practicing within their permitted scope?
- If anyone other than an MD/DO, RN or PA administers drugs or biologicals, are they supervised by an RN or, if permitted under State law and CAH policy, a PA?
 - Verify that nursing staff administering drugs have completed training consistent with CAH training policy.
 - Review a sample of medication orders and determine if they contain the required elements:
- Determine if orders are legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient.
- Was the administration of the medication consistent with the order, i.e., the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and procedures? Check that the practitioner's order was still in force at the time the drug was administered.
- Ask nursing staff if the CAH permits verbal orders and, if so, what the policy is for a verbal order. If staff are unaware of any policy, or if their description of a policy suggests it is incomplete or inconsistent with accepted standards of practice, ask to see the written policy.
- Ask nursing staff whether they initiate medications in accordance with standing orders. Are they familiar with the hospital's policies and procedures for using standing orders? Are they following the policies and procedures? Ask to see the protocol for a standing order used by nursing staff, and ask nursing staff to explain how their practice conforms to the protocol.
 - Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner.
- Ask nursing staff if the CAH permits patient self-administration of medications.
 - If yes, does the CAH have policies and procedures addressing this?

- Is there an order from a practitioner responsible for the care of the patient permitting self-administration of medications, either issued by the CAH or brought from home?
- Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed.
 - Is the patient's identity confirmed prior to medication administration?
 - Are procedures to assure the correct medication, dose, and route followed?
 - Are drugs administered in accordance with the hospital's established policies and procedures for timely medication administration?
 - Does the nurse remain with the patient until medication is taken, unless they are permitted to self-administer?
- Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?
- Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?
 - Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?
- Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.
 - Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?
 - Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?
- Interview nursing staff who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:
 - Venipuncture techniques;
 - Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps;

- Maintaining fluid and electrolyte balance;
- Patient assessment for risk related to IV medications and appropriate monitoring;
- Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients;
- With respect to blood transfusions:
 - Blood components;
 - Process for verification of the right blood product for the right patient; and
 - Transfusion reactions: identification, treatment, and reporting requirements.
- If able, observe blood transfusion and IV medication administration to assess staff adherence to accepted standards of practice.
 - Were safe medication administration practices used?
 - Was the transfused patient correctly identified and matched to the correct blood product prior to administration?
 - Was the appropriate access used for IV medications?
 - Were appropriate steps taken with regard to IV tubing and infusion pumps?
 - Are patients being monitored post-infusion for adverse reactions?
- If staff appear to not be following accepted standards of practice for patient risk assessment related to IV medications, particularly opioids, and appropriate monitoring of patients receiving IV medications and/or blood transfusions, review policies and procedures for IV medication administration and blood transfusion to determine if they address safe practices considerations.

C-1050
(Rev.)

§485.635(d)(4) A nursing care plan must be developed and kept current for each inpatient.

Interpretive Guidelines §485.635(d)(4)

There must be a nursing care plan for every CAH inpatient. Nursing care planning starts

upon admission. It includes planning the patient's care while in the CAH as well as planning for transfer to a hospital, to a post-acute care facility or for discharge. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs. One resource for information about nursing care plans is The American Nurses Association <https://www.nursingworld.org/practice-policy/workforce/what-is-nursing/the-nursing-process/>.

The nursing care plan is kept current by ongoing assessments of the patient's needs and of the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's clinical record and must comply with the clinical records requirements at §485.638.

CAHs have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient's care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient's health care team.

Survey Procedures §485.635(d)(4)

Select a representative sample of nursing care plans based on the number of inpatient records reviewed.

- Are the care plans created as soon as possible after admission for each patient?
- Are the care plans based on the nurse's assessment of the individual patient?
- Is there evidence that the care plans are reviewed on an ongoing basis?
- Is there evidence that the nursing care plan is revised as needed and is there documentation of nursing reassessment?
- Verify that there is evidence that the nursing care plans have been implemented.

C-1052
(Rev.)

§485.635(e) Standard: Rehabilitation Therapy Services

Physical therapy, occupational therapy, and speech-language therapy pathology services furnished at the CAH, if provided, are provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17 of

this subpart.

Interpretive Guidelines §485.635(e)

Rehabilitation services are optional CAH services. If a CAH provides any rehabilitative services to its patients, either directly or under arrangement or agreement, either inpatient or outpatient, the services must be provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17. Rehabilitation services can be initiated only upon the order of a practitioner responsible for the care of the patient. Physical therapy, occupational therapy, or speech-language pathology must be furnished in accordance with the regulation at 42 CFR 409.17, which specifies the following rehabilitation services plan of care requirements:

- Establishment of the plan: “The plan must be established before treatment begins by one of the following: (1) A physician; (2) A nurse practitioner, a clinical nurse specialist or a physician assistant; (3) The physical therapist furnishing the physical therapy services; (4) A speech-language pathologist furnishing the speech-language pathology services; (5) An occupational therapist furnishing the occupational therapy services.”
- Content of the plan: “The plan: (1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and (2) Indicates the diagnosis and anticipated goals.”
- Changes in the plan: “Any changes in the plan are implemented in accordance with the provider’s policies and procedures.”

Also in accordance with 42 CFR 409.17, rehabilitation services must be provided by qualified physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists who meet the personnel qualifications defined in 42 CFR 484.4. CAHs must have policies and procedures consistent with State law.

Rehabilitation services must be provided according to national standards of practice as established by professional organizations such as, but not limited to, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association.

Survey Procedures §485.635(e)

If the CAH provides rehabilitation services:

- Review clinical records of patients who received rehabilitation services. Determine whether the required care plan was developed and implemented.

- Review employee personnel files to verify the rehabilitation service providers (i.e., physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists) have the necessary education, experience, training, and documented competencies to provide rehabilitation services.
- Ask the CAH what national standards of rehabilitation practice provide the basis for its rehabilitation services. Is there supporting documentation?

C-1054
(Rev.)

§485.635(f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation....

Interpretive Guidelines §485.635(f)

Visitation plays an important role in the care of hospital patients, including CAHs. An article published in 2004 in the Journal of the American Medical Association (Berwick, D.M., and Kotagal, M.: “Restricted visiting hours in ICUs: time to change.” JAMA. 2004; Vol. 292, pp. 736-737) discusses the health and safety benefits of open visitation for patients, families, and intensive care unit (ICU) staff and debunks some of the myths surrounding the issue (physiologic stress for the patient; barriers to provision of care; exhaustion of family and friends). The article ultimately concluded that “available evidence indicates that hazards and problems regarding open visitation are generally overstated and manageable,” and that such visitation policies “do not harm patients but rather may help them by providing a support system and shaping a more familiar environment” as they “engender trust in families, creating a better working relationship between hospital staff and family members.” CAHs that unnecessarily restrict patient visitation often miss an opportunity to gain valuable patient information from those who may know the patient best with respect to the patient’s medical history, conditions, medications, and allergies, particularly if the patient has difficulties with recall or articulation, or is totally unable to recall or articulate this vital personal information. Many times visitors who may know the patient best act as an intermediary for the patient, helping to communicate the patient’s needs to CAH staff.

Although visitation policies are generally considered to relate to visitors of inpatients, “visitors” also play a role for outpatients who wish to have a support person present during their outpatient visit. For example, a same-day surgery patient may wish to have a support person present during the pre-operative patient preparation or post-operative recovery. Or an outpatient clinic patient may wish to have a support person present during their examination by a physician. Accordingly, CAH visitation policies must address both the inpatient and outpatient settings.

CAHs are required to develop and implement written policies and procedures that address the patient's right to have visitors. If the CAH's policy establishes restrictions or limitations on visitation, such restrictions/limitations must be clinically necessary. Furthermore, the CAH's policy must include the reasons for any restrictions/limitations. The right of a patient to have visitors may be limited or restricted when visitation would interfere with the care of the patient and/or the care of other patients. The regulation permits CAHs some flexibility, so that health care professionals may exercise their best clinical judgment when determining when visitation is, and is not, appropriate. Best clinical judgment takes into account all aspects of patient health and safety, including the benefits of visitation on a patient's care as well as potential negative impacts that visitors may have on other patients in the CAH.

Broad examples of clinically reasonable bases for a CAH to impose restrictions or limitations on visitors might include (but are not limited to) when:

- there may be infection control issues;
- visitation may interfere with the care of other patients;
- the CAH is aware that there is an existing court order restricting contact;
- visitors engage in disruptive, threatening, or violent behavior of any kind;
- the patient or patient's roommate needs rest or privacy;
- in the case of an inpatient substance abuse treatment program, there are protocols limiting visitation; and
- the patient is undergoing care interventions. However, while there may be valid reasons for limiting visitation during a care intervention, we encourage CAHs to try to accommodate the needs of any patient who requests that at least one visitor be allowed to remain in the room to provide support and comfort at such times.

It may also be reasonable to limit the number of visitors for any one patient during a specific period of time, as well as to establish minimum age requirements for child visitors. However, when a CAH adopts policies that limit or restrict patients' visitation rights, the burden of proof is upon the CAH to demonstrate that the visitation restriction is reasonably necessary to provide safe care.

CAHs are expected to provide a clear explanation in their written policy of the clinical rationale for any visitation restrictions or limitations reflected in that policy. CAHs are not required, however, to delineate each specific clinical reason for policies limiting or restricting visitation, given that it is not possible to anticipate every instance that may give rise to a clinically appropriate rationale for a restriction or limitation. If visitation policies differ by type of unit, e.g., separate policies for intensive care units, or for

newborn nurseries, the CAH policy must address the clinical rationale for this differentiation explicitly.

The CAH's policies and procedures are expected to address how CAH staff who play a role in facilitating or controlling visitor access to patients will be trained so as to assure appropriate implementation of the visitation policies and procedures and avoidance of unnecessary restrictions or limitations on patients' visitation rights.

Survey Procedures §485.635(f)

- Verify that the CAH has written policies and procedures that address the right of patients to have visitors.
- Review the policy to determine if there are limitations or restrictions on visitation. If there are, does the policy explain the clinical rationale for the restrictions or limitations? Is the rationale clear and reasonably related to clinical concerns?
- Is there documentation of how the CAH identifies and trains staff who play a role in facilitating or limiting/restricting access of visitors to patients?
- Are CAH staff aware of the visitation policies and procedures? Can staff on a given unit correctly describe the CAH's visitation policies for that unit?

C-1056 ***(Rev.)***

§485.635(f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

Interpretive Guidelines §482.635(f)(1)&(2)

CAHs are required to inform each patient (or the patient's support person, where appropriate) of his/her visitation rights. A patient's "support person" does not necessarily

have to be the same person as the patient's representative designated under an advance directive who is legally responsible for making medical decisions on the patient's behalf. A patient's support person could be a family member, friend, or other individual who supports the patient during the course of the CAH stay. Not only may the support person visit the patient, but he or she may also exercise a patient's visitation rights on behalf of the patient with respect to other visitors, when the patient is unable to do so. CAHs must accept a patient's designation, orally or in writing, of an individual as the patient's support person.

When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no advance directive designating a representative on file, and an individual provides an advance directive designating an individual as the patient's support person, (it is not necessary for the document to use this exact term), the CAH must accept this designation, provide the required notice of the patient's visitation rights, and allow the individual to exercise the patient's visitation rights on the patient's behalf.

When a patient is incapacitated or otherwise unable to communicate his or her wishes and no one has presented an advance directive designating them as the patient's support person, but an individual asserts that he or she, as the patient's spouse, domestic partner (including a same-sex domestic partner), parent or other family member, friend, or otherwise, is the patient's support person, the CAH is expected to accept this assertion, without demanding supporting documentation, provide the required notice of the patient's visitation rights, and allow the individual to exercise the patient's visitation rights on the patient's behalf. However, if more than one individual claims to be the patient's support person, it would not be inappropriate for the CAH to ask each individual for documentation supporting his/her claim to be the patient's support person.

- CAHs are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient's support person, given the critical role of the support person in exercising the patient's visitation rights.
- A refusal by the CAH of an individual's request to be treated as the patient's support person with respect to visitation rights must be documented in the patient's medical record must, along with the specific basis for the refusal.

The required notice of the patient's visitation rights must be provided, whenever possible, before the CAH provides patient care. The notice to patients must be in writing in a language or manner that the patient (or the patient's support person) can understand. This is consistent with the guidance related to Title VI of the Civil Rights Act of 1964 issued by the Department of Health and Human Services - "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" (August 8, 2003, 68 FR 47311). In accordance with §485.608(a), CAHs are expected to comply with Title VI and may use this guidance to assist the CAH in ensuring patient's rights information is provided in a language and manner that the patient understands. Surveyors do not assess

compliance with this guidance on limited English proficiency, but may refer concerns about possible noncompliance to the Office of Civil Rights in the applicable Department of Health and Human Services Regional Office.

The required visitation rights notice must address any clinically necessary or reasonable limitations or restrictions imposed by CAH policy on visitation rights, providing the clinical reasons for such limitations/restrictions, including how they are aimed at protecting the health and safety of all patients. The information must be sufficiently detailed to allow a patient (or the patient's support person) to determine what the visitation hours are and what restrictions, if any, apply to that patient's visitation rights.

The notice must also inform the patient (or the patient's support person, where appropriate) of the patient's right to:

- Consent to receive visitors he or she has designated, either orally or in writing, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend;
- Receive the visitors he or she has designated, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend; and
- Withdraw or deny his/her consent to receive specific visitors, either orally or in writing.

The medical record must contain documentation that the required notice was provided to the patient or, if appropriate, the patient's support person.

Survey Procedures §485.635(f)(1) & (2)

- Determine whether the CAH's visitation policies and procedures require providing notice of the patient's visitation rights to each patient or, if appropriate, to a patient's support person and/or, as applicable, the patient's representative .
- Review the CAH's standard notice of visitation rights. Does it clearly explain the:
 - CAH's visitation policy, including any limitations or restrictions, such as visiting hours, numbers of visitors, or unit-specific restrictions, etc., and the clinical rationale for such limitations or restrictions?
 - right of the patient to have designated visitors, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and the right to withdraw or deny consent to visitation?

- Review a sample of medical records to determine if there is documentation that the required notice was provided and if it was provided in advance of care, unless circumstances made this not feasible.
- Ask the CAH to identify how the required notice is provided. Ask staff responsible for providing the notice how they accomplish this. Ask the staff if they are familiar with the concept of a patient’s “support person” and what it means.
- Ask a sample of current CAH patients or patients’ support persons (where appropriate) whether they were provided notice of their right to have visitors. Ask if they were able to have visitors when they wanted to. If not, verify whether the restriction/limitation on visitors was addressed in the CAH’s visitation policies and notice, or was inappropriate.
- Ask a sample of current CAH patients or patients’ support persons (where appropriate) whether the CAH did not limit some or all visitors, contrary to the patient’s wishes.

C-1058
(Rev.)

§485.635(f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

Interpretive Guidelines §485.635(f)(3)&(4)

The CAH’s visitation policies and procedures may not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient’s support person, where appropriate) or the patient’s visitors (including individuals seeking to visit the patient) as a basis for limiting, restricting, or otherwise denying visitation privileges.

The CAH’s policies and procedures must ensure that all visitors (including individuals seeking to visit the patient) enjoy full and equal visitation privileges, consistent with the preferences the patient (or, where appropriate, the patient’s support person) has expressed

concerning visitors. In other words, it is permissible for the patient (or the patient's support person, where appropriate) to limit the visiting privileges of his/her visitors, including providing for more limited visiting privileges for some visitors than those for others. But it is not permissible for the CAH, on its own, to differentiate among visitors without any clinically necessary or reasonable basis. This includes visitors designated by the patient who have characteristics not addressed specifically in §485.635(f)(3), when those characteristics do not reasonably relate to a clinically reasonable basis for limiting or denying visitation. For example, it would not be appropriate to prohibit a designated visitor based on that individual's style of dress, unless there was a clinically reasonable basis for doing so.

The CAH is responsible for ensuring that CAH staff treat all individuals seeking to visit patients equally, consistent with the preferences of the patient (or, where appropriate, the patient's support person) and do not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient's support person, where appropriate) or the patient's visitors (including individuals seeking to visit the patient) as a basis for limiting, restricting, or otherwise denying visitation privileges. CAHs are expected to educate all staff who play a role in facilitating or controlling visitors on the CAH's visitation policies and procedures, and are responsible for ensuring that staff implement the CAH's policies correctly. CAHs are urged to develop culturally competent training programs designed to address the range of patients served by the CAH.

Survey Procedures §485.635(f)(3)&(4)

- Review the CAH's visitation policies and procedures to determine whether they restrict, limit, or otherwise deny visitation to individuals on a prohibited basis.
- Ask the CAH how it educates staff to assure that visitation policies are implemented in a non-discriminatory manner.
- Ask CAH staff who play a role in facilitating or controlling visitors to discuss their understanding of the circumstances under which visitors may be subject to restrictions/limitations. Are the restrictions/limitations appropriately based on the CAH's clinically-based policies?
- Ask CAH patients (or patients' support persons, where appropriate) whether the CAH has limited visitors against their wishes? If yes, verify whether the restriction/limitation on visitors was addressed in the CAH's visitation policies and in the patient notice, and whether it was appropriately based on a clinical rationale rather than impermissible discrimination.

C-1100
(Rev.)

§485.638 Condition of Participation: Clinical Records

C-1102
(Rev.)

§485.638(a) Standard: Records System

(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

Interpretive Guidelines §485.638(a)(1)

The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry. The medical record system must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records.

The CAH must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry.

If the CAH uses computer entries there must be security system in place to ensure the integrity of the record system, to ensure that the author of each entry is correctly identified, to ensure that record entries are not altered or lost, that limits access to medical records to only authorized persons, and ensures that records are not released to unauthorized individuals. For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirements for a signature.

There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. CAH policies and procedures should provide for appropriate sanctions for unauthorized or improper use of computer codes or signature stamps.

The CAH must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH. A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be used for both stays as long as the record is sectioned separately. Both sections must include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents,

any other pertinent documents, and discharge summaries.

The medical record must be properly filed and retained. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the CAH within the past 6 years.

The medical record must be accessible. The CAH must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the CAH within the past 6 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Survey Procedures §485.638(a)(1)

- Verify that a medical record is maintained for each person receiving care.
- Verify that written procedures ensure the integrity of authentication and protect the security of patient records.
- Verify that medical records are stored and maintained in locations where the records are secure, with protection from damage, flood, fire, theft, etc., and limits access to only authorized individuals.
- Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed.
- Verify that there is an established system that addresses at least the following activities of the medical records services:
 - Timely processing and retrieval of records;
 - Protecting the confidentiality of medical information;
 - Compiling and retrieval of data of quality assurance activities.
- Verify that the system policies and procedures are reviewed and revised as needed.
- Verify that the CAH employs adequate medical record personnel who possess adequate education, skills, qualifications and experience to ensure the CAH complies with requirements of the medical records regulations and other appropriate Federal and State laws and regulations.
- Are medical records promptly completed in accordance with State law and CAH policy?
- Select a sample of past patients of the CAH (inpatient and/or outpatient). Request

those patient's medical records. Can the CAH promptly retrieve those records?

C-1104

(Rev.)

§485.638(a)(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.638(a)(2)

All medical records must be accurately written. The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

Survey Procedures §485.638(a)(2)

For CAH surveys that are conducted after the initial certification survey, examine a sample of records using an adequate sample size to evaluate the scope of services provided. In a very small CAH, look at all inpatient and outpatients records, if appropriate.

C-1106

(Rev.)

§485.638(a)(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

Interpretive Guidelines §485.638(a)(3)

The CAH must have one unified medical record service with a department head that has been appointed by the governing body (or responsible individual). The director of medical records must have responsibility for all medical records to include both inpatient and outpatient records.

Survey Procedures §485.638(a)(3)

- Verify that the CAH employs adequate medical record personnel.
- Review the organizational structure and policy statements and interview the person responsible for the service to ascertain that the medical records service is structured appropriately to meet the needs of the CAH and the patients.

C-1110

(Rev.)

§485.638(a)(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable--

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

Interpretive Guidelines §485.638(a)(4)(i)

The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent.

Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.

A properly executed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedures(s);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.

The medical record must contain information such as progress and nursing notes, documentation, records, reports, recordings, test results, assessments etc. to:

- Justify admission;
- Support the diagnosis;

- Describe the patient's progress;
- Describe the patient's response to medications; and
- Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding medical history, assessment of the health status and health care needs of the patient, and a summary of the episode, disposition, and instructions to the patient. This information and documentation is contained in a discharge summary.

A discharge summary discusses the outcome of the CAH stay, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post CAH appointment, how post CAH patient care needs are to be met, and any plans for post-CAH care by providers such as swing-bed services, home health, hospice, nursing homes, or assisted living. A discharge summary is required following any CAH acute care stay prior to and following a swing-bed admission and discharge.

The MD/DO or other qualified practitioner with admitting privileges in accordance with State law and CAH policy, who admitted the patient is responsible for the patient during the patient's stay in the CAH. This responsibility would include developing and entering the discharge summary.

The MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and physician assistants to the extent recognized under State law or a State's regulatory mechanism. The MD/DO may also delegate writing the discharge summary to another MD/DO who is familiar with the patient.

Survey Procedures §485.638(a)(4)(i)

- Verify that the medical staff have specified which procedures or treatments require a written informed consent.
- Verify that medical records contain consent forms for all procedures or treatment that are required by CAH policy.
- Verify that consent forms are properly executed.
- Examine a sample of patient records and/or facility records of requests for information contained in patient records to determine if there are signed and dated consent forms, when required, medical history, health status and care needs assessment, and discharge summary in each record, as needed.
- Review of sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and CAH

policy. The sample should be at least 10 percent of the average daily census, as appropriate.

C-1114
(Rev.)

§485.638(a)(4)(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

Interpretive Guidelines §485.638(a)(4)(ii)

All or part of the history and physical exam (H & P) may be delegated to other practitioners in accordance with State law and CAH policy, but the MD/DO must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P.

Survey Procedures §485.638(a)(4)(ii)

- Determine that the bylaws require a physical examination and medical history be done for each patient.
- For sampled records, does the appropriate practitioner sign reports of physical examinations, diagnostic and laboratory test results, and consultative findings?

C-1116
(Rev.)

§485.638(a)(4)(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

Interpretive Guidelines §485.638(a)(4)(iii)

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record. In order for necessary information to be used it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve this information in order to monitor the patient's condition and provide appropriate care.

The medical record must contain:

- All practitioner's orders (properly authenticated);
- All nursing notes;

- All reports of treatment (including complications and CAH-acquired infections);
- All medication records (including unfavorable reactions to drugs);
- All radiology reports;
- All laboratory reports;
- All vital signs; and
- All other information necessary to monitor the patient's condition.

All medical records must be promptly completed. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care.

Survey Procedures §485.638(a)(4)(iii)

- Verify that the patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports and other information necessary to monitor the patient's condition.
- Is necessary information included in patient records in a prompt manner so that health care staff involved in the care of the patient have access to the information necessary to monitor the patient's condition?

C-1118
(Rev.)

§485.638(a)(4)(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

Interpretive Guidelines §485.635(a)(4)(iv)

Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual.

A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

All entries in the medical record must be authenticated.

Authentication would include at a minimum:

- The CAH has a method to establish the identity of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.
- The author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, that the entry is accurate.
- The timing of the entry is noted and correct.

Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries are necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events. There must be a specific action by the author to indicate that the entry is, in fact, verified and accurate. Failure to disapprove an entry within a specific time period is not acceptable as authentication.

A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.

Survey Procedures §485.635(a)(4)(iv)

- Verify that entries are authenticated.

- Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.
- Verify that computer or other code signatures are authorized by the CAH'S governing body and that a list of these codes is maintained under adequate safeguards by the CAH administration.
- Verify that the CAH'S policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.
- Examine the CAH'S policies and procedures for using the system, and determine if documents are being authenticated after transcription.
- For sampled records, are there dated and authenticated signatures by appropriate MD/DOs and/or mid-level practitioners, as needed?

C-1120
(Rev.)

§485.638(b) Standard: Protection of Record Information

(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

Interpretive Guidelines §485.638(b)(1)

The CAH has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, policy; or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. CAH staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

Survey Procedures §485.638(b)(1)

- Verify that only authorized persons are permitted access to records maintained by

the medical records department.

- Verify that the CAH has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., practitioner responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient.
- Verify that medical records are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with Federal or State law, court orders, or subpoenas.
- Verify that copies of medical records are released outside the CAH only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by statutes.
- Verify that precautions are taken to prevent unauthorized persons from gaining access to or altering patient records.
- Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

C-1122

(Rev.)

§485.638(b)(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

Interpretive Guidelines §485.638(b)(2)

The CAH'S patient record system must ensure the security of patient records. The CAH must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the CAH and outpatients in outpatient clinics.

Survey Procedures §485.638(b)(2)

- Observe the CAH'S security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records?
- If the CAH uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?

- Verify that the CAH has policies and procedures for the use and release of records and that these policies and procedures are enforced.

C-1124

(Rev.)

§485.638(b)(3) The patient's written consent is required for release of information not required by law.

C-1126

(Rev.)

§485.638(c) Standard: Retention of Records

The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

Interpretive Guidelines §485.638(c)

Medical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The CAH must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the CAH within the last 6 years.

In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 6 years (for example: FDA, OSHA, EPA).

Survey Procedures §485.638(c)

Determine that records are retained for at least 6 years, or more if required by State or local laws.

C-1140

(Rev.)

§485.639 Condition of Participation: Surgical Services.

If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section.

Interpretive Guidelines §485.639

The provision of surgical services is an optional CAH service. However, if a CAH

provides surgical services to its patients, the services must be organized and staffed in such a manner to ensure the health and safety of patients. Surgical services that are performed in a safe manner would be performed in accordance with acceptable standards of practice. In accordance with acceptable standards of practice includes maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of periOperative Registered Nurses, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the CAH'S outpatient surgical services must be integrated with the CAH's inpatient surgical services.

When the CAH offers surgical services, the CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the CAH in accordance with acceptable standards of practice.

The scope of surgical services provided by the CAH should be defined in writing and approved by the governing body or responsible individual.

Supervision in the OR

The operating room must be supervised by an experienced staff member authorized by State law. The supervisor's experience could include education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH'S operating rooms in its policies. If the CAH utilizes LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required in State law.

Policies and Procedures

Policies governing surgical care should contain:

- Aseptic surveillance and practice, including scrub techniques
- Identification of infected and non-infected cases
- Housekeeping requirements/procedures
- Patient care requirements
 - Preoperative work-up
 - Patient consents and releases

- Clinical procedures
- Safety practices
- Patient identification procedures
- Duties of scrub and circulating nurse
- Safety practices
- The requirement to conduct surgical counts in accordance with accepted standards of practice
- Scheduling of patients for surgery
- Personnel policies unique to the OR
- Resuscitative techniques
- DNR status
- Care of surgical specimens
- Malignant hyperthermia
- Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments.
- Sterilization and disinfection procedures
- Acceptable operating room attire
- Handling infections and biomedical/medical waste

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Pre-Operative History and Physical (H & P)

A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. All or part of the H & P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant,

meeting these criteria, may perform the H & P.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

Informed Consent

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's

explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits.

Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Post-Operative Care/Recovery

Adequate provisions for immediate post-operative care means:

- Post operative care must be in accordance with acceptable standards of practice.
- The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel.
- Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:
 - Level of activity
 - Respirations
 - Blood pressure
 - Level of consciousness
 - Patient color
- If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.

Operating Room Register

The register should include at least the following information:

- Patient's name
- Patient's CAH identification number
- Date of the operation
- Inclusive or total time of the operation
- Name of the surgeon and any assistant(s)
- Name of nursing personnel (scrub and circulating)
- Type of anesthesia used and name of person administering it
- Operation performed
- Pre and post-op diagnosis
- Age of patient

Operative Report

The operative report would include at least:

- Name and CAH identification number of the patient;
- Date and times of the surgery;
- Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
- Pre-operative and post-operative diagnosis;
- Name of the specific surgical procedure(s) performed;
- Type of anesthesia administered;
- Complications, if any;
- A description of techniques, findings, and tissues removed or altered;
- Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and

closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and

- Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §485.639

- Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:
 - That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;
 - The conformance to aseptic and sterile technique by all individuals in the surgical area;
 - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;
 - That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical attire, that surgical attire is designed for maximum skin and hair coverage;
 - That equipment is available for rapid and routine sterilization of operating room materials and that equipment is monitored, inspected, tested, and maintained by the CAH'S biomedical equipment program; and
 - That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.
- Review the CAH'S organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.
- If LPNs and surgical technologists (STs) are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures.
- Verify in situations where LPNs and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies.

- Review policies and procedures, to ascertain whether they contain the minimum policies specified in the interpretive guidelines.
- Review a sample of medical records of surgical patients to determine if a complete history and physical examination by a surgeon is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.
- Review a sample of medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.
- Check to determine that the operating room suite has available the items listed.
 - On-call system
 - Cardiac monitor
 - Resuscitator
 - Defibrillator
 - Aspirator (suction equipment)
 - Tracheotomy set (a cricothyroidotomy set is not a substitute)
- Verify that all equipment is working and, as applicable, in compliance with the CAH'S biomedical equipment inspection, testing, and maintenance program.
- Verify that the CAH has provisions for post-operative care.
- Determine that there are policies and procedures that govern the recovery room area.
- Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.
- Review a sample of medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

C-1142
(Rev.)

§485.639(a) Standard: Designation of Qualified Practitioners

The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by--

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

Interpretive Guidelines §485.639(a)

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must be retained in these area/locations.

The CAH must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the CAH'S QA program, credentialing process, the practitioner's adherence to CAH policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The CAH must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DOs, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is in the same OR in line of sight) be delineated in that practitioner's surgical privileges and included on the surgical roster.

When practitioners whose scope of practice for conducting surgical procedures requires the supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted surgical privileges in accordance with those criteria established by the governing body (or

responsible individual), and who is working within the scope of those granted and documented privileges.

Survey Procedures §485.639(a)

- Review the CAH'S method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.
- Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.
- Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

C-1144
(Rev.)

§485.639(b) Standard: Anesthetic Risk and Evaluation

- (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.**
- (2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.**
- (3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.**

Interpretive Guidelines §485.639(b)

The pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery. The pre-anesthesia evaluation must be performed by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation should include:

- Notation of anesthesia risk
- Anesthesia, drug and allergy history
- Any potential anesthesia problems identified
- Patient's condition prior to induction of anesthesia

The post-anesthesia follow-up report must be written on all inpatients and outpatients prior to discharge from surgery and anesthesia services. The post-anesthesia evaluation must be written by the individual who is qualified to administer the anesthesia. An MD/DO may delegate the post-anesthesia assessment and the writing of the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with State law and CAH policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. The post-anesthesia follow-up report must be documented in the patient's medical record, whether the patient is an inpatient or outpatient of the CAH, and must include at a minimum:

- Cardiopulmonary status;
- Level of consciousness;
- Any follow-up care and/or observations; and
- Any complications occurring during post-anesthesia recovery.

Survey Procedures §485.639(b)

- Review records to determine that each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed prior to surgery.
- Review medical records to determine that a post-anesthesia follow-up report is written for each patient receiving anesthesia services, by the individual who administered the anesthesia prior to discharge from anesthesia services. Documentation should include those items specified in interpretive guidelines.

C-1145
(Rev.)

§485.639(c) Standard: Administration of Anesthesia

The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only--

- (i) A qualified anesthesiologist;**
- (ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;**

- (iii) A doctor of dental surgery or dental medicine;**
- (iv) A doctor of podiatric medicine;**
- (v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;**
- (vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter;
or**
- (vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.**

Interpretive Guidelines §485.639(c)(1)

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The CAH must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and CAH policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, State law, the individual competencies of the practitioner and the practitioner's compliance with the CAH'S credentialing criteria.

When a CAH permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise. A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §485.639(e)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. Available to immediately intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is:

- Physically located within the operative suite or in the labor and delivery unit; and
- Is prepared to immediately conduct hands-on intervention if needed; and
- Is not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed

Survey Procedures §485.639(c)(1)

- Review the qualifications of individuals authorized to deliver anesthesia.
- Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

C-1147 ***(Rev.)***

§485.639(c)(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

C-1149 ***(Rev.)***

§485.639(d) Standard: Discharge

All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

Interpretive Guidelines §485.639(d)

Any exceptions to this requirement must be made by the attending practitioner and annotated on the clinical record.

Survey Procedures §485.639(d)

Verify that the CAH has policies and procedures in place to govern discharge procedures and instructions.

C-1150 ***(Rev.)***

§485.639(e) Standard: State Exemption

(1) A CAH may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has

concluded that it is in the best interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

C-1200
(Rev.)

§485.640 Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs

The CAH must have active facility-wide programs, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in coordination with the facility-wide quality assessment and performance improvement (QAPI) program.

Interpretive Guidelines §485.640

Guidance is pending and will be updated in future release.

Survey Procedures §485.640

Survey Procedures are pending and will be updated in future release.

C-1204
(Rev.)

§485.640(a) Standard: Infection prevention and control program organization and policies. The CAH must demonstrate that:

- (1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;***

Interpretive Guidelines §485.640(a)(1)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(a)(1)

Survey Procedures are pending and will be updated in future release.

***C-1206
(Rev.)***

§485.640(a)(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings;

Interpretive Guidelines §485.640(a)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(a)(2)

Survey Procedures are pending and will be updated in future release.

***C-1208
(Rev.)***

§485.640(a)(3) The infection prevention and control includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and

Interpretive Guidelines §485.640(a)(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(a)(3)

Survey Procedures are pending and will be updated in future release.

***C-1210
(Rev.)***

§485.640(a)(4) The infection prevention and control program reflects the scope and complexity of the CAH services provided.

Interpretive Guidelines §485.640(a)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(a)(4)

Survey Procedures are pending and will be updated in future release.

C-1212

(Rev. - Effective March 30, 2020)

§485.640(b) Standard: Antibiotic stewardship program organization and policies

The CAH must demonstrate that:

- (1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;***

Interpretive Guidelines §485.640(b)(1)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(b)(1)

Survey Procedures are pending and will be updated in future release.

C-1218

(Rev. - Effective March 30, 2020)

§485.640(b)(2) The facility-wide antibiotic stewardship program:

- (i) Demonstrates coordination among all components of the CAH responsible or antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;***

Interpretive Guidelines §485.640(b)(2)(i)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(b)(2)(i)

Survey Procedures are pending and will be updated in future release.

C-1219

(Rev. - Effective March 30, 2020)

§485.640(b)(2)(ii) Documents the evidence-based use of antibiotics in all departments and services of the CAH; and

Interpretive Guidelines §485.640(b)(2)(ii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(b)(2)(ii)

Survey Procedures are pending and will be updated in future release.

C-1220

(Rev. - Effective March 30, 2020)

§485.640(b)(2)(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

Interpretive Guidelines §485.640(b)(2)(iii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(b)(2)(iii)

Survey Procedures are pending and will be updated in future release.

C-1221

(Rev. - Effective March 30, 2020)

§485.640(b)(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

Interpretive Guidelines §485.640(b)(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(b)(3)

Survey Procedures are pending and will be updated in future release.

C-1223

(Rev. - Effective March 30, 2020)

§485.640(b)(4) The antibiotic stewardship program reflects the scope and complexity of the CAH services provided.

Interpretive Guidelines §485.640(b)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(b)(4)

Survey Procedures are pending and will be updated in future release.

C-1225

(Rev.)

§485.640(c) Standard: Leadership responsibilities

(1) The governing body, or responsible individual, must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

Interpretive Guidelines §485.640(c)(1)(i)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(1)(i)

Survey Procedures are pending and will be updated in future release.

C-1229

(Rev.)

[(c) Standard: Leadership responsibilities]

§485.640(c)(1)(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the CAH's QAPI leadership.

Interpretive Guidelines §485.640(c)(1)(ii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(1)(ii)

Survey Procedures are pending and will be updated in future release.

C-1231

(Rev.)

[\$485.640(c) Standard: Leadership responsibilities]

(2) The infection prevention and control professional(s) is responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

Interpretive Guidelines §485.640(c)(2)(i)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(i)

Survey Procedures are pending and will be updated in future release.

C-1235

(Rev.)

[\$485.640(c) Standard: Leadership responsibilities]

(2) The infection prevention and control professional(s) is responsible for:]

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

Interpretive Guidelines §485.640(c)(2)(ii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(ii)

Survey Procedures are pending and will be updated in future release.

C-1237

(Rev.)

[\$485.640(c) Standard: Leadership responsibilities]

(2) The infection prevention and control professional(s) is responsible for:]

(iii) Communication and collaboration with the CAH's QAPI program on infection prevention and control issues.

Interpretive Guidelines §485.640(c)(2)(iii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(iii)

Survey Procedures are pending and will be updated in future release.

C-1239

(Rev.)

[\$485.640(c) Standard: Leadership responsibilities

(2) The infection prevention and control professional(s) is responsible for:]

(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the practical applications of infection prevention and control guidelines, policies and procedures.

Interpretive Guidelines §485.640(c)(2)(iv)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(iv)

Survey Procedures are pending and will be updated in future release.

C-1240

(Rev.)

[\$485.640(c) Standard: Leadership responsibilities

(2) The infection prevention and control professional(s) is responsible for:]

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by CAH personnel.

Interpretive Guidelines §485.640(c)(2)(v)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(v)

Survey Procedures are pending and will be updated in future release.

C-1242

(Rev.)

[\$485.640(c) Standard: Leadership responsibilities

(2) The infection prevention and control professional(s) is responsible for:]

(vi) Communication and collaboration with the antibiotic stewardship program.

Interpretive Guidelines §485.640(c)(2)(vi)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(2)(vi)

Survey Procedures are pending and will be updated in future release.

C-1244

(Rev.)

[§485.640(c) Standard: Leadership responsibilities]

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

Interpretive Guidelines §485.640(c)(3)(i)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(3)(i)

Survey Procedures are pending and will be updated in future release.

C-1246

(Rev.)

[§485.640(c) Standard: Leadership responsibilities]

(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

Interpretive Guidelines §485.640(c)(3)(ii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(3)(ii)

Survey Procedures are pending and will be updated in future release.

C-1248

(Rev.)

[\$485.640(c) Standard: Leadership responsibilities

(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the CAH's infection prevention and control and QAPI programs, on antibiotic use issues.

Interpretive Guidelines §485.640(c)(3)(iii)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(3)(iii)

Survey Procedures are pending and will be updated in future release.

C-1250

(Rev.)

[\$485.640(c) Standard: Leadership responsibilities

(3) The leader(s) of the antibiotic stewardship program is responsible for:]

(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAHs, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

Interpretive Guidelines §485.640(c)(3)(iv)

Guidance is pending and will be updated in future release.

Survey Procedures §485.640(c)(3)(iv)

Survey Procedures are pending and will be updated in future release.

C-1300

(Rev. - Effective March 30, 2021)

§485.641 Condition of Participation: *Quality Assessment and Performance Improvement Program*

The CAH must develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven quality assessment and performance improvement (QAPI) program. The CAH must maintain and demonstrate evidence of the effectiveness of its QAPI program.

(a) Definitions. For the purposes of this section—

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. Error means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems; and Medical error means an error that occurs in the delivery of healthcare services.

Interpretive Guidelines §485.641(a)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(a)

Survey Procedures are pending and will be updated in future release.

C-1302

(Rev. - Effective March 30, 2021)

[\$485.641] (b) Standard: QAPI Program Design and scope. The CAH's QAPI program must:

(1) Be appropriate for the complexity of the CAH's organization and services provided.

Interpretive Guidelines §485.641(b)(1)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(b)(1)

Survey Procedures are pending and will be updated in future release.

C-1306

(Rev. – Effective March 30, 2021)

[\$485.641] (b) Standard: QAPI Program Design and scope. The CAH's QAPI program must:

(2) Be ongoing and comprehensive.

(3) Involve all departments of the CAH and services (including those services furnished under contract or arrangement).

Interpretive Guidelines §485.641(b)(2) and (3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(b)(2)and (3)

Survey Procedures are pending and will be updated in future release.

C-1309

(Rev. – Effective March 30, 2021)

[\$485.641] (b) Standard: QAPI Program Design and scope. The CAH's QAPI program must:

(4) Use objective measures to evaluate its organizational processes, functions and services.

Interpretive Guidelines §485.641(b)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(b)(4)

Survey Procedures are pending and will be updated in future release.

C-1311

(Rev. – Effective March 30, 2021)

[\$485.641] (b) Standard: QAPI Program Design and scope. The CAH's QAPI program must:

(5) Address outcome indicators related to improved health outcomes and the prevention and reduction of medical errors, adverse events, CAH acquired conditions, and transitions of care, including readmissions.

Interpretive Guidelines §485.641(b)(5)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(b)(5)

Survey Procedures are pending and will be updated in future release.

C-1313

(Rev. – Effective March 30, 2021)

[\$485.641](c) Standard: Governance and leadership. The CAH's governing body or responsible individual is ultimately responsible for the CAH's QAPI program and is

responsible and accountable for ensuring that the QAPI program meets the requirements of paragraph (b) of this section.

Interpretive Guidelines §485.641(c)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(c)

Survey Procedures are pending and will be updated in future release.

C-1315

(Rev. – Effective March 30, 2021)

[\$485.641] (d) Standard: Program activities. For each of the areas listed in paragraph (b) of this section, the CAH must:

(1) Focus on measures related to improved health outcomes that are shown to be predictive of desired patient outcomes.

Interpretive Guidelines §485.641(d)(1)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(d)(1)

Survey Procedures are pending and will be updated in future release.

C-1319

(Rev. – Effective March 30, 2021)

[\$485.641 (d) Standard: Program activities. For each of the areas listed in paragraph (b) of this section, the CAH must:]

(2) Use the measures to analyze and track its performance.

Interpretive Guidelines §485.641(d)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(d)(2)

Survey Procedures are pending and will be updated in future release.

C-1321

(Rev. – Effective March 30, 2021)

[§485.641 (d) Standard: Program activities. For each of the areas listed in paragraph (b) of this section, the CAH must:]

(3) Set priorities for performance improvement, considering either high volume, high-risk services, or problem prone areas.

Interpretive Guidelines §485.641(d)(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(d)(3)

Survey Procedures are pending and will be updated in future release.

C-1325

(Rev. – Effective March 30, 2021)

[§485.641](e) Standard: Program data collection and analysis. The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.

Interpretive Guidelines §485.641(e)

Guidance is pending and will be updated in future release.

Survey Procedures §485.641(e)

Survey Procedures are pending and will be updated in future release.

C-0330

(Tag remains effective until March 30, 2021)

§485.641 Condition of Participation: Periodic Evaluation and Quality Assurance Review

Interpretive Guidelines §485.641

While conducting the survey, a surveyor may identify a patient care practice or other CAH practice with which the surveyor is unfamiliar. Health care and CAH practice are continually changing due to new laws, regulations and standards of practice. In order for the surveyor to determine compliance with the CAH CoP, the surveyor should interview appropriate CAH staff to gather additional information, such as:

- Tell me about this practice.
- Is the practice a requirement or standard of practice?

- What is your source for this requirement, activity or standard of practice?
- Show me your source material for this practice.

If the CAH produces a law, regulation, or standard of practice from a nationally recognized organization, evaluate whether the CAH'S policies and procedures reflect the law, regulation, or standard of practice. Then, evaluate whether the CAH'S actual practice reflects their policies and procedures, as well as the law, regulation or standard of practice.

C-0331

(Tag remains effective until March 30, 2021)

§485.641(a) Standard: Periodic Evaluation

- (1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—**

Survey Procedures §485.641(a)(1)

- How is information obtained to be included in the periodic evaluation?
- How does the CAH conduct the periodic evaluation?
- Who is responsible for conducting the periodic evaluation?

C-0332

(Tag remains effective until March 30, 2021)

§485.641(a)(1)(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

Survey Procedures §485.641(a)(1)(i)

How does the CAH ensure that the yearly program evaluation includes a review of all CAH services, the number of patients served and the volume of services provided?

C-0333

(Tag remains effective until March 30, 2021)

§485.641(a)(1)(ii) A representative sample of both active and closed clinical records; and

Interpretive Guidelines §485.641(a)(1)(ii)

“A representative sample of both active and closed clinical records” means not less than 10 percent of both active and closed patient records.

Survey Procedures §485.641(a)(1)(ii)

- Who is responsible for the review of both active and closed clinical records?
- How are records selected and reviewed in the periodic evaluation?
- How does the evaluation process ensure that the sample of records is representative of services furnished?
- What criteria are utilized in the review of both active and closed records?

C-0334

(Tag remains effective until March 30, 2021)

§485.641(a)(1)(iii) The CAH'S health care policies.

Survey Procedures §485.641(a)(1)(iii)

What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed and/or revised as part of the annual program evaluation?

C-0335

(Tag remains effective until March 30, 2021)

§485.641(a)(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

Survey Procedures §485.641(a)(2)

- How does the CAH use the results of the yearly program evaluation?
- Were policies, procedures and /or facility practices added, deleted or revised as a result of the yearly program evaluation if needed?

C-0336

(Tag remains effective until March 30, 2021)

§485.641(b) Standard: Quality Assurance

The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--

Interpretive Guidelines §485.641(b)

There is nothing in this requirement to preclude a CAH from obtaining QA through arrangement. Whether the CAH has a freestanding QA program or QA by arrangement, all of the requirements for QA must be met. If a CAH chooses to have a freestanding QA program, the QA program should be facility wide, including all departments and all services provided under contract. For services provided to the CAH under contract, there should be established channels of communication between the contractor and CAH staff.

“An effective quality assurance program” means a QA program that includes:

- Ongoing monitoring and data collection;
- Problem prevention, identification and data analysis;
- Identification of corrective actions;
- Implementation of corrective actions;
- Evaluation of corrective actions; and
- Measures to improve quality on a continuous basis.

Survey Procedures §485.641(b)

Review a copy of the CAH QA plan and other documentation regarding QA activities, (e.g., meeting notes from QA committees, reports produced by the QA director and/or QA committees, if designated, and follow-up communication relative to corrective actions) to become familiar with the scope, methodology and organization of the CAH QA program.

C-0337

(Tag remains effective until March 30, 2021)

§485.641(b)(1) All patient care services and other services affecting patient health and safety, are evaluated;

Survey Procedures §485.641(b)(1)

- Who is responsible to evaluate CAH patient care services?
- How are patient care services evaluated?
- What other services are evaluated?
- How does the CAH ensure quality assurance data is provided to the medical staff and governing body?

C-0338

(Tag remains effective until March 30, 2021)

§485.641(b)(2) Nosocomial infections and medication therapy are evaluated;

Survey Procedures §485.641(b)(2)

- What methodology does the CAH use to evaluate nosocomial infections and medications therapy?
- Review committee meeting minutes for current issues or projects, etc.

C-0339

(Tag remains effective until March 30, 2021)

§485.641(b)(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

Survey Procedures §485.641(b)(3)

- How does the CAH ensure that a doctor of medicine or osteopathy evaluates the quality of care provided by mid-level practitioners in the CAH?
- How is clinical performance of mid-level practitioners evaluated?
- What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, QA meeting notes)?
- How does the reviewing MD/DO inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners?
- What follow-up actions are called for in the QA plan?

C-0340

(Tag remains effective until March 30, 2021)

§485.641(b)(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by--
(i) One hospital that is a member of the network, when applicable;
(ii) One QIO or equivalent entity;
(iii) One other appropriate and qualified entity identified in the State rural health care plan;

(iv) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital; or

(v) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (b)(4)(i) through (iii) of this section;

Interpretive Guidelines §485.641(b)(4)

All CAHs must, as a part of their quality assurance program, have an arrangement with an outside entity to review the appropriateness of the diagnosis and treatment provided by each MD/DO providing services to the CAH's patients. This includes MDs and DOs providing telemedicine services to the CAH's patients from a distant-site hospital or distant-site telemedicine entity. (See §485.616(c) for more information about requirements for telemedicine services.

Some CAHs may prefer to conduct their own internal review in addition to the outside review; this is neither prohibited nor required under the regulation. The regulation does not specify the frequency of the outside review, since a quality assurance program is ongoing in nature. The CAH and the outside entity must reach a mutual agreement on the extent and frequency of the outside review.

Entities eligible to provide this outside review include, for MDs and DOs who provide services on-site at the CAH, a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; or another appropriate and qualified entity identified in the State's Rural Health Plan to perform this function.

In the case of MDs or DOs who provide telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital is the outside entity responsible for reviewing the quality of care provided by these physicians.

In the case of MDs or DOs who provide telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the outside entity responsible for reviewing the quality of care provided by these physicians include a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; another appropriate and qualified entity identified in the State's Rural Health Plan to perform this function; or a distant-site hospital with which the CAH has an agreement for provision of telemedicine services.

Survey Procedures §485.641 (b)(4)

- Is there evidence that the CAH has an agreement for outside review of the quality of care provided on-site (i.e., not including telemedicine services) by the CAH's MDs and DOs with at least one of the following: a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; or another appropriate and qualified entity identified in the State's Rural Health Plan?
- If the CAH has one or more agreements for the provision of telemedicine services to CAH patients by a distant-site hospital(s), does each such agreement include a provision for the distant-site hospital to conduct the required outside review of the quality of telemedicine services provided by the MDs and DOs covered by the agreement?
- If the CAH has one or more agreements for the provision of telemedicine services to CAH patients by a distant-site telemedicine entity, does the CAH have an agreement for outside review of the quality of telemedicine services provided by the MDs and DOs covered under the agreement? Is the outside review agreement with at least one of the following: a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; another appropriate and qualified entity identified in the State's Rural Health Plan; or a distant-site hospital with which the CAH has an agreement for telemedicine services?
- Can the CAH provide examples of any reviews of the quality and appropriateness of diagnosis and treatment of the CAHs MDs and DOs conducted by an eligible outside entity in the prior 12 – 24 months?

C-0341

(Tag remains effective until March 30, 2021)

§485.641(b)(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

C-0342

(Tag remains effective until March 30, 2021)

§485.641(b)(5)(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

Survey Procedures §485.641(b)(5)(ii)

- How does the CAH ensure that proper remedial actions are taken to correct deficiencies identified in the quality assurance program?
- Who is responsible for implementing remedial actions to correct deficiencies identified by the quality assurance program?

C-0343

(Tag remains effective until March 30, 2021)

**§485.641(b)(5)(iii) The CAH documents the outcome of all remedial action.
Survey Procedures §485.641(b)(5)(iii)**

How does the CAH document the outcome of any remedial action?

C-1400

(Rev.)

§485.642 Condition of Participation: Discharge Planning

A Critical Access Hospital (CAH) must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from the CAH to post-discharge care, and reduce the factors leading to preventable CAH and hospital readmissions.

Interpretive Guidelines §485.642

Guidance is pending and will be updated in future release.

Survey Procedures §485.642

Survey Procedures are pending and will be updated in future release.

C-1404

(Rev.)

(a) Standard: Discharge planning process. The CAH's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

Interpretive Guidelines §485.642(a)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)

Survey Procedures are pending and will be updated in future release.

C-1406
(Rev.)

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-CAH care will be made before discharge and to avoid unnecessary delays in discharge.

Interpretive Guidelines §485.642(a)(1)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(1)

Survey Procedures are pending and will be updated in future release.

C-1408
(Rev.)

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-CAH services, including, but not limited to, hospice care services, post- CAH extended care services, home health services, and non-health care services and community based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

Interpretive Guidelines §485.642(a)(2)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(2)

Survey Procedures are pending and will be updated in future release.

C-1410
(Rev.)

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

Interpretive Guidelines §485.642(a)(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(3)

Survey Procedures are pending and will be updated in future release.

C-1412

(Rev.)

(4) Upon the request of a patient's physician, the CAH must arrange for the development and initial implementation of a discharge plan for the patient.

Interpretive Guidelines §485.642(a)(4)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(4)

Survey Procedures are pending and will be updated in future release.

C-1417

(Rev.)

(5) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

Interpretive Guidelines §485.642(a)(5)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(5)

Survey Procedures are pending and will be updated in future release.

C-1420

(Rev.)

(6) The CAH's discharge planning process must require regular reevaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

Interpretive Guidelines §485.642(a)(6)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(6)

Survey Procedures are pending and will be updated in future release.

C-1422
(Rev.)

(7) The CAH must assess its discharge planning process on a regular basis. The assessment must include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs.

Interpretive Guidelines §485.642(a)(7)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(7)

Survey Procedures are pending and will be updated in future release.

C-1425
(Rev.)

(8) The CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The CAH must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

Interpretive Guidelines §485.642(a)(8)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(a)(8)

Survey Procedures are pending and will be updated in future release.

C-1430
(Rev.)

(b) Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information. The CAH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, postdischarge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary

care.

Interpretive Guidelines §485.642(b)

Guidance is pending and will be updated in future release.

Survey Procedures §485.642(b)

Survey Procedures are pending and will be updated in future release.

C-1500

(Rev.)

§485.643 Condition of Participation: Organ, Tissue, and Eye Procurement

The CAH must have and implement written protocols that:

Interpretive Guidelines §485.643

The CAH must have written policies and procedures to address its organ procurement responsibilities.

C-1503

(Rev.)

§485.643(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

Interpretive Guidelines §485.643(a)

The CAH must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH;
- Includes a definition of “imminent death”;
- Includes a definition of “timely notification”;

- Addresses the OPO’s responsibility to determine medical suitability for organ donation;
- Specifies how the tissue and/or eye bank will be notified about potential donors using S notification protocols developed by the OPO in consultation with the CAH-designated tissue and eye bank(s);
- Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement;
- Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the CAH;
- Permits the OPO, tissue bank, and eye bank access to the CAH’S death record information according to a designated schedule, e.g., monthly or quarterly;
- Includes that the CAH is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only “qualified, trained individuals” to perform organ recovery; and
- The interventions the CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable.

CAHs must notify the OPO of every death or imminent death in the CAH. When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor’s organs are still viable. The CAH should have a written policy, developed in coordination with the OPO and approved by the CAH’S medical staff and governing body, to define “imminent death.” The definition for “imminent death” should strike a balance between the needs of the OPO and the needs of the CAH’S care givers to continue treatment of a patient until brain death is declared or the patient’s family has made the decision to withdraw supportive measures.

Collaboration between OPOs and CAHs will create a partnership that furthers donation, while respecting the perspective of CAH staff.

The definition for “imminent death” might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;
- Is in an intensive care unit (ICU) or emergency department; **AND**
- Has clinical findings consistent with a Glasgow Coma Score that is less than or equal to a mutually-agreed-upon threshold; **or**

- MD/DOs are evaluating a diagnosis of brain death; **or**
- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

CAHs and their OPO should develop a definition of “imminent death” that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many “premature” deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the CAH'S OPO or organizations such as the Association of Organ Procurement Organizations.

Note that a patient with “severe, acute brain injury” is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the CAH and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each CAH.

CAHs may not use “batch reporting” for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one CAH to another, it is the receiving CAH'S responsibility to notify the OPO.

“**Timely notification**” means a CAH must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a CAH must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a CAH to an OPO is timely if it is made:

- As soon as it is anticipated a patient will meet the criteria for imminent death agreed to by the OPO and CAH or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the CAH (ideally, within one hour); **AND**
- Prior to the withdrawal of any life sustaining therapies (i.e., medical **or** pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), ensures that the family is approached only if the patient is medically suitable for organ donation, and ensures that an OPO representative is available to collaborate with the CAH staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose.

Survey Procedures §485.643(a)

- Review the CAH'S written agreement with the OPO to verify that it addresses all required information.
- Verify that the CAH'S governing body has approved the CAH'S organ procurement policies.
- Review a sample of death records to verify that the CAH has implemented its organ procurement policies.
- Interview the staff to verify that they are aware of the CAH'S policies and procedures for organ, tissue and eye procurement.
- Verify that the organ, tissue and eye donation program is integrated into the CAH'S QA program.

C-1505 ***(Rev.)***

§485.643(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretive Guidelines §485.643(b)

The CAH must have an agreement with at least one tissue bank and at least one eye bank.

The OPO may serve as a “gatekeeper” receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors.

It is not necessary for a CAH to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; not is it necessary for a CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define “usable tissues” and “usable eyes.”

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §485.643(b)

Verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. The agreement must also acknowledge that it is the OPO’s responsibility to determine medical suitability for tissue and eye donation, unless the CAH has an alternative agreement with a different tissue and/or eye bank.

C-1507 ***(Rev.)***

§485.643(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

Interpretive Guidelines §485.643(c)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person’s family must be informed of the family’s donation options.

Ideally, the OPO and the CAH will decide together how and by whom the family will be approached.

The individual designated by the CAH to initiate the request to the family must be a designated requestor.

A “**designated requestor**” is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community. If possible, the OPO representative and a designated requestor should approach the family together.

The CAH must ensure that any “designated requestor” for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §485.643(c)

- Verify that the CAH ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate.
- Review training schedules and personnel files to verify that all designated requestors have completed the required training.
- How does the CAH ensure that only designated requestors are approaching families to ask them to donate?

C-1509 ***(Rev.)***

§485.643(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the family of potential donors;

Interpretive Guidelines §485.643(d)

Using discretion does not mean a judgment can be made by the CAH that certain families should not be approached about donation. CAHs should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The staff’s perception that a family’s grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §485.643(d)

- Interview a CAH-designated requestor regarding approaches to donation requests.
- Review the designated requestor training program to verify that it addresses the use of discretion.

- Review the facility complaint file for any relevant complaints.

C-1511

(Rev.)

§485.643(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

§485.643(f) For purpose of these standards, the term “organ” means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Interpretive Guidelines §485.643(e)

Appropriate staff, including all patient care staff, must be trained regarding donation issues and how to work with the OPO, tissue bank and eye bank. Those CAH staff who may have to contact or work with the OPO, tissue bank and eye bank staff, must have appropriate training on donation issues including their duties and roles.

The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process;
- Importance of using discretion and sensitivity when approaching families;
- Role of the designated requestor;
- Transplantation and donation, including pediatrics, if appropriate;
- Quality improvement activities; and
- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the CAH'S QA program.

CAHs must cooperate with OPOs, tissue banks and eye banks in regularly/periodically reviewing death records. This means that a CAH must develop policies and procedures which permit the OPO, tissue bank and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the CAH'S donor potential, ensure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the CAH, OPO, tissue bank and eye bank staff

performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

The CAH must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintain the viability of their organs. The CAH must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §485.643(e)

- Review inservice training schedules and attendance sheets.
- How does the CAH ensure that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?
- Verify by review of policies and records that the CAH works with the OPO, tissue bank, and eye bank in reviewing death records.
- Verify that the effectiveness of any protocols and policies is monitored as part of the CAH'S quality improvement program.
- Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.
- Determine how confidentiality is ensured.
- Verify that there are policies and procedures in place to ensure coordination between the facility staff and the OPO staff in maintaining the potential donor.
- Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

C-1600 ***(Rev.)***

§485.645 Special Requirements for CAH Providers of Long-Term Care Services (“Swing-Beds”).

A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-CAH SNF care, as specified in §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

Interpretive Guidelines §485.645

The swing-bed concept allows a CAH to use their beds interchangeably for either acute-care or post-acute care. A “swing-bed” is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.

Medicare allows a CAH to operate swing-beds through the issuance of a “swing-bed approval.” If the facility fails to meet the swing-bed requirements, and the facility does not develop and implement an accepted plan of correction, the facility loses the approval to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a termination track. If the CAH continues to meet the CoP for the provider type, it continues to operate but loses swing-bed approval.

Swing-beds need not be located in a special section of the CAH. The patient need not change locations in the facility merely because his/her status changes unless the facility requires it.

The change in status from acute care to swing-bed status can occur within one facility or the patient can be transferred from another facility for swing-bed admission.

There must be discharge orders from acute inpatient care services and subsequent admission orders for swing-bed services, the same as if the patient had been transferred to a separately certified skilled nursing facility. The same clinical record may be used for a swing-bed patient, but it must include discharge orders from acute care and admission orders to swing-bed services, and the swing-bed services (which may be SNF or NF level services) must be clearly delineated within the clinical record.

There is no length of stay restriction for any CAH swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between CAHs and nursing homes. While there is no length of stay limit for patients in swing-bed status, the intended use for swing beds is for a transitional time period to allow the patient to fully recover to return home or while awaiting placement into a nursing facility. The CAH should document in the patient’s medical record efforts made for nursing facility placement.

Medicare coverage rules require that, in order to be eligible for coverage of post-hospital swing-bed care, a beneficiary must have a qualifying 3-day inpatient stay in a participating or qualified hospital or participating CAH prior to admission to a swing-bed.

There is no requirement for a CAH to use the MDS form for recording the patient assessment or for nursing care planning.

Swing-bed patients receive a SNF level of care, and the CAH is reimbursed for providing a SNF level of care, however swing-bed patients are not SNF patients. Swing-bed

patients in CAHs are considered to be patients of the CAH.

NOTE: Swing-beds must not be confused with beds in a skilled nursing facility (SNF) or nursing facility (NF), including a distinct part SNF/NF, that shares the same building/campus as the CAH but is a separately certified provider with its own Medicare provider agreement.

C-1602
(Rev.)

§485.645(a) Eligibility

A CAH must meet the following eligibility requirements:

- (1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and**
- (2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.**

Interpretive Guidelines §485.645(a) Eligibility

CAHs seeking swing-bed approval are screened prior to survey for their eligibility for swing-beds. However, the CMS RO makes the determination whether the CAH has satisfied the eligibility criteria, regardless of whether the SA or AO, as applicable, recommends approval of swing-bed status (this responsibility may not be delegated to the SA).

The eligibility criteria at 42 CFR 485.645(a) requires:

- The CAH has a Medicare provider agreement;
- An initial CAH applicant may seek swing-bed approval. If the CAH applicant meets all Federal Requirements for participation, including those for swing-bed approval, the CAH applicant's approval for swing-bed services will be effective with the CAH's effective date of Medicare participation;

C-1604
(Rev.)

§485.645(b) Facilities Participating as Rural Primary Care Hospitals (RPCHs) on September 30, 1997

These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a hospital that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and limitations that were applicable at the time these approvals were granted..

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

C-1606
(Rev.)

§485.645(c) Payment

Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter.

C-1608
(Rev.)

§485.645(d) SNF Services.

The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

§485.645(d)(1) Resident Rights (§483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) *and* (4), (f)(4)(ii) *and* (iii), (g)(8) and (17), (g)(18) introductory text, (h) of this chapter).

- §483.10(b)(7) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf. The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law.**
- §483.10(c) Planning and implementing care. The resident has the right to be informed of, and participate in, his or her treatment, including:**

- (1) The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.**
- **§483.10(c)(2)(iii) The right to be informed, in advance, of changes to the plan of care.**
 - **§483.10(c)(6) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.**
 - **§483.10(d) Choice of attending physician. The resident has the right to choose his or her attending physician.**
 - (1) The physician must be licensed to practice, and**
 - (2) If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in paragraphs (d)(4) and (5) of this section to assure provision of appropriate and adequate care and treatment.**
 - (3) The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.**
 - (4) The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.**
 - (5) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.**
 - **§483.10(e)(2) The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.**
 - **§483.10(e)(4) The right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.**

- **§483.10(f)(4)(ii)** The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time;
- **§483.10(f)(4)(iii)** The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time;
- **§483.10(g)(8)** The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:
 - (i) Privacy of such communications consistent with this section; and
 - (ii) Access to stationery, postage, and writing implements at the resident's own expense.
- **§483.10(g)(17)** The facility must—
 - (i) Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and when the resident becomes eligible for Medicaid of—
 - (A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;
 - (B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and
 - (ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in §483.10(g)(17)(i)(A) and (B) of this section.
- **§483.10(g)(18)[introductory text only]** The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/Medicaid or by the facility's per diem rate.
- **§483.10(h)** Privacy and confidentiality. The resident has a right to personal privacy and confidentiality of his or her personal and medical records.

- (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.**
- (2) The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.**
- (3) The resident has a right to secure and confidential personal and medical records.**
 - (i) The resident has the right to refuse the release of personal and medical records except as provided at §483.70(i)(2) or other applicable federal or state laws.**
 - (ii) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.**

Interpretive Guidelines §485.645(d)(1)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(1)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1610 ***(Rev.)***

§485.645(d)(2) Admission, Transfer and Discharge Rights (§483.5 definition of transfer & discharge, §483.15(c)(1), (c)(2), (c)(3), (c)(4), (c)(5), (c)(7), (c)(8), and (c)(9) of this chapter).

- §483.5 definition of transfer & discharge: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.**
- §483.15(c)(1) Transfer and discharge—(1) Facility requirements—**

(i) The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(A) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(B) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;

(D) The health of individuals in the facility would otherwise be endangered;

(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(F) The facility ceases to operate.

(ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to §431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to §431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.

- **§483.15(c)(2) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.**

(i) Documentation in the resident's medical record must include:

- (A) The basis for the transfer per paragraph (c)(1)(i) of this section.
 - (B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).
- (ii) The documentation required by paragraph (c)(2)(i) of this section must be made by—
- (A) The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(A) or (B) of this section; and
 - (B) A physician when transfer or discharge is necessary under paragraph (c)(1)(i)(C) or (D) of this section.
- (iii) Information provided to the receiving provider must include a minimum of the following:
- (A) Contact information of the practitioner responsible for the care of the resident
 - (B) Resident representative information including contact information.
 - (C) Advance Directive information.
 - (D) All special instructions or precautions for ongoing care, as appropriate.
 - (E) Comprehensive care plan goals,
 - (F) All other necessary information, including a copy of the resident's discharge summary, consistent with §483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.
- §483.15(c)(3) Notice before transfer. Before a facility transfers or discharges a resident, the facility must—
 - (i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

- (ii) Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this section; and
 - (iii) Include in the notice the items described in paragraph (c)(5) of this section.
- **§483.15(c)(4) Timing of the notice.**
 - (i) Except as specified in paragraphs (c)(4)(ii) and (8) of this section, the notice of transfer or discharge required under this section must be made by the facility at least 30 days before the resident is transferred or discharged.
 - (ii) Notice must be made as soon as practicable before transfer or discharge when—
 - (A) The safety of individuals in the facility would be endangered under paragraph (c)(1)(i)(C) of this section;
 - (B) The health of individuals in the facility would be endangered, under paragraph (c)(1)(i)(D) of this section;
 - (C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (c)(1)(i)(B) of this section;
 - (D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (c)(1)(i)(A) of this section; or
 - (E) A resident has not resided in the facility for 30 days.
- **§483.15(c)(5) Contents of the notice.** The written notice specified in paragraph (c)(3) of this section must include the following:
 - (i) The reason for transfer or discharge;
 - (ii) The effective date of transfer or discharge;
 - (iii) The location to which the resident is transferred or discharged;
 - (iv) A statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an

appeal form and assistance in completing the form and submitting the appeal hearing request;

- (v) The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;**
- (vi) For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106-402, codified at 42 U.S.C. 15001 et seq.); and**
- (vii) For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.**

- §483.15(c)(7) Orientation for transfer or discharge. A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.**
- §483.15(c)(8) Notice in advance of facility closure. In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at §483.70(l).**
- §483.15(c)(9) Room changes in a composite distinct part. Room changes in a facility that is a composite distinct part (as defined in §483.5) are subject to the requirements of §483.10(e)(7) and must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.**

Interpretive Guidelines §485.645(d)(2)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(2)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1612
(Rev.)

§485.645(d)(3) Freedom from abuse, neglect and exploitation (§483.12(a)(1), (a)(2), (a)(3)(i), (a)(3)(ii), (a)(4), (b)(1), (b)(2), (c)(1), (c)(2), (c)(3), and (c)(4) of this chapter).

- **§483.12(a)(1) Freedom from abuse, neglect, and exploitation. The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.(a) The facility must—(1) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;**
- **§483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.**
- **§483.12(a)(3) Not employ or otherwise engage individuals who—**
 - (i) Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law;**
 - (ii) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property.**
- **§483.12(a)(4) Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.**
- **§483.12(b) The facility must develop and implement written policies and procedures that:**
 - (1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,**
 - (2) Establish policies and procedures to investigate any such allegations,**
- **§483.12(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:**

- (1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.**
- (2) Have evidence that all alleged violations are thoroughly investigated.**
- (3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.**
- (4) Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.**

Interpretive Guidelines §485.645(d)(3)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(3)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1616
(Rev.)

§485.645(d)(4) Social Services (§483.40(d) of this chapter).

- §483.40(d) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.**

Interpretive Guidelines §485.645(d)(4)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(4)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1620
(Rev.)

§485.645(d)(5) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), and §483.21(b) and (c)(2) of this chapter), except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).

- **§483.20(b) Comprehensive assessments—**
 - (1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. The assessment must include at least the following:**
 - (i) Identification and demographic information.**
 - (ii) Customary routine.**
 - (iii) Cognitive patterns.**
 - (iv) Communication.**
 - (v) Vision.**
 - (vi) Mood and behavior patterns.**
 - (vii) Psychosocial well-being.**
 - (viii) Physical functioning and structural problems.**
 - (ix) Continence.**
 - (x) Disease diagnoses and health conditions.**
 - (xi) Dental and nutritional status.**
 - (xii) Skin condition.**
 - (xiii) Activity pursuit.**

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge planning.

(xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2) (i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

- **§483.21(b) Comprehensive care plans.**

(1) The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at §483.10(c)(2) and §483.10(c)(3), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the

comprehensive assessment. The comprehensive care plan must describe the following:

- (i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.24, §483.25, or §483.40; and**
- (ii) Any services that would otherwise be required under §483.24, §483.25, or §483.40 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(c)(6).**

(6) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.

(7) In consultation with the resident and the resident's representative(s)—

(A) The resident's goals for admission and desired outcomes.

(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment.

(ii) Prepared by an interdisciplinary team, that includes but is not limited to-

(A) The attending physician.

(B) A registered nurse with responsibility for the resident.

(C) A nurse aide with responsibility for the resident.

- (D) A member of food and nutrition services staff.**
- (E) To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.**
- (F) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.**
- (iii) Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.**
- (3) The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—**

 - (i) Meet professional standards of quality.**
 - (ii) Be provided by qualified persons in accordance with each resident's written plan of care.**
 - (iii) Be culturally-competent and trauma-informed.**
- §483.21(c)(2) Discharge summary. When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to, the following:**

 - (i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.**
 - (ii) A final summary of the resident's status to include items in paragraph (b)(1) of §483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.**
 - (iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).**
 - (iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to**

his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.

Interpretive Guidelines §485.645(d)(5)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(5)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

***NOTE:** The CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter). Also, note that CAHs are not required to complete the PASARR. **However, if a patient had a PASARR completed by a facility that was required to do so prior to admission into a CAH swing bed, the recommendations from the PASARR should be included in the CAHs comprehensive treatment plan for the patient.**

C-1622
(Rev.)

§485.645(d)(6) Specialized Rehabilitative Services (§483.65 of this chapter).

- **§483.65 (a) Provision of services. If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as set forth at §483.120(c), are required in the resident's comprehensive plan of care, the facility must—**
 - (1) Provide the required services; or**
 - (2) In accordance with §483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.**
- (b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.**

Interpretive Guidelines §485.645(d)(6)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(6)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1624
(Rev.)

§485.645(d)(7) Dental Services (§483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

- **§483.55 Dental services. The facility must assist residents in obtaining routine and 24-hour emergency dental care.**

(a) Skilled nursing facilities. A facility-

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

(3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

(4) Must if necessary or if requested, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dental services location; and

(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

(b) Nursing facilities. The facility-

(1) Must provide or obtain from an outside resource, in accordance with §483.70(g), the following dental services to meet the needs of each resident:

- (i) Routine dental services (to the extent covered under the State plan); and
 - (ii) Emergency dental services;
- (2) Must, if necessary or if requested, assist the resident—
 - (i) In making appointments; and
 - (ii) By arranging for transportation to and from the dental services locations;
- (3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;
- (4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and
- (5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

Interpretive Guidelines §485.645(d)(7)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(7)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

C-1626
(Rev.)

§485.645(d)(8) Nutrition (§483.25(g)(1) and (g)(2) of this chapter).

- **§483.25(g) Assisted nutrition and hydration. (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident—**

- (1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;**
- (2) Is offered sufficient fluid intake to maintain proper hydration and health.**

Interpretive Guidelines §485.645(d)(8)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(8)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

Refer to Appendix A of the State Operations Manual (SOM) for Critical Access Hospital Distinct Part Unit interpretive guidelines and survey procedures.

C-0500 **(Rev.)**

§485.647 (1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

C-0501 **(Rev.)**

§485.647 (b)(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the

distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

C-0504

(Rev.)

[...the services furnished by the distinct part unit must comply with ... §412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)(2)):

" In order to be excluded from the prospective payment systems ... a psychiatric ... unit must meet the following requirements:

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients."

C-0505

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)):

" In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements:]

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

C-0506

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the hospital."

C-0507

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(5) Meet all applicable State licensure laws."

C-0508

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(6) Have utilization review standards applicable for the type of care offered in the unit."

C-0509

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds."

C-0510

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(8) Be serviced by the same fiscal intermediary as the hospital."

C-0511

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(9) Be treated as a separate cost center for cost finding and apportionment purposes."

C-0512

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(10) Use an accounting system that properly allocates costs."

C-0513

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(11) Maintain adequate statistical data to support the basis of allocation."

C-0514
(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(12) Report its cost in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital."

C-0515
(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date."

C-0516
(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)).]

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.

(1) Increase in size. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost reporting period."

C-0517

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)):

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.]

(2) Decrease in size. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period."

C-0518

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)):

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.]

(3) Exception to changes in square footage and bed size. The number of beds in an excluded unit may be decreased, and the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

C-0519

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Changes in the status of hospital units (§412.25(c)):

["For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period. "

C-0520

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Changes in the status of hospital units (§412.25(c)):

"For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period."

C-0521

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Number of excluded units (§412.25(d)):

"Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems."

C-0522
(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)):

"(1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital."

C-0523
(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)):]

"(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period.

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997."

C-0524
(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(2)):

"(ii) The satellite facility independently complies with-

(A) For a rehabilitation unit, the requirements under §412.23(b)(2); or

(B) For a psychiatric unit, the requirements under §412.27(a)."

C-0525

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)).]

"(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located."

C-0526

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

C-0527

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)).

" (iii) The satellite facility meets all of the following requirements:]

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located."

C-0528

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part."

C-0529

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(E) It is treated as a separate cost center of the hospital unit of which it is a part."

C-0530

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation."

C-0531

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)):

“(iii) The satellite facility meets all of the following requirements:]

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.”

§412.25 (e)(2)(iv) Effective for cost reporting periods beginning on or after October 1, 2019, the requirements of paragraph (e)(2)(iii)(A) of this section do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in §412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1).

C-0532

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(3)):

“Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999.”

C-0533

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(4)):

“ In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility

considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

C-0534

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(5)&(6)):

"(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (e)(3) of this section-

(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and

(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning of a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003."

C-0535

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Changes in classification (§412.25(f)):

"For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period."

§412.25(g) CAH units not meeting applicable requirements. If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of §485.647 with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of §485.647.

C-0547
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system as specified in §412.1(a)(1), and paid under the prospective payment system as specified in §412.1(a)(2), a psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Fourth Edition, Text Revision of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification."

C-0548
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system ... a psychiatric unit must meet the following requirements:]

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and therapeutic activities."

C-0549

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system ... a psychiatric unit must meet the following requirements:]

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit."

C-0550

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):]

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) Identification data must include the inpatient's legal status."

C-0551

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(ii) A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of every inpatient at the time of admission,

and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses."

C-0552

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both."

C-0553

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history."

C-0554

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination."

C-0555

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c) (2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-

(i) Be completed within 60 hours of admission."

C-0556

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(ii) Include a medical history."

C-0557

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(iii) Contain a record of mental status."

C-0558

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(iv) Note the onset of illness and the circumstances leading to admission."

C-0559

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(v) describe attitudes and behavior."

C-0560

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(vi) Estimate intellectual functioning, memory functioning, and orientation."

C-0561

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion."

C-0562

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis."

C-0563

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] short-term and long-term goals."

C-0564

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] the specific treatment modalities utilized."

C-0565
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] the responsibilities of each member of the treatment team."

C-0566
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out."

C-0567
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan]

(ii) The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included."

C-0568
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient."

C-0569

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] a nurse."

C-0570

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] a social worker."

C-0571

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] others significantly involved in active treatment modalities, when appropriate."

C-0572

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress.] ...The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter."

C-0573
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress.] ...progress notes must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan."

C-0574
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit ..."

C-0575
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have ...] recommendations from appropriate services concerning follow-up or aftercare ..."

C-0576
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have ...] a brief summary of the patient's condition on discharge."

C-0577
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning ..."

C-0578
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(1) Personnel. The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to-

(i) evaluate inpatients;

(ii) formulate written, individualized, comprehensive treatment plans;

(iii) provide active treatment measures; and

(iv) engage in discharge planning."

C-0579
(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(2) Director of inpatient psychiatric services: Medical staff. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program."

C-0580

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

...The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services."

C-0581

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

(i) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry."

C-0582

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

(ii) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff."

C-0583

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(3) Nursing services. The unit must have a qualified director of psychiatric nursing services ..."

C-0584

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

...In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient."

C-0585

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill."

C-0586

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

...The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished."

C-0587

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day..."

C-0588

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services]

(ii) ...There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program."

C-0589

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(4) Psychological services. The unit must provide or have available psychological services to meet the needs of the inpatients"

C-0590

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(4) Psychological services.]

...The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures."

C-0591

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(5) Social services. There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished ..."

C-0592

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(5) Social services.]

...The social services must be furnished in accordance with accepted standards of practice and established policies and procedures ..."

C-0593

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(5) Social services.]

...Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital."

C-0594

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program."

C-0595

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program.]

(i) The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning."

C-0596

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program.]

(ii) The number of qualified therapeutic activities therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program."

C-0700

(Rev.)

§485.647(a)(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for

hospital units excluded from the prospective payment systems, and the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

C-0701

(Rev.)

§485.647(b)(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

C-0704

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)(2)):

"In order to be excluded from the prospective payment systems ... a rehabilitation unit must meet the following requirements:

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients."

C-0705

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)(3)):

"In order to be excluded from the prospective payment systems ... a rehabilitation unit must meet the following requirements:]

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

C-0706

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(4)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the hospital."

C-0707

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(5)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(5) Meet all applicable State licensure laws."

C-0708

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(6)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(6) Have utilization review standards applicable for the type of care offered in the unit."

C-0709

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(7)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds."

C-0710

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(8)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(8) Be serviced by the same fiscal intermediary as the hospital."

C-0711

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(9)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(9) Be treated as a separate cost center for cost finding and apportionment purposes."

C-0712

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(10)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(10) Use an accounting system that properly allocates costs."

C-0713

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(11)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(11) Maintain adequate statistical data to support the basis of allocation."

C-0714

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(12)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(12) Report its cost in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital."

C-0715

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)(13)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, be fully equipped and staffed and capable of providing hospital

inpatient rehabilitation care, regardless of whether there are any inpatients in the unit on that date."

C-0716

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)(1)).]

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.

(1) Increase in size. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost reporting period."

C-0717

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)(2)):

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.]

"(2) Decrease in size. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period."

C-0718

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)(3)):

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.]

(3) Exception to changes in square footage and bed size. The number of beds in an excluded unit may be decreased, and the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

C-0719

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the status of hospital units (§412.25(c)(1)):

"For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period. "

C-0720

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the status of hospital units (§412.25(c)(2)):

"For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period."

C-0721

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Number of excluded units (§412.25(d)):

"Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems."

C-0722

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(1)):

"(1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital."

C-0723

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(2)(i)).]

"(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite

facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period.

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's on the last day of the unit's last cost reporting period beginning before October 1, 1997."

C-0724

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(ii)(A)(B)).]

"(ii) The satellite facility independently complies with-

(A) For a rehabilitation unit, the requirements under §412.23(b)(2); or

(B) For a psychiatric unit, the requirements under §412.27(a)."

C-0725

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(A)).]

"(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located."

C-0726

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(B)):

"(iii) The satellite facility meets all of the following requirements:]

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

C-0727

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(C)):

"(iii) The satellite facility meets all of the following requirements:]

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located."

C-0728

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(D)):

"(iii) The satellite facility meets all of the following requirements:]

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part."

C-0729

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(E)):

"(iii) The satellite facility meets all of the following requirements:]

(E) It is treated as a separate cost center of the hospital unit of which it is a part."

C-0730

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(F)):

“(iii) The satellite facility meets all of the following requirements:]

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.”

C-0731

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)(iii)(G)):

“(iii) The satellite facility meets all of the following requirements:]

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.”

C-0732

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(3)):

“Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999.”

C-0733

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(4)):

"In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

C-0734

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(5)&(6)):

"(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (e)(3) of this section-

(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and

(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning of a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003."

C-0735

(Rev.)

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in classification (§412.25(f)):

"For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period."

C-0747

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.]

Excluded rehabilitation units: Additional requirements (§412.29):

"In order to be excluded from the prospective payment systems described in §412.1(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(2), a rehabilitation unit must meet the following requirements:

(a) Have met either the requirements for-

(1) New units under §412.30(a); or

(2) Converted units under §412.30(c)."

C-0748

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29).]

"...A rehabilitation unit must ...

(b) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment."

C-0749

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing."

C-0750

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel ...]

...physical therapy and occupational therapy."

C-0751

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel ...]

... plus, as needed speech therapy, social services or psychological services, and orthotic and prosthetic services."

C-0752

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(d) :Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient."

C-0753

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(e) " Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment."

C-0754

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(e) Use ...team conferences [that] are held at least every two weeks to determine the appropriateness of treatment."

C-0755

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(f) Have a director of rehabilitation who-

(1) Provides services to the unit and to its inpatients for at least 20 hours per week."

C-0756

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(f) Have a director of rehabilitation who-

(2) Is a doctor of medicine or osteopathy."

C-0757

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(f) Have a director of rehabilitation who-

(3) Is licensed under State law to practice medicine or surgery."

C-0758

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(f) Have a director of rehabilitation who-

(4) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services."

C-0770

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.]

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30):

"(a) Bed capacity in units. A decrease in bed capacity must remain in effect for at least a full 12-month cost reporting period before an equal or lesser number of beds can be added to the hospital's licensure and certification and considered "new" under paragraph (b) of this section..."

C-0771

(Rev.)

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(a) Bed capacity in units ...When a hospital seeks to establish a new unit under the criteria under paragraph (b) of this section, or to enlarge an existing unit under the criteria under paragraph (d) of this section, the regional office will review its records on the facility to determine whether any beds have been delicensed and decertified during the 12-month cost reporting period before the period for which the hospital seeks to add the beds. To the extent bed capacity was removed from the hospital's

licensure and certification during that period, that amount of bed capacity may not be considered "new" under paragraph (b) of this section."

C-0772

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(b) New units. (1) A hospital unit is considered a new unit if the hospital-

(i) has not previously sought exclusion for any rehabilitation unit, and

(ii) has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit."

C-0773

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(2) A hospital that seeks exclusion of a new rehabilitation unit may provide a written certification that the inpatient population the hospital intends the unit to serve meets the requirements of §412.23(b)(2) instead of showing that the unit has treated such a population during the hospital's most recent cost reporting period."

C-0774

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(3) The written certification described in paragraph (b)(2) of this section is effective for the first full cost reporting period during which the unit is used to provide hospital inpatient care."

C-0775

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

*Exclusion of new rehabilitation units and expansion of units already excluded
(§412.30).]*

"(4) If a hospital that has not previously participated in the Medicare program seeks exclusion of a rehabilitation unit, it may designate certain beds as a new rehabilitation unit for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital. The written certification described in paragraph (b)(2) of this section also is effective for any cost reporting period of not less than 1 month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period."

C-0776

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

*Exclusion of new rehabilitation units and expansion of units already excluded
(§412.30).]*

"(5) A hospital that has undergone a change of ownership or leasing as defined in §489.18 of this chapter is not considered to have participated previously in the Medicare program."

C-0777

(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

*Exclusion of new rehabilitation units and expansion of units already excluded
(§412.30).]*

"(c) Converted units. A hospital unit is considered a converted unit if it does not qualify as a new unit under paragraph (a) of this section. A converted unit must have treated, for the hospital's most recent, consecutive, and appropriate 12-month cost reporting period (as defined by CMS or the fiscal intermediary), an inpatient population meeting the requirements of §412.23(b)(2)."

C-0778
(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(d) Expansion of excluded rehabilitation units. -(1) New bed capacity. The beds that a hospital seeks to add to its excluded rehabilitation unit are considered new beds only if-

(i) the hospital's State-licensed and Medicare-certified bed capacity increases at the start of the cost reporting period for which the hospital seeks to increase the size of its excluded rehabilitation unit, or at any time after the start of the preceding cost reporting period; and

(ii) the hospital has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds it seeks to add to the unit."

C-0779
(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(2) Conversion of existing bed capacity.

(i) Bed capacity is considered to be existing bed capacity if it does not meet the definition of new bed capacity under paragraph (d)(1) of this section."

C-0780
(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(ii) A hospital may increase the size of its excluded rehabilitation unit through the conversion of existing bed capacity only if it shows that, for all of the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), the beds have been used to treat an inpatient population meeting the requirements of §412.23(b)(2)."

C-0781
(Rev.)

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30):]

" (e) Retroactive adjustments for certain units. For cost reporting periods beginning on or after October 1, 1991, if a hospital has a new rehabilitation unit excluded from the prospective payment systems for a cost reporting period under paragraph (a) of this section or expands an existing rehabilitation unit under paragraph (c) of this section, but the inpatient population actually treated in the new unit or the beds added to the existing unit during that cost reporting period does not meet the requirements in §412.23(b)(2), CMS adjusts payments to the hospital retroactively in accordance with the provisions in §412.130 of this part. "

Refer to Appendix V of the State Operations Manual (SOM) for Critical Access Hospital Emergency Medical Treatment and Labor Act (EMTALA) interpretive guidelines and survey procedures.

C-2400
(Rev.)

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to comply with §489.24.

C-2401

(Rev.)

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to report to CMS or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of §489.24(e).

C-2402

(Rev.)

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

C-2403

(Rev.)

[The provider agrees,] in the case of a hospital as defined in §489.24(b), (including both the transferring and receiving hospitals), to maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of transfer.

C-2404

(Rev.)

§489.20(r)(2)

[The hospital (including both the transferring and receiving hospitals), must maintain] a list of physicians who are on call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition.

§489.24(j)(1)

Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

§489.24(j)(2)(i)

The hospital must have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.

§489.24(j)(2)(ii)

The hospital must have written policies and procedures in place to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

C-2405

(Rev.)

[The provider agrees,] in the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain a central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

§489.24 The provisions of this regulation apply to all hospitals that participate in Medicare and provide emergency services.

C-2406

(Rev.)

Applicability of provisions of this section.

(1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) "comes to the emergency department", as defined in paragraph (b) of this section, the hospital must (i) provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of §482.55 of this chapter concerning emergency services personnel and direction; and

(b) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section ends, as specified in paragraph (d)(2) of this section.

(2) Nonapplicability of provisions of this section.

Sanctions under this section for inappropriate transfer during a national emergency or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided for by section 1135(e)(1)(B) of the Act.

(c) Use of Dedicated Emergency Department for Nonemergency Services

If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

C-2407

(Rev.)

(1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either-

(i) within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.

(ii) For for transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) Exception: Application to inpatients.

(i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual

(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) Refusal to consent to treatment.

A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

C-2408

(Rev.)

(4) Delay in treatment.

(i) A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (d)(1) of this section in order to inquire about the individual's method of payment or insurance status.

(ii) A participating hospital may not seek, or direct an individual to seek, authorization from the individual's insurance company for screening or stabilization services to be furnished by a hospital, physician, or nonphysician practitioner to an individual until after the hospital has provided the appropriate medical screening examination required under paragraph (a) of this section, and initiated any further medical examination and treatment that may be required to stabilize the emergency medical condition under paragraph (d)(1) of this section.

(iii) An emergency physician or nonphysician practitioner is not precluded from contacting the individual's physician at any time to seek advice regarding the individual's medical history and needs that may be relevant to the medical treatment and screening of the patient, as long as this consultation does not inappropriately delay services required under paragraph (a) or paragraphs (d)(1) and (d)(2) of this section.

Hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required by this section, including asking whether an individual is insured and, if so, what that insurance is, as long as that inquiry does not delay screening or treatment. Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation.

A hospital meets the requirements of paragraph (d)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility

in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) does not consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

C-2409

(Rev.)

(1) General

If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless –

(i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and

(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer.

The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer.

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which –

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment.

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

C-2410

(Rev.)

A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (e)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.

C-2411

(Rev.)

A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers, which, for purposes of this subpart, means hospitals meeting the requirements of referral centers found at

§412.96 of this chapter) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual. This requirement applies to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department.

State Operations Manual

Appendix X – Guidance to Surveyors: Organ Transplant Programs

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(Rev.)

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Abbreviations:

Abbreviations:	
CMS Certification Number	CCN
The Centers for Medicare & Medicaid Services	CMS
The Centers for Medicare & Medicaid Services Central Office	CO
The Centers for Medicare & Medicaid Services Regional Office	RO
Clinical Transplant Coordinator	CTC
Conditions of Participation	CoPs
Conditions for Coverage	CfCs
Contract Officer Representative	COR
End Stage Renal Disease	ESRD
Health Resources and Services Administration	HRSA
Hepatitis B Virus	HBV
Hepatitis C Virus	HCV
Human Leukocyte Antigen	HLA
Independent Living Donor Advocate	ILDA
Licensed Clinical Social Worker	LCSW
Licensed Practical Nurse	LPN
Licensed Vocational Nurse	LVN
Living Donor	LD
Lung Allocation Score	LAS
Master of Social Work	MSW
Model for End Stage Liver Disease	MELD
Model for Pediatric End Stage Liver Disease	PELD
Organ Procurement Organization	OPO
Organ Procurement and Transplantation Network	OPTN

Abbreviations:	
Other Vital Data	OVD
Peripheral Parenteral Nutrition	PPN
Program Specific Reports	PSR
Project Officer	PO
Potential Living Donor	Potential LD
Quality Assessment and Performance Improvement	QAPI
Social Worker	SW
Scientific Registry of Transplant Recipients	SRTR
State Operations Manual	SOM
State Survey Agency	SA
Statement of Work	SOW
Transplant Candidate	TC
Transplant Recipient	TR
United Network of Organ Sharing	UNOS
United Network of Organ Sharing Identification/OPTN (LD&TR)	UNOS/OPTN ID

II. Survey Protocol Tasks

(Rev.)

The Components of the Standard Transplant Program Survey Protocol	
TASK #	Task
1	Pre-survey: Off-site Preparation
2	Entrance Activities
3	Sample Selection
4	Tracer for Selected Patients and Living Donors including Observations of Care, Interviews and Medical Record Review
5	Administrative Review
6	Personnel Record Review (If Indicated)
7	Pre-exit
8	Exit Conference
9	Post Survey Activities

TASK 1 - PRE-SURVEY: OFF-SITE PREPARATION

Prior to the survey, determine the number and types of transplant programs at the transplant hospital to be surveyed to determine survey team composition. Review each program using the information below:

1. Any prior survey and certification issues, e.g. previous complaints that indicate further investigation or follow-up;
2. Has the program exceeded a 12 month inactivation period; (X172)
3. Was any inactivation reported to CMS within seven (7) days; (X172)

TASK 2 - ENTRANCE ACTIVITIES

All transplant program surveys must include these entrance activities:

- All Transplant Program surveys are unannounced;
- The entire survey team should enter the hospital together;
- With the team present, the survey team lead will ask to speak to the Hospital Administrator or the designated person in charge;
- All team members must display their surveyor identification badge during on-site surveys.
- The entrance conference should begin within 20-30 minutes, or as soon as possible, upon entry to the facility.

Activities conducted during the entrance conference include the following:

- Introduction of surveyors;
- Explain that the purpose of the survey is to determine the program's compliance with the Medicare CoPs for each transplant program being surveyed (list the programs).
- Discuss the projected survey schedule for the survey including the projected time and date for the exit conference.
- Confirm that the primary transplant surgeon and primary transplant physician are consistent with the information on file with the SA; (if information is not consistent, the surveyor must confirm that the OPTN was notified of the change.).
- Determine whether living donor transplants are performed at the transplant *program*.
- Determine whether the hospital uses any contracted services that also serve that transplant program.
- As applicable, determine whether adult transplants are performed under a pediatric program or pediatric transplants are performed under an adult program (to enable sample selection).
- Explain that interviews may be conducted with transplant program staff and patients as indicated.
Request that surveyors be granted access to medical records as indicated.
Identify the areas in the hospital or on the hospital campus where transplant services including inpatient transplant care and outpatient care, are provided.

Request that the program create the following lists described below. The surveyor should observe the development of these lists.

Lists Requested During Entrance Conference:

1. Each transplant program's complete current active waiting list including the following information: name, date of listing, wait list status, medical record number, age (at time of transplant), race and gender of each patient;
2. List of all patients (to include their medical record number) removed from the waiting list within the past 12 months of each program for reasons other than death or transplant;

3. List of all persons evaluated within the last 12 months by each transplant program who were not placed on the waiting list. (Do not include persons that are currently in the evaluation process). The list should include patient name and medical record number.
4. List of all of the transplants performed within the last 18 months (including patient name, medical record number, age (at time of transplant), and date of transplant);
5. If applicable, list of all of the living donors who were evaluated during the past 12 months denoting those potential donors who proceeded to donation. Include name, medical record number, the organ(s) donated and date of donation within the designated time period;
6. List of all of the transplant recipients and living donors who are currently inpatient(s) and the location of the patient(s) within the hospital;

Request Program Administration Materials

1. Request an organizational chart of the transplant program, which includes the chains of command and how the transplant program fits within the overall hospital structure;
2. Request a log of any and all reported adverse events for the past 12 months (extend to 24 months if no reports found in the 12 month log). This list will be used to select the patient sample for adverse events.
3. Inform the administrator that policies, procedures, personnel, and QAPI manuals will be requested, as needed, for review.

TASK 3 – SAMPLE SELECTION

Refer to the lists requested during the entrance conference (1-6) above and the adverse event log requested during the entrance conference to accomplish the patient sample selection. The goal is to choose, within the sample, a representation of the overall transplant program services and patients.

Seven categories that must be included in the patient sample; the chart below reflects the minimum number of patients that must be selected randomly for each area.

Patients Transplanted <6 months ago	Patients Transplanted 7-18 months ago	Patients on Current Waitlist	Patient Adverse Events	Patients Removed from Waitlist	Patients Removed from the waiting list within the past 12 months for reasons other than death or transplant	Patients Evaluated but not Waitlisted	Living Donors (if applicable)
2	2	2	2	2	2	2	2

If a program performs both adult and pediatric transplants under one approval, there must be at least one patient from each age group selected for each category.

If there were no patients transplanted within the last six months, add two additional patients to the Patients on Current Waitlist category sample.

Select waitlist patients based upon the time they have been on the waitlist. Review a patient who has been on the list three years or more and a patient who has been on the list less than 3 years.

TASK 4 – TRACER FOR PATIENT AND LIVING DONORS

Once the patient sample has been selected, the surveyors will then trace the patient experience from evaluation through discharge planning for those receiving transplants. For those patients who are currently on the waitlist, the surveyor will trace their experience from evaluation until the most current stage in the phases of transplant.

During the tracer activities, the surveyor will spend no more than two hours reviewing each medical record to get an overview of the patient experience and identify those multidisciplinary team members that must be interviewed based upon findings from the medical record review. During the record review, the surveyor should verify that the plan established for the patient to achieve successful transplantation was individualized for the needs of the particular patient.

I. Patient Experience- Evaluation

Each patient experience should begin with an evaluation regardless of whether they are or are not ultimately placed on the waitlist. This evaluation must include multidisciplinary involvement to identify all the patient characteristics and attributes to determine suitability for transplant. Multidisciplinary involvement means that each member of the patient care team (designated by the facility) must complete an evaluation of the potential

recipient. The evaluation process may appear differently based on the individualized needs of the patient during the evaluation. When reviewing the medical record, identify the members of the multidisciplinary team that have been involved in the care of the patient, identify recommendations, and review for follow-up on these recommendations. Please note that there are specifics in the evaluation that must occur such as medical evaluation, psychological evaluation, and the informed consent process.

Completion of the informed consent process may be documented in a single document or throughout the record. The surveyor must confirm, through medical record documentation, that the facility ensured that the patient has made an informed decision to proceed with the process of transplantation. The process includes informing the candidate of medical and psychosocial risks, the right to refuse transplantation, donor risk factors, alternative treatments, potential costs outside insurance, the surgical procedure, and the transplant program's patient outcomes. A surgical consent for the actual transplantation surgery does not confirm the informed consent process.

II. Patient Experience- Patient Selection

(Waitlist Sample) The medical record must include the rationale for the decision to place the patient on the waitlist. This rationale should be consistent with the written criteria of the facility. If not, the record must include rationale for waitlisting outside the criteria.

(Evaluated but not Listed Sample) In instances where a patient was evaluated but not placed on the waiting list, there should be documentation of the reason for not placing the patient on the waitlist and whether the patient was informed of the decision not to place him/her on the wait list based on the evaluation. If there is evidence that the potential candidate meets the wait list criteria but was not listed, there must be documentation by the facility as to why they were not placed on the waitlist.

III. Patient Experience- Waitlist Management

(Waitlist and Transplant Recipient Sample) For those patients who were placed on the transplant waitlist, there should be evidence of periodic follow up during their time on the wait list. There are no set requirements for the frequency of the periodic follow-up or any requirement that the follow-up must be conducted by the transplant program. However, based on the identified needs of the patient and the policy of the transplant program the transplant program would see the patients periodically or maintain on-going communication with the patient's community health care providers.

While the patient is on the waitlist, under 42 C.F.R. § 482.94(a)(1) there should be evidence that any recommendations made by a multidisciplinary team member are being followed up by the team member and that any referrals to multidisciplinary team member are promptly addressed.

Please note that the length of time on the waitlist may vary for each individual.

IV. Patient Experience- Transplantation

(Transplant Recipient Sample) For those patients who received a transplant, the medical record must include evidence that prior to the transplant: an ABO verification occurred (blood type and other vital Data (OVD)); there is evidence that the facility discussed any potential risks associated with the organ being offered and whether the patient agrees to accept the organ; and there is a documented surgical consent for the transplant procedure. It is expected that all members of the multidisciplinary team will continually assess the patient and provide any recommendations which would facilitate discharge.

Recommendations may or may not require ongoing involvement with the team member based upon the individual patient's needs and any complications which may prolong the hospital stay.

V. Patient Experience- Living Donation

(Living Donor Sample) The record must include documentation of the evaluation process conducted with the living donor. The evaluation includes a final recommendation and justification as to whether the living donor/ is suitable for donation. The donor is notified as to suitability and rationale for the decision.

The medical record must include evidence that the Independent Living Donor Advocate (ILDA)/TEAM was made available to the living donor, to include the name and contact information of the ILDA. Every living donor must be assigned and have an interview with the ILDA or ILDA team prior to the initiation of the evaluation and throughout the donation phase.

VI. Patient Experience- Patient Care

Once the medical record has been reviewed for each sampled patient, the surveyor should move to the clinical areas where inpatient and outpatient care is provided. During the time the surveyor spends in the clinical areas, all available inpatient and outpatients receiving transplant care on the unit or in the clinic are interviewed. If an interviewed patient was part of the original sample, then compare the information received from the patient with the information received in his/her medical record. . If an interviewed patient is not part of the original sample, the medical record must be reviewed and the information compared to the information provided by the patient regarding his/her patient experience.

General observations should be made during the time the surveyor spends in the clinical areas. Any concerns, whether related to specifically transplant CoPs or hospital CoPs, should be investigated further as warranted. Interviews with transplant staff in general should be conducted pursuant to medical record findings, patient interview findings, or specific observations.

Interviews with both patients and staff should be conducted one-on-one with the surveyor when possible. It is acceptable for surveyors to conduct telephone interviews with key personnel in the event that they are unavailable during the survey.

TASK 5 – QUALITY ASSURANCE AND IMPROVEMENT

Review of Quality Assessment and Performance

Review the medical records for the adverse events sample. The surveyor should examine the record for events leading up to the event. In addition, the QAPI materials associated with the adverse event should be reviewed for each sampled event. Review the QAPI materials to look for the analysis of the event, actions taken following the event, and safeguards to prevent future occurrence. Review the data the program is tracking associated with the adverse event to ensure there is no recurrence. If the program has effectively addressed all the activities outlined above, the surveyor concludes from the sample review that the program does do QAPI activities reactively. However the QAPI director must be interviewed to determine the proactive activities of the QAPI program and the integration of the transplant program QAPI and the hospital QAPI program.

TASK 6 – PERSONNEL RECORD REVIEW

If concerns regarding staff education, qualifications, and training for staff providing transplant care are identified during observations or interviews, the surveyor may request applicable personnel records. For staff new to transplant, or who appear unfamiliar with the care of transplant patients, the surveyor validates the presence of orientation education and/or additional training to ensure that the staff are prepared to care for patients undergoing transplants.

TASK 7 - PRE-EXIT CONFERENCE

Survey Team Discussion Meeting

Each team member will review and share the evidence he/she has gathered with the other team members. The team should determine any non-compliance and document any such findings including making photocopies of medical records or other documents needed to support the non-compliance. Make all copies prior to the exit conference.

TASK 8 – EXIT CONFERENCE

A single exit conference will be held regardless of the number of programs surveyed. At the beginning of the exit conference, each participant will identify him/herself.

During the conference:

- Identify each deficiency found and restate those deficiencies being cited;
- Provide an opportunity for the transplant program to present additional information that may not have been presented during the survey (except for

- deficiencies cited from the at 482.80);
- Outline the next steps
 - The hospital administration will receive a written form (the CMS-2567 Statement of Deficiencies and Plan of Correction) from the State Survey Agency that describes the survey findings and cited noncompliance deficiencies. Findings for all programs that were surveyed together will be included on one CMS-2567. Each deficiency will be identified by the applicable program. Following receipt of the CMS-2567 (generally within 10 days of the exit conference), the transplant program must submit a plan of correction within 10 days of receipt of the CMS-2567 for each individually cited deficiency.
 - Explain that all findings are preliminary and subject to administrative review.

Although it is CMS' general policy to conduct an exit conference, be aware of situations that would justify refusal to continue an exit conference. For example, if the hospital administrator or transplant program administrator is represented by counsel, surveyors may refuse to continue the conference if the lawyer tries to turn it into an evidentiary hearing.

If the program records the conference, the surveyor should request a copy for the survey file.

TASK 9 - POST SURVEY ACTIVITIES

Following the survey, the surveyor will complete the Organ Transplant Hospital Worksheet, Form CMS-670 (Survey Team Composition and Workload), and the CMS-2567 forms. Form CMS-670 and the CMS-2567 are entered into the Automated Survey Process Environment System (ASPEN).

There will be a single CMS-2567 form prepared, even if the survey included multiple transplant programs within a hospital. Each regulation that is cited must specify the applicable transplant program to which it applies. ASPEN has been modified to include this information.

Once the CMS-2567 is finalized, the SA is responsible for sending the CMS-2567 to the hospital administrator and requesting a plan of correction (note the plan of correction may address more than one type of transplant program). Once an acceptable plan of correction has been submitted, the SA is responsible for scheduling the follow-up visit (if applicable) to ensure that any cited deficiencies have been corrected.

III. Alternate Survey Protocol: Pediatric Heart Program (Rev.)

Survey Protocol for Pediatric Heart Transplant Programs Operating Jointly with Associated Heart Transplant Program

Under §482.76(d), instead of meeting all conditions of participation at §482.72 through §482.74 and §482.80 through §482.104, a heart transplant *program* that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants by meeting the Omnibus Budget Reconciliation Act of 1987 criteria in section 4009(b) (Pub.L.100-203).

The pediatric heart transplant program is responsible for providing evidence that:

1. The pediatric transplant program is operated jointly with another Medicare-approved facility. This joint operation may occur pursuant to a structured affiliation between the two hospitals or pursuant to a written agreement;
2. The surgeons who perform the heart transplants at the pediatric hospital are credentialed for cardiac surgery at both hospitals under the unified program; The QAPI programs must be shared by both hospitals and include review, analysis and recommendations for the pediatric transplants; Collaboration between both QAPI programs would consist of reviewing and evaluating the need for any changes between the jointly operated entities; and
3. Demonstrates to the satisfaction of CMS that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

TASK 1 – PRE-SURVEY PREPARATION OFF-SITE

None required:

TASK 2 – ENTRANCE ACTIVITIES

Meet with the program administrator upon entrance and explain the purpose of the review. Provide an estimated timeframe for the survey and list the materials that will be reviewed.

Requested Items for Review:

Lists of Transplant Candidates and Patients:

Log of the transplants performed including name and date of transplant for both the pediatric heart transplant program and the associated heart transplant program within the past three years;

Program Administration: Policies, Procedures, Personnel, and QAPI

1. A copy of the joint operating agreement between the pediatric heart transplant program and the associated heart transplant program that is jointly operating this program;
2. An organizational chart of the pediatric heart transplant program and the associated program;
3. Credentials for cardiac transplant surgeons and physicians and

- confirmation they are permitted to practice at both facilities; and
4. Log of any reported adverse events (by the pediatric heart transplant program and the associated program) and corresponding documentation of the investigation and analysis of those events for the past 12 months.

TASK 3 – SAMPLE SELECTION

Using the lists of recipients of the pediatric heart transplant program and the associated heart transplant program, select the samples as early in the survey as possible so that the transplant program has time to obtain all the records requested. At any time, the surveyor may add additional records to any sample based on observations or interviews.

Pediatric Heart Transplant Recipients Sample Selection

Based on the list of transplants done over, but not prior to, the past three years by the pediatric heart transplant program, select a minimum of five or if less than 5 transplants have been completed, all available records pediatric heart transplant recipients and request their medical records for review.

TASK 4 – REVIEW OF TRANSPLANT PATIENT MEDICAL RECORDS

Task 2 describes the number of transplant patient medical records that must be selected for review both in the pediatric heart transplant program and the associated program.

Surveyors will focus the review of medical records on the following sections:

1. Evaluations: psychosocial and medical;
2. Patient selection criteria;
3. Informed consent documentation;
4. Blood type, ABO and UNOS ID verification;
5. Operative reports;
6. Progress Notes for patient care, staff activities, informed consent discussions, etc.;
7. Multidisciplinary care plan and patient teaching tools for involvement of all key personnel;
8. Discharge planning; and
9. Follow-up (outpatient) chart or section of record.

Surveyors will make photocopies of any documents needed to support survey findings. If requested, the surveyor will make the hospital a copy of all items photocopied. The photocopies must include the recipient's anonymous code, the type of document and the date and time the photocopy was made, for example, "Patient #3, Progress Notes, 2-25-07, 1400."

TASK 5 – STAFF INTERVIEW

Follow standard protocol for interviews.

TASK 6 – PERSONNEL RECORD REVIEW

Follow standard protocol for personnel file review.

TASK 7 – ADMINISTRATIVE REVIEW

Operating Agreement

Review the operating agreement between the pediatric heart transplant program and the associated heart transplant program to ensure that it meets the requirements of the guidelines (Tags X024 through X026).

Refer to the QAPI Administrative Review in the standard protocol. Ensure that the QAPI program is a single, unified program between the jointly operating hospitals.

TASK 8 – PRE-EXIT CONFERENCE

Review and analyze all the information collected from any observations, interviews, and record reviews to determine whether or not the program meets the requirement of 42 CFR 482.76(d) for approval of a pediatric heart transplant program. The team identifies any non-compliance that may prohibit the alternative approval.

Refer to the standard survey protocol for discussion by the survey team, determining compliance, and ensuring that any non-compliance is adequately supported.

If the program is not in compliance with the requirements of 42 CFR 482.76(d), then the pediatric heart transplant program cannot be approved under the alternate approval requirements.

TASK 9 – EXIT CONFERENCE

Refer to the standard protocol for the exit conference. However, pediatric heart programs under the alternate approval are only required to meet tags X024 through X026. Therefore, the exit conference will be limited to findings on these requirements.

TASK 10 – POST SURVEY ACTIVITIES

Refer to standard survey protocol. Approval of a pediatric heart transplant program does not require a separate form CMS-2567, and may be listed with other types of transplant programs surveyed simultaneously.

X-001

(Rev.)

§482.68 – Special Requirements for Transplant *Programs*.

A transplant *program* located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§482.72 through 482.104, a transplant *program* must also meet the conditions of participation specified in §482.1 through §482.57, except for §482.15.

Guideline §482.68

As noted by their definitions in §482.70, pancreas and intestine programs are approved as a part of their associated “parent” approval (kidney and liver, , respectively) and therefore these programs are reviewed as a component of the survey of the associated parent transplant program.

If any Condition of Participation is found to be out of compliance, then this Condition must also be cited as being out of compliance.

General Requirements for Transplant *Programs*

X-002

(Rev.)

§482.72 Condition of Participation: OPTN Membership.

A transplant *program* must be located in a transplant hospital that is a member of, and abides by the rules and requirements of, the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term “rules and requirements of the OPTN” means those rules and requirements approved by the Secretary pursuant to §121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

Guideline §482.72

The hospital in which the organ transplant program(s) is a part of must be a member of the Organ Procurement and Transplantation Network (OPTN) prior to Medicare approval and for as long as it is approved. In the event that the Secretary issues formal notice of his approval of a recommendation for the exclusion of a program from the OPTN, the associated Medicare approval will be terminated pursuant to non-compliance with 42 CFR 482.72.

X-011

(Rev.)

§482.74 Condition of Participation: Notification to CMS

(a) A transplant *program* must notify CMS immediately of any significant changes related to the *hospital's* transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow-up, as appropriate, include, but are not limited to:

Guideline §482.74

For purpose of this condition and its relative tags at X-012, X-014 and X-015, “immediately” means within seven business days of when the transplant program becomes aware that either a change will occur or has occurred.

X-012

(Rev.)

§482.74(a)(1) Change in key staff members of the transplant team, such as a change in the individual the transplant *program* designated to the OPTN as the *program's* “primary transplant surgeon” or “primary transplant physician;”

X-014

(Rev.)

§482.74(a)(2) Termination of an agreement between the hospital in which the transplant *program* is located and an OPO for the recovery and receipt of organs as required by section 482.100; and

Guideline §482.74(a)(2)

Outside an approved waiver process, a hospital may not terminate its agreement with its designated OPO. Via a waiver request submitted to CMS, a hospital may request to work with an OPO in another OPO Donation Service Area. Should the waiver be granted, a hospital may then terminate the agreement with its designated OPO. See also 42 CFR 486.308. The transplant program must notify the applicable State Survey Agency (SA) of its hospital's intention to seek a waiver of its designated OPO. The hospital must submit the actual request for an OPO waiver to the Center for Medicare within CMS Central Office in Baltimore. Once the waiver is granted or denied, the hospital must provide a copy of the decisional document to the SA.

X-015

(Rev.)

§482.74(a)(3) Inactivation of the transplant *program*.

§482.74(b) Upon receiving notification of significant changes, CMS will follow up with the transplant *program* as appropriate, including (but not limited to):

- (1) Requesting additional information;
- (2) Analyzing the information; or
- (3) Conducting an on-site review.

Guideline §482.74(a)(3)

Upon notification of a program's plan for inactivation, CMS may request additional information from the program pertaining to the reason for the inactivation and the communications that have occurred to notify and assist the patients on the program's waitlist in association with the inactivation period.

Per §488.61(e) Transplant *Program* Inactivity, "A transplant *program* may remain inactive and retain its Medicare approval for a period not to exceed 12 months." Program inactivity does not preclude a program from survey for compliance with the Conditions of Participation during the inactivation period. If a program's inactivity period exceeds 12 months, it must reactivate, voluntarily withdraw from Medicare participation, or be subject to termination of its Medicare approval.

X-031

(Rev.)

§482.80 Condition of Participation: Data Submission, Clinical Experience, and Outcome Requirements for Initial Approval of Transplant *Programs*.

Except as specified in paragraph (d) of this section, and §488.61 of this chapter, transplant *programs* must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

Guideline §482.80

The Standards of this Condition are evaluated by the surveyor off-site, prior to the survey. The determination of compliance or non-compliance will be communicated to the program at the time of the survey entrance conference. Since this finding is based upon data submitted to the OPTN prior to the survey, the program may not submit any additional or corrected data, during the survey, to change the compliance determination.

X-032

(Rev.)

§482.80(a) Standard: Data Submission.

No later than 90 days after the due date established by the OPTN, a transplant *program* must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN

forms for transplant candidate registration, transplant recipient registration and follow-up and living donor registration and follow-up.

Guideline §482.80 (a)

The determination of compliance or non-compliance with this Standard is made prior to the on-site survey. The determination is shared with the program at the time of the survey entrance conference. Since this finding is based upon data submitted to the OPTN prior to the survey, the program may not submit any additional or corrected data, during the survey, to change the compliance determination.

X-033

(Rev.)

§482.80(b) Standard: Clinical Experience.

To be considered for initial approval, an organ-specific transplant *program* must generally perform 10 transplants over a 12-month period.

Guideline §482.80(b)

Generally means in all instances except where specifically exempted by the regulations.

The following types of programs are subject to a clinical experience requirement of having performed generally 10 transplants over a 12-month period for initial approval:

- Adult Heart-Only
- Adult Lung-Only
- Adult Liver
- Adult Intestinal and/or Multivisceral

For purposes of the clinical experience requirement, multi-organ transplantation will be included as separate transplants for each organ. For example, a combined liver-kidney transplant will account for one liver transplant and one kidney transplant.

X-035

(Rev.)

§482.80(c) Standard: Outcome requirements. CMS will review outcomes for all transplants performed at a *program*, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a *program* requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant *program*'s observed number of patient deaths and graft failures 1-year post-transplant to the *program*'s expected number of patient deaths and graft failures 1-year post-transplant using the data contained in

the most recent Scientific Registry of Transplant *Recipients* (SRTR) *program*-specific report.

(2) CMS will not consider a *program*'s patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.85.

(d) Exceptions

(1) A heart-lung transplant *program* is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the *program*.

(2) An intestine transplant *program* is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multivisceral transplants performed at the *program*.

(3) A pancreas transplant *program* is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the *program*.

(4) A *program* that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant *program*.

Guideline §§482.80(c) and (d)(1)-(4)

The program types subject to this requirement and not exempted include:

- Adult Kidney-Only
- Adult Heart-Only
- Adult Lung-Only
- Adult Liver-Only
- Pediatric Kidney-Only (Includes only 1-year graft survival)
- Pediatric Heart-Only
- Pediatric Lung-Only
- Pediatric Liver-Only

X-036

(Rev.)

§482.80(d)(5) A kidney transplant *program* that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval

Transplant Center Process Requirements

X-051

(Rev.)

§482.90 Condition of Participation: Patient and Living Donor Selection.

The transplant *program* must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. If a *program* performs living donor transplants, the *program* also must use written donor selection criteria in determining the suitability of candidates for donation.

Guideline §482.90

Transplant programs are required to develop their own hospital-approved selection criteria to determine suitability for organ transplantation and living donation. There must be evidence that the written selection criteria are followed for the selection of transplant candidates to be placed on the transplant waitlist and, if applicable, potential living donors. Any changes to the hospital-approved, written selection criteria are approved according to the hospital policy approval process.

The selection criteria (medical, psychosocial, financial, etc.) must clearly define all the factors that are considered in determining suitability for transplantation or living donation. These criteria may not exclude groups or individuals without documentation supporting the exclusionary foundation(s).

X-053

(Rev.)

§482.90(a)(1) Prior to placement on the *program*'s waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

Guideline §482.90(a)(1)

An evaluation of each candidate's psychosocial status must be conducted in all situations in which it is possible to do so in order to determine suitability for transplantation and/or identify resources that potentially will be needed for the safe care and discharge of the patient post-discharge. The transplant program must conduct and document the psychosocial evaluation performed on a potential recipient before their placement on the waitlist. The only exception for not completing the psychosocial *evaluation* prior to placement on the waitlist would be an emergent situation where the need for transplant is imminent or the patient is very young. Justification for not conducting a psychosocial

evaluation prior to a potential recipient's placement on the waitlist must be documented in the medical record.

While the transplant program has flexibility in the selection of a specific psychosocial evaluation tool(s) to be used, it is expected that the psychosocial evaluation would be conducted by transplant program personnel who have the professional qualifications to administer psychosocial evaluations, make resultant assessments and make recommendations to the multidisciplinary team. Evaluations should include, at a minimum, the following:

- Social, personal, housing, vocational, financial, and environmental supports;
- Coping abilities and strategies;
- Understanding of the risks and benefits of transplantation;
- Ability to adhere to a therapeutic regimen; and
- Ongoing psychological issues that may impact the success or failure of organ transplantation.

X-054

(Rev.)

§482.90(a)(2) Before a transplant *program* places a transplant candidate on its waiting list, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

X-055

(Rev.)

§482.90(a)(3) When a patient is placed on a *program*'s waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

Guideline §482.90(a)(3)

The potential recipient medical record must contain documentation that the multidisciplinary team considered all evaluations in the context of the hospital-approved *selection* criteria. If the potential recipient does not meet the hospital-approved selection criteria, but was placed on the waiting list anyway, the exception justification for listing must be clearly documented in the potential recipient's medical record.

X-056

(Rev.)

§482.90(a)(4) A transplant *program* must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

Guideline 482.90(a)(4)

Interviews with transplant patients and dialysis facilities should confirm the receipt of the written selection criteria upon request.

X-058

(Rev.)

§482.90(b) Standard: Living Donor Selection.

The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant *programs* must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

Guideline §482.90(b)(1)

Each prospective living donor must receive a medical and psychosocial assessment prior to donation to ensure that any risks to the donor are identified and to assist in the determination of appropriateness for donation. It is expected that a psychosocial evaluation for living donors would address the following:

- Social, personal, housing, vocational, financial, and environmental supports;
- Coping abilities and strategies;
- Understanding of the risks and benefits of donation;
- Ability to adhere to a therapeutic regimen; and
- Mental health history, including substance and alcohol use or abuse and how it may impact the success or failure of organ transplantation.

X-071

(Rev.)

§482.92 Condition of Participation: Organ Recovery and Receipt.

Transplant *programs* must have written protocols for validation of donor-recipient blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant *program* is responsible for ensuring the medical suitability of donor organs for transplantation into the intended *recipient*.

X-073

(Rev.)

§482.92(a) Standard: Organ Receipt. After an organ arrives at a transplant *program*, prior to transplantation, the transplanting surgeon and another licensed healthcare professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended *recipient*.

Guideline §482.92(a)

The verification occurs once the organ arrives in the operating room, prior to transplantation. The second person verifying the blood type (and other data) may be any licensed health care professional who is in the operating room at the time of the verification. The transplant program should identify in *its* protocols which categories of health care professional(s) may do the second verification. If the transplant surgeon is already scrubbed and gloved, he/she may do a visual verification and sign that verification in the medical record at the end of the surgery. The time of the visual verification should be entered into the recipient's record by the second person at the time it is done and should state that the verification was visual by the transplant surgeon. The second person will sign their verification at that time. After the case is concluded, the surgeon confirms his visual verification in the record by either co-signing the verification entry by the second person or writing a separate progress note which chronicles the verification (including times).

The reference to "other vital data" is considered to be the OPTN Identification Number.

X-074

(Rev.)

§482.92(b) Standard: Living Donor Transplantation.

If a *program* performs living donor transplants, the transplanting surgeon and another licensed healthcare professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the *recipient's* organ(s).

Guideline §482.92(b)

See above discussion at X073 regarding surgeon and other health care professional verification.

Verification that the living donor blood type and other vital data are compatible with the intended recipient must occur onsite, after the donor arrival in the operating room but prior to the induction of general anesthesia.

The verification must be completed by the transplanting surgeon and another licensed healthcare professional. The program should identify in *its* protocols which categories of health care professional(s) may do the second verification.

Verification by the transplant surgeon and another licensed healthcare professional must be documented. The documentation must include signatures and corresponding date and time of the verification. To ensure that verification is completed immediately before the removal of the donor organ(s), documentation must include the time of donor arrival into the operating room, time of organ verification and time general anesthesia was started.

Verification of correct organ for the correct recipient and verification that the blood type and other vital data are compatible with the potential recipient must occur immediately before the removal of the living donor organ(s).

If the donor organ recovery surgeon is also the transplanting surgeon, verification prior to removal of the living donor organ(s) and verification prior to transplantation must occur separately.

X-081
(Rev.)

§482.94 Condition of Participation: Patient and Living Donor Management.

Transplant *programs* must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant *program* performs living donor transplants, the *program* also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

Guideline §482.94

Transplantation and Living Donor Care Phases are generally defined as:

Transplantation Care Phases:

- Transplant Phase: Begins when the potential transplant candidate is evaluated for transplantation and continues through completion of the transplantation surgery.
- Discharge Phase: Begins at the transplant *candidate* admission to the hospital and continues through to his/her discharge from the inpatient stay.

Living Donor Care Phases:

- Evaluation Phase: Begins from first presentation by the potential donor until the time he/she enters the OR for the donation surgery.
- Donation Phase: Begins from the time the potential donor enters the OR for the donation surgery until the donor is discharged from the inpatient surgery stay.
- Discharge Phase: Begins at admission to the hospital and continues through the donor's discharge from the inpatient stay.

Some transplant programs perform living donor services under arrangement with other hospitals. In these cases, the transplant program retains all responsibility for compliance with management of the living donor. The transplant program must communicate the donor management activities that are required as a part of the living donor organ recovery to the hospital under the arrangement and ensure that the activities are completed appropriately.

X-082

(Rev.)

§482.94(a) Standard: Patient and Living Donor Care.

The transplant *program*'s patient and donor management policies must ensure that:

- (1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and
- (2) If a *program* performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

Guideline §482.94(a)

In those instances where it is determined that the transplant recipient or living donor is not receiving or did not receive the services needed as identified by assessment, consultation and the multidisciplinary plan of care, the resulting deficiency should be cited at this regulatory cite.

X-083

(Rev.)

§482.94(b) Standard: Waiting List Management.

Transplant *programs* must keep their waiting lists up to date on an ongoing basis, including:

X-085

(Rev.)

§482.94(b)(2) Removing patients from the *program*'s waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a *program*'s waiting list; and

Guideline §482.94(b)(2)

There may be instances where a recently transplanted recipient is placed back on the wait list. In these instances, documentation must include the original date of removal and the date of the new placement on the list.

X-086

(Rev.)

§482.94(b)(3) Notifying the OPTN no later than 24 hours after a patient's removal from the *program*'s waiting list.

Guideline §482.94(b)(3)

For the purpose of this Standard, the 24 hour period to notify the OPTN of a patient's removal begins at the time of the patient's death; transplantation; the patient's decision to be removed from the list; or notification of death or *transplantation* from an outside source (family or another transplant hospital if the patient was listed with more than one transplant program).

The OPTN is considered to have been automatically notified once the patient is removed from the waitlist in UNET by the transplant program. No additional notification is required by the transplant program to the OPTN.

X-087

(Rev.)

§482.94(c) Standard: Patient Records.

Transplant *programs* must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a *program's* waiting list and who is admitted for organ transplantation.

X-088

(Rev.)

§482.94(c)(1) For each patient who receives an evaluation for placement on a *program's* waiting list, the *program* must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of:

- (i) The patient's placement on the *program's* waiting list;
- (ii) The *program's* decision not to place the patient on its waiting list; or
- (iii) The *program's* inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

X-089

(Rev.)

§482.94(c)(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant *program* must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

Guideline §482.94(c)(2)

Transplant programs determine the most appropriate method for communication with the patient and the dialysis facility. The communication must be evidenced by documentation in the medical record.

X-090
(Rev.)

§482.94(c)(3) In the case of patients admitted for organ transplants, transplant *programs* must maintain written records of:

(i) Multidisciplinary patient care planning during the transplant period; and

Guideline §482.94(c)(3)

A multidisciplinary care plan includes ongoing assessments to identify any new patient needs and/or to determine if any currently identified patient's needs have changed. A multidisciplinary team must be identified for each patient at the time the evaluation for wait listing begins. This multidisciplinary team participates in the patient care planning from evaluation through transplantation. At the time of the initial evaluation, each member of the team participates in the evaluation of the patient. It may not be necessary for all team disciplines to see the patient again until transplant is imminent unless there are identified needs. Following the transplant, each discipline must, as appropriate: 1) reassess the recipient following the surgery; 2) see the recipient as often as indicated by identified issues; and 3) see the recipient prior to discharge.

X-092
(Rev.)

§482.94(d) Standard: Social Services.

The transplant *program* must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their families....

Guideline §482.94(d)

Making social services available means that if a social service need for a recipient/donor/family is identified at any point from evaluation through discharge, the program must provide a qualified social worker to address the need/issue and documentation in the medical record should confirm the social worker intervention.

X-093
(Rev.)

§482.94(d)(cont'd)

...A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and

(1) Completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or

(2) Is working as a social worker in a transplant *program* as of effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under (d)(1) of this paragraph.

Guideline §§482.94(d)(cont'd) and (d)(1)-(2).

Non-MSW employees functioning as a transplant program social worker prior to the June 28, 2007, which is the effective date of the final rule, “Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants” (72 FR 15198, Mar. 30, 2007), must have a consultative relationship with an MSW who meets the requirements of §482.94(d)(1). The purpose of the consultative relationship is for the MSW to advise, support and often guide a social worker in their position. A consultative relationship generally would include:

- Meetings between the MSW and the non-MSW on a routine or re-occurring basis; and
- Evidence that the MSW is available and responsive for ad hoc consultation with the non-MSW employee.

X-094

(Rev.)

§482.94(e) Standard: Nutritional Services.

Transplant *programs* must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

Guideline §482.94(e)

Transplant programs must have a process in place to ensure that a qualified dietitian is available to provide nutritional assessments or diet counseling to all transplant patients and living donors that require such services. Nutritional services include consultation, assessment, intervention(s) and education. If a need is identified by any member of the multidisciplinary team, and a request is made for nutritional services, but the requested services are not provided due to the lack of nutritional staff available in the hospital, a deficiency would be cited.

X-099

(Rev.)

§482.96 Condition of Participation: Quality Assessment and Performance Improvement (QAPI)

Transplant *programs* must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

Guideline §482.96

The transplant center develops its transplant program-specific quality assessment and performance improvement (QAPI) program either individually or collaboratively with the transplant hospital QAPI program and functions as a component of the associated hospital QAPI program required at 42 CFR §482.21. There should be evidence of communication between the two entities to ensure that both entities are actively involved in QAPI activities which address the specific requirements of the transplant CoPs. If the transplant program has a separate QAPI program, it must provide evidence that it is interrelated with the hospital QAPI plan.

A comprehensive transplant QAPI program evaluates and monitors performance of transplantation services across every aspect of the program from the evaluation of a potential recipient/donor candidate through his/her discharge from the hospital. A comprehensive QAPI program approach embraces a broad, multidisciplinary, system-wide perspective. It encompasses all aspects of clinical care and all relevant hospital services and includes input from a broad representation of staff at all levels, including individuals with authority to make decisions about the transplant program's policies, practices and resources. It continuously monitors, evaluates and improves all organ transplantation services for transplant candidates, transplant recipients, potential living donors across all phases of transplantation and living donation, including transplant services provided under contract or arrangement..

A data-driven transplant QAPI program continually uses data to guide quality assessment and performance improvement activities with respect to all transplantation services. The program proactively, systematically and at regular specified intervals:

- Identifies, implements, assesses and re-assesses the data to be collected for each measure and other information needed to monitor and evaluate performance of transplantation services in all areas;
- Collects, records and reviews the data for accuracy;
- Analyzes the data and uses the data/analyses to assess the program's performance; and
- Uses the results of its analyses to monitor, evaluate and improve the quality and safety of all transplantation/donation services on an ongoing basis.

X-100

(Rev.)

§482.96(a) Standard: Components of a QAPI Program.

The transplant *program's* QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and *recipient* matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights....

Guideline §482.96(a)

This standard requires transplant QAPI programs to identify, implement, assess and re-assess objective measures to evaluate and improve both their transplantation outcomes as well as the quality, safety and performance of their transplantation activities, across all phases of transplant and living donation.

Transplantation and living donor care - including but not limited to the potential areas for measurement listed in this standard – involve multiple phases, activities and potential outcomes, each with various aspects that may be amenable to objective measurement. Objective measures can mean that a transplant program will select some measures for routine monitoring on an ongoing basis; others will be identified and implemented in order to address, evaluate and monitor a particular problem or opportunity for improvement. Each transplant QAPI program should identify and implement multiple objective measures that are relevant and meaningful for evaluating its own performance with regard to both transplantation activities and outcomes to:

- Collect and analyze data to assess its baseline performance and to track performance on the selected measures over time; and
- Use the information gained to evaluate and improve performance and to ensure that improvements are sustained over time.

Measuring an outcome means measuring the health status of a patient resulting from health care. For example, the SRTR reports contain a number of objective outcome measures useful for performance monitoring and improvement (such as patient and graft survival), but additional patient outcomes not reported by the SRTR may also be important for a program to measure (for example, rates of specific intra- and post-operative complications for transplant recipients and living donors).

In addition to measuring relevant outcomes, other types of clinical quality measures are needed to evaluate transplantation activities. Each program must critically examine its own services and performance to determine which activities (and which aspects of the activity) within each phase of transplantation or donation should be evaluated and monitored using objective measures.

X-101

(Rev.)

§482.96(a)(cont'd)

...The transplant *program* must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

Guideline §482.96(a)(cont'd)

The transplant program must use what it learns from monitoring the objective measures described under Tag X100 to identify and implement actions to improve its performance.

The program should review the available evidence, if any, for particular performance improvement strategies and implement activities that are most likely to be effective in

addressing the specific factors that are contributing to the program's performance. If successful, performance will need to be monitored over time to verify that improvements are sustained. If not, the program will need to re-evaluate, determine an appropriate alternative course of action, and track performance.

X-102

(Rev.)

§482.96(b) Standard: Adverse Events.

A transplant *program* must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

(1) The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

Guideline §482.96(b)(1)

An adverse event is defined at 42 CFR §482.70 as “an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.”

The facility policies should include:

- A clear definition of what the transplant program considers an adverse event incorporating the CMS regulatory definition;
- The procedures for internal reporting of adverse events in all phases of transplant recipient or living donor care within the hospital;
- The process(es) used for analyzing adverse events in the transplant program;
- The process for developing, evaluating and tracking actions to prevent recurrence; and
- The required timeframe for reporting, investigating and analyzing adverse events.

The policies should also address any external adverse event reporting obligations, such as:

- External reporting of events to the OPTN, ESRD Network, etc. as required and applicable;
- Reporting to other federal or state agencies as required by law (e.g., for suspected medical device-related deaths or serious injury, transmission of an infectious disease, etc.); and
- Reporting to the OPO if a transplant recipient infection is related to an infectious disease present in a transplanted organ to ensure that other recipients who received organs from the same donor can be notified.

X-103

(Rev.)

§482.96(b)(2) The transplant *program* must conduct a thorough analysis of and document any adverse event... .

Guideline §482.96(b)(2)

A thorough analysis is a planned, systematic investigative process that considers all of the phases of transplantation/living donation in identifying the causes of and factors contributing to an adverse event. The scope and depth of analysis, as well as the extent of multi-disciplinary involvement, may be scaled in proportion to the scope and severity of the harm experienced and/or the risk of harm involved.

A thorough analysis would include, but is not limited to:

- A description of the key facts of the event in enough detail so that one can clearly understand the facts and chronology of what occurred, the severity of the event, and how the potential recipient or potential living donor was affected;
- A review of whether similar events have occurred in the past;
- All of the information needed to identify factors that may have caused or contributed to the outcome, directly or indirectly;
- Analysis of the information to identify actual and potential vulnerabilities and opportunities to reduce risks and improve care;
- Use of the results of the analysis to design improvement actions to address the factors that caused or contributed to the event's occurrence, including factors and processes; and
- Specific plan for implementing, evaluating and monitoring improvement actions (timeframes, responsible parties, measurement strategy to assess effectiveness, etc.).

X-104

(Rev.)

§482.96(b)(2)(cont'd)

...and must utilize the analysis to effect changes in the transplant *program's* policies and practices to prevent repeat incidents.

X-109

(Rev.)

§482.98 Condition of Participation:

The transplant *program* must ensure that all individuals who provide services and/or supervise services at the *program* including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

X-110

(Rev.)

§482.98(a) Standard: Director of a Transplant *Program*.

The transplant *program* must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant

***program* need not serve full-time and may also serve as a *program*'s primary transplant surgeon or transplant physician in accordance with §482.98(b)... .**

Guideline §482.98(a)

The designated director of a transplant *program* must be either a transplant surgeon credentialed in the hospital for transplant surgeries or a qualified physician. Qualified *physician* means a physician that is credentialed in the hospital to provide transplant medical services for the specific organ program type.

Serving as the director on a less than full time basis means that the director may continue his/her clinical responsibilities in addition to his/her role in general supervision of the program.

See Tags X-111 through X-114 for the responsibilities of the director of a transplant *program*.

X-111

(Rev.)

§482.98(a)(cont'd) ... The director is responsible for planning, organizing, conducting, and directing the transplant *program* and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:

X-112

(Rev.)

§482.98(a)(1) Coordinating with the hospital in which the transplant *program* is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

Guideline §482.98(a)(1)

Care of transplant patients and living donors is unique and complex, requiring clarification of roles and responsibilities and appropriate training for nursing staff and clinical transplant coordinators. The director of the transplant center is responsible for coordination with the hospital's Nursing Department to determine the appropriate depth and type of orientation and training that will be provided to nursing staff that care for the transplant patients.

Evidence of coordination should include:

1. The transplant director has participated in the development of training and orientation plans for nurses who work or will work with transplant recipients and living donors;
2. The transplant director offers ongoing training opportunities for nursing staff; and
3. The transplant director provides feedback to the Nursing Department on the clinical competency of those nursing staff *working* with transplant recipients or

living donors.

X-115

(Rev.)

§482.98(b) Standard: Transplant Surgeon and Physician.

The transplant *program* must identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

X-118

(Rev.)

§482.98(c) Standard: Clinical Transplant Coordinator.

The transplant *program* must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation... .

Guideline §482.98(c)

Clinicians other than nurses may also serve in the role of the clinical coordinator. The expectations of the coordinator, as defined by the individual transplant program, will determine the particular professional clinical background required for the coordinator. However, regardless of the clinical background of the coordinator, the most critical factor of this Standard is the requirement for experience and knowledge. Clinical coordinators must have experience working with transplant patients or living donors in any setting.

X-120

(Rev.)

§482.98(c)(cont'd)

... The clinical transplant coordinator's responsibilities must include, but are not limited to, the following:

- (1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and
- (2) Acting as a liaison between a kidney transplant *program* and dialysis facilities, as applicable.

Guideline §§482.98(c)(cont'd) and (c)(1)-(2)

Clinical transplant coordinators are important links between transplant recipients/living donors and the transplant program and dialysis facilities, as applicable. A transplant coordinator is often the patient's primary contact for communication and direction on transplantation or donation related activities. This communication involves patients,

families, medical team, organ procurement organizations, donor hospitals, and all other members of the transplant team.

The primary purpose of the coordinator is to ensure that all the multidisciplinary needs of the patients are met in all phases of transplantation or donation.

The coordinator is also the primary contact with the ESRD facility in the case of kidney transplant patients. Evidence of the collaboration between the coordinator and the ESRD includes wait list changes; laboratory results; and changes in medical condition.

X-121

(Rev.)

§482.98(d) Standard: Independent Living Donor Advocate or *Independent* Living Donor Advocate Team. The transplant *program* that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

Guideline §482.98 (d)

Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or an Independent Living Donor Advocate Team (ILDAT) prior to the initiation of the evaluation and continuing to and through the discharge phase.

X122

(Rev.)

§482.98(d)(1) The *independent* living donor advocate or *independent* living donor advocate team must not be involved in transplantation activities on a routine basis.

Guideline §482.98(d)(1)

Because of the conflict of interest which would be created for an advocate to perform any transplant activities, even on an infrequent basis, the ILDA or ILDAT must not be associated with the transplant program in any capacity even on a temporary or intermittent basis.

X-123

(Rev.)

§482.98(d)(2) The independent living donor advocate or *independent* living donor advocate team must demonstrate:

(i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and

(ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

Guideline §482.98(d)(2)

The advocate/team must be able to provide evidence of successful training which addressed the topics listed in the standard.

Interviews with living donors confirm that the advocate/team provided information concerning:

- The organ donation process;
- The requirements of the informed consent process;
- The immediate and long-term expectations following donation;
- The immediate and long-term risks of donation;
- The expected outcomes for the recipient;
- The potential financial responsibilities related to donation; and
- Any alternative treatment(s) for the potential transplant recipient, if available.

The living donor medical record should fully chronical the interactions between the advocate or advocate team and donor candidate including the assessed level of understanding by the donor candidate during interactions.

X-124

(Rev.)

§482.98(d)(3) The independent living donor advocate or *independent* living donor advocate team is responsible for:

- (i) Representing and advising the donor;**
- (ii) Protecting and promoting the interests of the donor; and**
- (iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.**

Guideline §482.98(d)(3)

The ILDA or ILDAT are primarily the *representatives* of the donor candidate. There may be instances where the advocate/team advises the potential donor candidate where to seek additional information, encourages the candidate to ask pertinent questions, encourages the candidate to have additional discussions with the family or advises the donor candidate to delay the decision to donate at any point without reprisal if they choose. However, the advocate/team does not advise as to a decision on donation.

All discussions and meetings between the potential donor candidate and the advocate/team must center upon the needs, interests and choices of the potential donor. These discussions must not address the needs of the potential recipient. If at any point in the process the donor changes his/her mind and decides not to donate, the advocate must support and intercede on behalf of the donor candidate if indicated.

X-125

(Rev.)

§482.98(e) Standard: Transplant Team.

The transplant *program* must identify a multi-disciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

Guideline §482.98(e)

While it is desirable that each multidisciplinary team include a pharmacist member, there may be other disciplines on the team who may also be qualified to provide pharmacology services. Examples of individuals other than a pharmacist who are also qualified to provide pharmacology services on the team, are a physician, advanced nurse *practitioner*, or *physician* assistant.

X-126

(Rev.)

§482.98(f) Standard: Resource Commitment.

The transplant *program* must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services.

X-139

(Rev.)

§482.100 Condition of Participation: Organ Procurement.

The transplant *program* must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

Guideline §482.100

The hospital in which the transplant program is located must have a written agreement with their designated OPO for cooperation with the OPO in the recovery of donor organs. The agreement must meet the requirements of §482.45.

X-149

(Rev.)

§482.102 Condition of Participation: Patient and Living Donor Rights.

In addition to meeting the condition of participation “Patients rights” requirements at §482.13, the transplant *program* must protect and promote each transplant patient’s and living donor’s rights.

X-150

(Rev.)

§482.102(a) Standard: Informed Consent for Transplant Patients.

Transplant *programs* must implement written transplant patient informed consent policies that inform each patient of:

Guideline §482.102(a)

As a standard of practice for any type of surgical procedure, a hospital has the obligation to provide a potential transplant recipient with sufficient information to make an informed decision. Informed consent is a process that requires a health care provider to disclose all available information to a potential recipient who makes the voluntary choice to accept or refuse treatment. The transplant physician must ensure each potential recipient that is considered for organ transplantation has full knowledge and understanding of the purpose, possible risks, benefits and other options available to them.

The signed hospital surgical consent form alone is not considered evidence that the informed consent process for transplant patients was completed to include the requirements of §482.102(a)(1)-(8).

X-155

(Rev.)

§482.102(a)(5) National and transplant *program*-specific outcomes, from the most recent SRTR *program*-specific report, including (but not limited to) the transplant *program*’s observed and expected 1-year patient and graft survival, *and* national 1-year patient and graft **survival**;

Guideline §482.102(a)(5)

Prior to undergoing an evaluation, the transplant program informs the potential recipient of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program’s performance. The potential recipient should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website. This information allows the patient to make an informed decision about listing with the program.

X-158

(Rev.)

§482.102(a)(8) The fact that if his or her transplant is not provided in a Medicare-approved transplant *program* it could affect the transplant recipient's ability to have his or her immuno-suppressive drugs paid for under Medicare Part B.

X-159

(Rev.)

§482.102(b) Standard: Informed consent for living donors.

Transplant *programs* must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant *programs* must ensure that the prospective living donor is fully informed about the following:

Guideline §482.102(b)

As a standard of practice for any type of surgical procedure, a hospital has the obligation to provide patients with sufficient information to make an informed decision. Informed consent is a process that requires a health care provider to disclose appropriate information to a patient which allows them to make the voluntary choice to accept or refuse treatment. The physician must ensure each patient that is considered for organ donation has full knowledge and understanding of the purpose, possible risks, benefits and other options available to the recipient.

Transplant programs must develop and implement informed consent policies for living donors that delineate the information to be shared and the responsibilities of any transplant staff member that will consult with the patient.

The signed informed consent form and/or hospital surgical informed consent form alone is not considered evidence that the informed consent process for the prospective living donor is complete. Transplant programs must provide documentation that ensures the living donor candidate was informed of subparagraphs (1) through (8) of this standard.

X-160

(Rev.)

§482.102(b)(1) The fact that communication between the donor and the transplant *program* will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.

Guideline §482.102(b)(1)

Requirements in 45 CFR part 160 and subparts A and E of part 164 relate to the privacy of individually identifiable health information and prevention from fraud and abuse related to the provision of or payment for health care for the purpose of protecting the privacy of health information.

Requirements in subpart C of 45 CFR part 164 relate to the security standards for the protection of electronic protected health information, notification procedures in the case

of breach of unsecured protected health information, and the privacy, uses, and disclosure of individually identifiable health information.

Accordingly, any information shared between the living donor candidate and the transplant program may not be shared with the potential recipient and/or their families except as permitted by 45 CFR parts 160 and 164.

X-163

(Rev.)

§482.102(b)(4) The availability of alternative treatments for the transplant recipient;

Guideline §482.102(b)(4)

A potential donor must be made aware of all alternative treatments that are available for the potential recipient which may include the possibility of a deceased donor transplant.

X-165

(Rev.)

§482.102(b)(6) The national and transplant *program*-specific outcomes for recipients, and the national and *program* -specific outcomes for living donors, as data are available;

Guideline §482.102(b)(6)

Prior to undergoing an evaluation, the transplant program informs the potential donor of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program performance. The potential recipient should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website.

There are currently no national or center specific outcomes for living donors calculated by the SRTR.

X-168

(Rev.)

§482.102(b)(9) The fact that if a transplant is not provided in a Medicare-approved transplant *program* it could affect the transplant *recipient*'s ability to have his or her immuno-suppressive drugs paid for under Medicare Part B.

X169

(Rev.)

§482.102(c) Standard: Notification to patients.

Transplant *programs* must notify patients placed on the *program's* waiting list of information about the *program* that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

X-170

(Rev.)

§482.102(c)(1) A transplant *program* served by a single transplant surgeon or physician must inform patients placed on the *program's* waiting list of:

- (i) The potential unavailability of the transplant surgeon or physician; and
- (ii) Whether the center has a mechanism to provide an alternate transplant surgeon or transplant physician.

Guideline §482.102(c)(1)

The absence of a transplant surgeon or physician may impact a transplant candidate's ability to receive a transplant if an organ becomes available. Transplant programs must disclose the possibility of such an event as well as whether the program has a process to provide an alternate transplant surgeon or transplant physician in such an event prior to the potential recipient undergoing evaluation. Any changes that occur following the informed consent process must also be shared with each candidate on the waiting list.

X-171

(Rev.)

§482.102(c)(2) At least 30 days before a *program's* Medicare approval is terminated, whether voluntarily or involuntarily, the center must:

- (i) Inform patients on the *program's* waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant *program* without loss of time accrued on the waiting list; and
- (ii) Inform Medicare *recipients* on the *program's* waiting list that Medicare will no longer pay for transplants performed at the *program* after the effective date of the *program's* termination of approval.

X-172

(Rev.)

§482.102(c)(3) As soon as possible prior to a transplant *program's* voluntary inactivation, the *program* must inform patients on the *program's* waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant *program* without loss of time accrued on the waiting list.

Guideline §482.102(c)(3)

A transplant program may choose to inactivate for reasons including: the inability to meet clinical experience (volume) requirements; temporarily lacking medical or surgical coverage; and a significant change in operations that require a temporary cessation of transplant activity.

Transplant programs that *intend* to become inactive must notify the patient group that will be affected by the inactivity. If the determination is made to inactivate a transplant program or a component of a transplant program, all potential recipients on the waiting list would be unable to receive an organ offer during the time period of inactivity. As such, transplant programs must notify all affected patients of the upcoming inactivation.. It must also inform the potential recipients of the expected time period of inactivation, if known, and options for waitlisted patients to transfer to another facility.

Waiting list patients should receive notification of the program's voluntary inactivation at least 30 days prior to the planned inactivation date. Transplant programs determine the method of communication with the potential recipients and the program must be able to document the communication.

If a transplant candidate elects to be transferred to a another transplant program, the inactivating transplant program must facilitate communication and help with the exchange of information. The transplant program should coordinate with the receiving facility to place the patient on their waiting list.

X-184

(Rev.)

§482.104 Condition of Participation: Additional Requirements for Kidney Transplant *Programs*.

X-185

(Rev.)

§482.104(a) Standard: End stage renal disease (ESRD) services. Kidney transplant *programs* must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients... .

X-186

(Rev.)

§482.104(a)(cont'd) ... A kidney transplant *program* must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

Guideline §482.104(a)(cont'd)

Transplant programs must have policies in place on how information is shared with dialysis facilities for patients currently receiving dialysis. Transplant programs must have bi-directional communication with the dialysis facility about any waiting list status changes or changes in patient condition. The communications usually include laboratory values and change in inpatient status. There will be communication periodically between the two entities, however, the frequency is determined by patient status changes and the policies of the transplant program.

X-187

(Rev.)

§482.104(b) Standard: Dialysis services.

Kidney transplant *programs* must furnish inpatient dialysis services directly or under arrangement.

X-188

(Rev.)

§482.104(c) Standard: Participation in network activities.

Kidney transplant *programs* must cooperate with the ESRD Network designated for their geographic area, in fulfilling the terms of the Network's current statement of work.

Guideline §482.104(c)

The most current ESRD Network statement of work includes the direction and goals that are set by the Network and completed through partnership with other stakeholders, such as a transplant programs. Transplant programs are expected to cooperate, and participate if necessary, in fulfilling the goals set by the Networks.

The most current Statement of Work can be found on the CMS website for ESRD Networks at: <https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/>

Information on the geographic areas of Networks and the SOW can be found on the CMS Website (<http://www.cms.hhs.gov/ESRDNetworkOrganizations>).

State Operations Manual

Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types

Interpretive Guidance

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§486.360, Condition of Participation for Organ Procurement Organizations (OPOs)

§491.12, Conditions for Certification for Rural Health Clinics (RHCs) and Conditions for Coverage for Federally Qualified Health Centers (FQHCs)

§494.62, Condition for Coverage for End-Stage Renal Disease (ESRD) Facilities

E-0001

(Rev.)

§403.748, §416.54, §418.113, §441.184, §460.84, §482.15, §483.73, §483.475, §484.102, §485.68, §485.625, §485.727, §485.920, §486.360, §491.12

The [facility, except for Transplant *Programs*] must comply with all applicable Federal, State and local emergency preparedness requirements. The [facility] must establish and maintain a [comprehensive] emergency preparedness program that meets the requirements of this section.* The emergency preparedness program must include, but not be limited to, the following elements:

* (Unless otherwise indicated, the general use of the terms “facility” or “facilities” in this Appendix refers to all provider and suppliers addressed in this appendix. This is a generic moniker used in lieu of the specific provider or supplier noted in the regulations. For varying requirements, the specific regulation for that provider/supplier will be noted as well.)

***[For hospitals at §482.15:] The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:**

***[For CAHs at §485.625:] The CAH must comply with all applicable Federal, State, and local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:**

Interpretive Guidelines applies to: §403.748, §416.54, §418.113, §441.184, §460.84, §482.15, §483.73, §483.475, §484.102, §485.68, §485.625, §485.727, §485.920, §486.360, §491.12.

NOTE: This does not apply to Transplant *Programs*.

NOTE: The word comprehensive is not used in the language for ASCs.

Guidance is pending and will be updated in future release.

E-0002

(Rev.)

§482.78 Condition of participation: Emergency preparedness for transplant *programs*. A transplant *program* must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant *program* is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

Interpretive Guidelines for §482.78.

A representative from each transplant *program* must be actively involved in the development and maintenance of the hospital's emergency preparedness program, as required under §482.15(g)(1).

Transplant *programs* would still be required to have their own emergency preparedness policies and procedures as required under §482.78(a), as well as participate in mutually-agreed upon protocols that address the transplant *program*, hospital, and OPO's duties and responsibilities during an emergency.

Survey Procedures

- Verify that a representative from the transplant *program* was included in the planning of the emergency preparedness program of the hospital in which the transplant *program* is located.

E-0004

(Rev.)

§403.748(a), §416.54(a), §418.113(a), §441.184(a), §460.84(a), §482.15(a), §483.73(a), §483.475(a), §484.102(a), §485.68(a), §485.625(a), §485.727(a), §485.920(a), §486.360(a), §491.12(a), §494.62(a).

The [facility] must comply with all applicable Federal, State and local emergency preparedness requirements. The [facility] must develop establish and maintain a comprehensive emergency preparedness program that meets the requirements of this section.

The emergency preparedness program must include, but not be limited to, the following elements:

(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be [reviewed], and updated at least *every 2 years*. The plan must do all of the following:

* [For hospitals at §482.15 and CAHs at §485.625(a):] **Emergency Plan.** The [hospital or CAH] must comply with all applicable Federal, State, and local emergency preparedness requirements. The [hospital or CAH] must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach.

* [For LTC Facilities at §483.73(a):] **Emergency Plan.** The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed and updated at least annually.

* [For ESRD Facilities at §494.62(a):] **Emergency Plan.** The ESRD facility must develop and maintain an emergency preparedness plan that must be [evaluated], and updated at least *every 2 years*.

Interpretive Guidelines applies to: §403.748(a), §416.54(a), §418.113(a), §441.184(a), §460.84(a), §482.15(a), §483.73(a), §483.475(a), §484.102(a), §485.68(a), §485.625(a), §485.727(a), §485.920(a), §486.360(a), §491.12(a), §494.62(a).

NOTE: This does not apply to Transplant **Programs**.
Guidance is pending and will be updated in future release.

E-0005 *(Rev.)*

§482.78(a) Standard: Policies and procedures. A transplant **program** must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program.

Interpretive Guidelines for §482.78(a).

Transplant **programs** must be actively involved in their hospital's emergency planning and programming under §482.15(g). The transplant **program's** emergency preparedness plans must be included in the hospital's emergency plans. All of the Medicare-approved transplant **programs** are located within certified hospitals and, as part of the hospital, must be included in the hospital's emergency preparedness plans. The transplant **program** needs to be involved in the hospital's risk assessment because there may be risks to the transplant **program** that others in the hospital may not be aware of or appreciate. However, most of the risk assessment of the hospital and transplant **program** would be the same since the transplant **program** is located within the hospital. Therefore a separate risk assessment would be unnecessary and overly burdensome.

Survey Procedures

- Verify the transplant **program** has emergency preparedness policies and procedures.
- Verify that the transplant **program's** emergency preparedness policies and procedures are included in the hospital's emergency preparedness program.

E-0006

(Rev.)

§403.748(a)(1)-(2), §416.54(a)(1)-(2), §418.113(a)(1)-(2), §441.184(a)(1)-(2), §460.84(a)(1)-(2), §482.15(a)(1)-(2), §483.73(a)(1)-(2), §483.475(a)(1)-(2), §484.102(a)(1)-(2), §485.68(a)(1)-(2), §485.625(a)(1)-(2), §485.727(a)(1)-(2), §485.920(a)(1)-(2), §486.360(a)(1)-(2), §491.12(a)(1)-(2), §494.62(a)(1)-(2)

[(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least *every 2 years*. The plan must do the following:]

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.*

(2) Include strategies for addressing emergency events identified by the risk assessment.

****[For LTC facilities at §483.73(a)(1):] Emergency Plan. The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:***

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing residents.

(2) Include strategies for addressing emergency events identified by the risk assessment.

****[For ICF/IIDs at §483.475(a)(1):] Emergency Plan. The ICF/IID must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:***

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, including missing clients.

(2) Include strategies for addressing emergency events identified by the risk assessment.

**** [For Hospices at §418.113(a)(2):] Emergency Plan. The Hospice must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:***

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment, including the management of the consequences of power failures, natural disasters, and other emergencies that would affect the hospice's ability to provide care.

Interpretive Guidelines applies to: §403.748(a)(1)-(2), §416.54(a)(1)-(2), §418.113(a)(1)-(2), §441.184(a)(1)-(2), §460.84(a)(1)-(2), §482.15(a)(1)-(2), §483.73(a)(1)-(2), §483.475(a)(1)-(2), §484.102(a)(1)-(2), §485.68(a)(1)-(2),

§485.625(a)(1)-(2), §485.727(a)(1)-(2), §485.920(a)(1)-(2), §491.12(a)(1)-(2), §494.62(a)(1)-(2).

NOTE: This does not apply to Transplant *Programs*.
Guidance is pending and will be updated in future release.

E-0007
(Rev.)

§403.748(a)(3), §416.54(a)(3), §418.113(a)(3), §441.184(a)(3), §460.84(a)(3), §482.15(a)(3), §483.73(a)(3), §483.475(a)(3), §484.102(a)(3), §485.68(a)(3), §485.625(a)(3), §485.727(a)(3), §485.920(a)(3), §491.12(a)(3), §494.62(a)(3).

[(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least *every 2 years*. The plan must do the following:]

(3) Address [patient/client] population, including, but not limited to, persons at-risk; the type of services the [facility] has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.**

**[For LTC facilities at §483.73(a)(3):] Emergency Plan. The LTC facility must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually.*

(3) Address resident population, including, but not limited to, persons at-risk; the type of services the LTC facility has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

Interpretive Guidelines applies to: §403.748(a)(3), §416.54(a)(3), §418.113(a)(3), §441.184(a)(3), §460.84(a)(3), §482.15(a)(3), §483.73(a)(3), §483.475(a)(3), §484.102(a)(3), §485.68(a)(3), §485.625(a)(3), §485.727(a)(3), §485.920(a)(3), §491.12(a)(3), §494.62(a)(3).

NOTE: This does not apply to Transplant *Programs* and OPOs.

***NOTE:** [“Persons at risk” does not apply to: ASC, hospice, PACE, HHA, CORF, CMCH, RHC/FQHC, or ESRD facilities.]

Guidance is pending and will be updated in future release.

E-0008
(Rev.)

§486.360(a)(3) Condition for Participation:

[(a) Emergency Plan. The OPO must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least *every 2 years*. The plan must do the following:]

(3) Address the type of hospitals with which the OPO has agreements; the type of services the OPO has the capacity to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

Interpretive Guidelines for §486.360(a)(3).

The emergency plan must address the type of hospitals with which the OPO has agreements and the types of services that the OPO would be able to provide in an emergency. The emergency plan must also identify which staff would assume specific roles in another's absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing staff with the potential to fill key business leadership positions in the company. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become necessary. During times of emergency, facilities must have internal employees who are capable of assuming various critical roles in the event that current staff and leaders are not available. At a minimum, facilities should designate a qualified person who is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility.

In addition to the facility- and community-based risk assessment, continuity of operations planning generally considers elements such as: essential personnel, essential functions, critical resources, vital records and IT data protection, alternate facility identification and location, and financial resources. Facilities are encouraged to refer to and utilize resources from various agencies such as FEMA and ASPR when developing strategies for ensuring continuity of operations.

Survey Procedures

Interview leadership and ask them to describe the following:

- Services the OPO would be able to provide during an emergency;
- How the OPO plans to continue operations during an emergency;
- Delegations of authority and succession plans.
- How the OPO has included/addressed all of the hospitals with which it has agreements into its emergency plan.

Verify that all of the above are included in the written emergency plan.

E-0009

(Rev.)

§403.748(a)(4), §416.54(a)(4), §418.113(a)(4), §441.184(a)(4), §460.84(a)(4), §482.15(a)(4), §483.73(a)(4), §483.475(a)(4), §484.102(a)(4), §485.68(a)(4), §485.625(a)(4), §485.727(a)(5), §485.920(a)(4), §486.360(a)(4), §491.12(a)(4), §494.62(a)(4)

[(a) Emergency Plan. The [facility] must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least *every 2 years (annually for LTC facilities)*. The plan must do the following:]

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. **

*** [For ESRD facilities only at §494.62(a)(4)]: (4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. The dialysis facility must contact the local emergency preparedness agency at least annually to confirm that the agency is aware of the dialysis facility's needs in the event of an emergency.**

Interpretive Guidelines applies to: §403.748(a)(4), §416.54(a)(4), §418.113(a)(4), §441.184(a)(4), §460.84(a)(4), §482.15(a)(4), §483.73(a)(4), §483.475(a)(4), §484.102(a)(4), §485.68(a)(4), §485.625(a)(4), §485.727(a)(5), §485.920(a)(4), §486.360(a)(4), §491.12(a)(4), §494.62(a)(4).

**NOTE: This does not apply to Transplant *Programs*.
*Guidance is pending and will be updated in future release.***

E-0010 ***(Rev.)***

§485.727(a)(4) Condition for Participation:

[(a) Emergency Plan. The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (“Organizations”) must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least *every 2 years*. The plan must do the following:]

(4) Address the location and use of alarm systems and signals; and methods of containing fire.

**Interpretive Guidelines for §485.727(a)(4).
*Guidance is pending and will be updated in future release.***

E-0011 ***(Rev.)***

§485.68(a)(5) Condition for Participation:

[(a) Emergency Plan. The Comprehensive Outpatient Rehabilitation Facility (CORF) must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least *every 2 years*. The plan must do the following:]

(a)(5) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

§485.727(a)(6) Condition for Participation:

[(a) Emergency Plan. The Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (“Organizations”) must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least *every 2 years*. The plan must do the following:]

(a)(6) Be developed and maintained with assistance from fire, safety, and other appropriate experts.

Interpretive Guidelines applies to: §485.68(a)(5), §485.727(a)(6).

The CORF and Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services must collaborate with fire, safety and other appropriate experts to develop and maintain its emergency plan. They must document their collaboration with these experts and include them in the *2-year* review of the plan.

Survey Procedures

- Ask for a list of/documentation for which experts were collaborated with to develop and maintain its plan.

E-0012

(Rev.)

§ 482.78 Condition of participation: Emergency preparedness for transplant *programs*. A transplant *program* must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant *program* is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

(a) Standard: Policies and procedures.

A transplant *program* must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital’s emergency preparedness program.

(b) Standard: Protocols with hospital and OPO. A transplant *program* must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant *program*, the hospital in which the transplant

program is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.

Interpretive Guidelines applies to: §482.78(a), and §482.78(b).

Hospitals which have transplant *programs* must include within their emergency planning and preparedness process one representative, at minimum, from the transplant *program*. If a hospital has multiple transplant *programs*, each *program* must have at least one representative who is involved in the development and maintenance of the hospital's emergency preparedness process. The hospital must include the transplant *programs* in its emergency preparedness plan policies and procedures, communication plans, as well as the training and testing programs.

Both the hospital and the transplant *programs* are required to demonstrate during a survey that they have coordinated in planning and the development of the emergency program. Both are required to have written documentation of the emergency preparedness plans. However, the transplant *programs* is not individually responsible for the emergency preparedness requirements under §482.15.

Survey Procedures

- Verify the hospital has written documentation to demonstrate that a representative of each transplant *programs* participated in the development of the emergency program.
- Ask to see documentation of emergency protocols that address transplant protocols that include the hospital, the transplant *programs* and the associated OPOs.

E-0013

(Rev.)

§403.748(b), §416.54(b), §418.113(b), §441.184(b), §460.84(b), §482.15(b), §483.73(b), §483.475(b), §484.102(b), §485.68(b), §485.625(b), §485.727(b), §485.920(b), §486.360(b), §491.12(b), §494.62(b).

(b) Policies and procedures. [Facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years*.

****[For LTC facilities at §483.73(b):] Policies and procedures. The LTC facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually.***

*Additional Requirements for PACE and ESRD Facilities:

*[For PACE at §460.84(b):] **Policies and procedures.** The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: **Fire**; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. The policies and procedures must be reviewed and updated at least **every 2 years**.

*[For ESRD Facilities at §494.62(b):] **Policies and procedures.** The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least **every 2 years**. These emergencies include, but are not limited to, fire, equipment or power failures, care-related emergencies, water supply interruption, and natural disasters likely to occur in the facility's geographic area.

Interpretive Guidelines applies to: §403.748(b), §416.54(b), §418.113(b), §441.184(b), §460.84(b), §482.15(b), §483.73(b), §483.475(b), §484.102(b), §485.68(b), §485.625(b), §485.727(b), §485.920(b), §486.360(b), §491.12(b), §494.62(b).

NOTE: This does not apply to Transplant **Programs**.
Guidance is pending and will be updated in future release.

E-0014 **(Rev.)**

§482.78(b) Standard: Protocols with hospital and OPO. A transplant **program** must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant **program**, the hospital in which the transplant **program** is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.

Interpretive Guidelines for §482.78(b).

Transplant **programs** must be involved in the development of mutually agreed upon protocols that address the duties and responsibilities of the hospital, transplant program and the designated OPO during emergencies.

All transplant **programs** are located within Medicare participating hospitals. Any hospital that furnishes organ transplants and other medical and surgical specialty services for the care of transplant patients is defined as a transplant hospital (42 CFR 482.70). Therefore, transplant **programs** must meet all hospital CoPs at §§482.1 through 482.57 (as set forth at §482.68(b)), and the hospitals in which they are located must meet the

provisions of § 482.15, however, a transplant *program* is not individually responsible for the emergency preparedness requirements in §482.15.

The hospital in which a transplant *program* is located (i.e., a transplant hospital) would be responsible for ensuring that the transplant *program* is involved in the development of an emergency preparedness program. This requirement does not oblige a transplant *program* that agrees to care for another transplant *program*'s patients during an emergency to put those patients on its waiting lists. We anticipate that most emergencies would be of short duration and that the transplant *program* that is affected by an emergency will resume its normal operations within a short period of time. However, if a transplant *program* does arrange for its patients to be transferred to another transplant *program* during an emergency, both transplant *program* would need to determine what care would be provided to the transferring patients, including whether and under what circumstances the patients from the transferring transplant *program* would be added to the receiving *transplant program's* waiting lists.

Survey Procedures

- Verify the transplant *program* has developed mutually agreed upon protocols that address the duties and responsibilities of the transplant *program*, the hospital in which the transplant *program* is operated, and the designated OPO.
- Ask to see documentation of the protocols.

E-0015

(Rev.)

§403.748(b)(1), §418.113(b)(6)(iii), §441.184(b)(1), §460.84(b)(1), §482.15(b)(1), §483.73(b)(1), §483.475(b)(1), §485.625(b)(1)

[(b) Policies and procedures. [Facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated *every 2 years (annually for LTC)*. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients whether they evacuate or shelter in place, include, but are not limited to the following:

- (i) Food, water, medical and pharmaceutical supplies**
- (ii) Alternate sources of energy to maintain the following:**
 - (A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.**
 - (B) Emergency lighting.**
 - (C) Fire detection, extinguishing, and alarm systems.**
 - (D) Sewage and waste disposal.**

*[For Inpatient Hospice at §418.113(b)(6)(iii):] **Policies and procedures.**

(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

(iii) The provision of subsistence needs for hospice employees and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

- (A) Food, water, medical, and pharmaceutical supplies.**
- (B) Alternate sources of energy to maintain the following:**
 - (1) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.**
 - (2) Emergency lighting.**
 - (3) Fire detection, extinguishing, and alarm systems.**
- (C) Sewage and waste disposal.**

Interpretive Guidelines applies to: §403.748(b)(1), §418.113(b)(6)(iii), §441.184(b)(1), §460.84(b)(1), §482.15(b)(1), §483.73(b)(1), §483.475(b)(1), §485.625(b)(1).

NOTE: This does not apply to ASCs, Outpatient Hospice Providers [applies to inpatient hospices], Transplant *Programs*, HHA, CORFs, CMHCs, RHCs/FQHCs, ESRD facilities.

Guidance is pending and will be updated in future release.

E-0016

(Rev.)

§418.113(b)(1): Condition for Participation:

[(b) Policies and procedures. The hospice must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years*.] At a minimum, the policies and procedures must address the following:

(1) Procedures to follow up with on duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The hospice must inform State and local officials of any on-duty staff or patients that they are unable to contact.

Interpretive Guidelines for §418.113(b)(1).

Hospices have the flexibility to determine how best to develop these policies and procedures. For administrative purposes, all hospices should already have some mechanism in place to keep track of patients and staff contact information. However, the information regarding patient services that are needed during or after an interruption in their services and on-duty staff and patients that were not able to be contacted must be readily available, accurate, and shareable among officials within and across the emergency response system, as needed, in the interest of the patient.

Survey Procedures

- Review the emergency plan to verify it includes policies and procedures for following up with staff and patients.
- Interview a staff member or leadership and ask them to explain the procedures in place in the event they are unable to contact a staff member or patient.

E-0017

(Rev.)

§484.102(b)(1) Condition for Participation:

[(b) Policies and procedures. The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years*.]

At a minimum, the policies and procedures must address the following:]

(1) The plans for the HHA's patients during a natural or man-made disaster. Individual plans for each patient must be included as part of the comprehensive patient assessment, which must be conducted according to the provisions at §484.55.

Interpretive Guidelines for §484.102(b)(1).

HHAs must include policies and procedures in its emergency plan for ensuring all patients have an individualized plan in the event of an emergency. That plan must be included as part of the patient's comprehensive assessment.

For example, discussions to develop individualized emergency preparedness plans could include potential disasters that the patient may face within the home such as fire hazards, flooding, and tornados; and how and when a patient is to contact local emergency officials. Discussions may also include patient, care providers, patient representative, or any person involved in the clinical care aspects to educate them on steps that can be taken to improve the patient's safety. The individualized emergency plan should be in writing and could be as simple as a detailed emergency card to be kept with the patient. HHA personnel should document that these discussions occurred and also keep a copy of the individualized emergency plan in the patient's file as well as provide a copy to the patient and or their caregiver.

Survey Procedures

- Through record review, verify that each patient has an individualized emergency plan documented as part of the patient's comprehensive assessment.

E-0018

(Rev.)

§403.748(b)(2), §416.54(b)(1), §418.113(b)(6)(ii) and (v), §441.184(b)(2), §460.84(b)(2), §482.15(b)(2), §483.73(b)(2), §483.475(b)(2), §485.625(b)(2), §485.920(b)(1), §486.360(b)(1), §494.62(b)(1).

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years (annually for LTC).*] At a minimum, the policies and procedures must address the following:]

[(2) or (1)] A system to track the location of on-duty staff and sheltered patients in the [facility's] care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the [facility] must document the specific name and location of the receiving facility or other location.

***[For PRTFs at §441.184(b), LTC at §483.73(b), ICF/IIDs at §483.475(b), PACE at §460.84(b):] Policies and procedures. (2) A system to track the location of on-duty staff and sheltered residents in the [PRTF's, LTC, ICF/IID or PACE] care during and after an emergency. If on-duty staff and sheltered residents are relocated during the emergency, the [PRTF's, LTC, ICF/IID or PACE] must document the specific name and location of the receiving facility or other location.**

***[For Inpatient Hospice at §418.113(b)(6):] Policies and procedures.**
(ii) Safe evacuation from the hospice, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s) and primary and alternate means of communication with external sources of assistance.
(v) A system to track the location of hospice employees' on-duty and sheltered patients in the hospice's care during an emergency. If the on-duty employees or sheltered patients are relocated during the emergency, the hospice must document the specific name and location of the receiving facility or other location.

***[For CMHCs at §485.920(b):] Policies and procedures. (2) Safe evacuation from the CMHC, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.**

***[For OPOs at § 486.360(b):] Policies and procedures. (2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.**

*[For ESRD at § 494.62(b):] **Policies and procedures. (2) Safe evacuation from the dialysis facility, which includes staff responsibilities, and needs of the patients.**

Interpretive Guidelines applies to: §403.748(b)(2), §416.54(b)(1), §418.113(b)(6)(ii) and (v), §441.184(b)(2), §460.84(b)(2), §482.15(b)(2), §483.73(b)(2), §483.475(b)(2), §485.625(b)(2), §485.920(b)(1), §486.360(b)(1), §494.62(b)(1).

NOTE: This does not apply to Transplant *Programs*, HHAs, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, RHCs/FQHCs.

Guidance is pending and will be updated in future release.

E-0019

(Rev.)

§418.113(b)(2), §460.84(b)(4), §484.102(b)(2)

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years*. At a minimum, the policies and procedures must address the following:]

*[For homebound Hospice at §418.113(b)(2), PACE at §460.84(b)(4), and HHAs at §484.102(b)(2):] **The procedures to inform State and local emergency preparedness officials about [homebound Hospice, PACE or HHA] patients in need of evacuation from their residences at any time due to an emergency situation based on the patient’s medical and psychiatric condition and home environment.**

Interpretive Guidelines applies to: §418.113(b)(2), §460.84(b)(4), §484.102(b)(2).

NOTE: The regulatory language for hospices under §418.113(b)(2) does not include the terms “emergency preparedness” when describing officials.

NOTE: This only applies to homebound Hospice, PACE and HHAs.

Guidance is pending and will be updated in future release.

E-0020

(Rev.)

§403.748(b)(3), §416.54(b)(2), §418.113(b)(6)(ii), §441.184(b)(3), §460.84(b)(3), §482.15(b)(3), §483.73(b)(3), §483.475(b)(3), §485.68(b)(1), §485.625(b)(3), §485.727(b)(1), §485.920(b)(2), §491.12(b)(1), §494.62(b)(2)

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set

forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years (annually for LTC)*. At a minimum, the policies and procedures must address the following:]

[(3) or (1), (2), (6)] Safe evacuation from the [facility], which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

*[For RNHCs at §403.748(b)(3) and ASCs at §416.54(b)(2):]

Safe evacuation from the [RNHCI or ASC] which includes the following:

- (i) Consideration of care needs of evacuees.**
- (ii) Staff responsibilities.**
- (iii) Transportation.**
- (iv) Identification of evacuation location(s).**
- (v) Primary and alternate means of communication with external sources of assistance.**

* [For CORFs at §485.68(b)(1), Clinics, Rehabilitation Agencies, OPT/Speech at §485.727(b)(1), and ESRD Facilities at §494.62(b)(2):]

Safe evacuation from the [CORF; Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services; and ESRD Facilities], which includes staff responsibilities, and needs of the patients.

* [For RHCs/FQHCs at §491.12(b)(1):] **Safe evacuation from the RHC/FQHC, which includes appropriate placement of exit signs; staff responsibilities and needs of the patients.**

Interpretive Guidelines applies to: §403.748(b)(3), §416.54(b)(2), §418.113(b)(6)(ii), §441.184(b)(3), §460.84(b)(3), §482.15(b)(3), §483.73(b)(3), §483.475(b)(3), §485.68(b)(1), §485.625(b)(3), §485.727(b)(1), §485.920(b)(2), §491.12(b)(1), §494.62(b)(2)

NOTE: This does not apply to HHAs, OPOs, and Transplant *Programs*.

NOTE: The requirements under §418.113(b)(6)(ii) is not a requirement for outpatient hospice providers.

Guidance is pending and will be updated in future release.

E-0021

(Rev.)

§484.102(b)(3) Condition of Participation:

[(b) Policies and procedures. The HHA must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in

paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years*.] At a minimum, the policies and procedures must address the following:]

(3) The procedures to follow up with on-duty staff and patients to determine services that are needed, in the event that there is an interruption in services during or due to an emergency. The HHA must inform State and local officials of any on-duty staff or patients that they are unable to contact.

Interpretive Guidelines for §484.102(b)(3).

Guidance is pending and will be updated in future release.

E-0022

(Rev.)

§403.748(b)(4), §416.54(b)(3), §418.113(b)(6)(i), §441.184(b)(4), §460.84(b)(5), §482.15(b)(4), §483.73(b)(4), §483.475(b)(4), §485.68(b)(2), §485.625(b)(4), §485.727(b)(2), §485.920(b)(3), §491.12(b)(2), §494.62(b)(3).

(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years (annually for LTC)*.] At a minimum, the policies and procedures must address the following:]

[(4) or (2),(3),(5),(6)] A means to shelter in place for patients, staff, and volunteers who remain in the [facility].

*[For Inpatient Hospices at §418.113(b):] **Policies and procedures.**

(6) The following are additional requirements for hospice-operated inpatient care facilities only. The policies and procedures must address the following:

(i) A means to shelter in place for patients, hospice employees who remain in the hospice.

Interpretive Guidelines applies to: §403.748(b)(4), §416.54(b)(3), §418.113(b)(6)(i), §441.184(b)(4), §460.84(b)(5), §482.15(b)(4), §483.73(b)(4), §483.475(b)(4), §485.68(b)(2), §485.625(b)(4), §485.727(b)(2), §485.920(b)(3), §491.12(b)(2), §494.62(b)(3).

NOTE: This does not apply to Transplant *Programs*, HHAs or OPOs.

Guidance is pending and will be updated in future release.

E-0023

(Rev.)

§403.748(b)(5), §416.54(b)(4), §418.113(b)(3), §441.184(b)(5), §460.84(b)(6), §482.15(b)(5), §483.73(b)(5), §483.475(b)(5), §484.102(b)(4), §485.68(b)(3), §485.625(b)(5), §485.727(b)(3), §485.920(b)(4), §486.360(b)(2), §491.12(b)(3), §494.62(b)(4).

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years (annually for LTC).*] At a minimum, the policies and procedures must address the following:]

[(5) or (3),(4),(6)] A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains availability of records.

***[For RNHCIs at §403.748(b):] Policies and procedures. (5) A system of care documentation that does the following:**

- (i) Preserves patient information.**
- (ii) Protects confidentiality of patient information.**
- (iii) Secures and maintains the availability of records.**

***[For OPOs at §486.360(b):] Policies and procedures. (2) A system of medical documentation that preserves potential and actual donor information, protects confidentiality of potential and actual donor information, and secures and maintains the availability of records.**

Interpretive Guidelines applies to: §403.748(b)(5), §416.54(b)(4), §418.113(b)(3), §441.184(b)(5), §460.84(b)(6), §482.15(b)(5), §483.73(b)(5), §483.475(b)(5), §484.102(b)(4), §485.68(b)(3), §485.625(b)(5), §485.727(b)(3), §485.920(b)(4), §486.360 (b)(2), §491.12(b)(3), §494.62(b)(4).

**NOTE: This does not apply to Transplant *Programs*.
*Guidance is pending and will be updated in future release.***

E-0024 ***(Rev.)***

§403.748(b)(6), §416.54(b)(5), §418.113(b)(4), §441.184(b)(6), §460.84(b)(7), §482.15(b)(6), §483.73(b)(6), §483.475(b)(6), §484.102(b)(5), §485.68(b)(4), §485.625(b)(6), §485.727(b)(4), §485.920(b)(5), §491.12(b)(4), §494.62(b)(5).

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this

section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years (annually for LTC).*] At a minimum, the policies and procedures must address the following:]

(6) [or (4), (5), or (7) as noted above] The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

*[For RNHCIs at §403.748(b):] Policies and procedures. (6) The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.

*[For Hospice at §418.113(b):] Policies and procedures. (4) The use of hospice employees in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

Interpretive Guidelines applies to: §403.748(b)(6), §416.54(b)(5), §418.113(b)(4), §441.184(b)(6), §460.84(b)(7), §482.15(b)(6), §483.73(b)(6), §483.475(b)(6), §484.102(b)(5), §485.68(b)(4), §485.625(b)(6), §485.727(b)(4), §485.920(b)(5), §491.12(b)(4), §494.62(b)(5).

NOTE: This does not apply to Transplant *Programs*, or OPOs.
Guidance is pending and will be updated in future release.

E-0025 *(Rev.)*

§403.748(b)(7), §418.113(b)(5), §441.184(b)(7), §460.84(b)(8), §482.15(b)(7), §483.73(b)(7), §483.475(b)(7), §485.625(b)(7), §485.920(b)(6), §494.62(b)(6).

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years (annually for LTC).*] At a minimum, the policies and procedures must address the following:]

*[For Hospices at §418.113(b), PRFTs at §441.184(b) Hospitals at §482.15(b), and LTC Facilities at §483.73(b):] Policies and procedures. (7) [or (5)] The development of arrangements with other [facilities] [and] other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.

*[For PACE at §460.84(b), ICF/IIDs at §483.475(b), CAHs at §486.625(b), CMHCs at §485.920(b) and ESRD Facilities at §494.62(b):] **Policies and procedures. (7) [or (6), (8)] The development of arrangements with other [facilities] [or] other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to facility patients.**

*[For RNHCIs at §403.748(b):] **Policies and procedures. (7) The development of arrangements with other RNHCIs and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of non-medical services to RNHCI patients.**

Interpretive Guidelines applies to: §403.748(b)(7), §418.113(b)(5), §441.184(b)(7), §460.84(b)(8), §482.15(b)(7), §483.73(b)(7), §483.475(b)(7), §485.625(b)(7), §485.920(b)(6), §494.62(b)(6).

NOTE: The differences for some providers and suppliers between “and” and “or” are referenced above. Additionally, there are differences between continuity of “operations” and “services” within the regulatory language.

NOTE: This does not apply to ASCs, Transplant *Programs*, HHAs, CORFs, Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, OPOs, RHCs/FQHCs. *Guidance is pending and will be updated in future release.*

E-0026 ***(Rev.)***

§403.748(b)(8), §416.54(b)(6), §418.113(b)(6)(C)(iv), §441.184(b)(8), §460.84(b)(9), §482.15(b)(8), §483.73(b)(8), §483.475(b)(8), §485.625(b)(8), §485.920(b)(7), §494.62(b)(7).

[(b) Policies and procedures. The [facilities] must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years (annually for LTC).*] At a minimum, the policies and procedures must address the following:]

(8) [(6), (6)(C)(iv), (7), or (9)] The role of the [facility] under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

*[For RNHCIs at §403.748(b):] **Policies and procedures. (8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in**

the provision of care at an alternative care site identified by emergency management officials.

Interpretive Guidelines applies to: §403.748(b)(8), §416.54(b)(6), §418.113(b)(6)(C)(iv), §441.184(b)(8), §460.84(b)(9), §482.15(b)(8), §483.73(b)(8), §483.475(b)(8), §485.625(b)(8), §485.920(b)(7), §494.62(b)(7)

NOTE: This does not apply to Transplant *Programs*, HHAs, CORFs, Clinics, Rehabilitation Agencies and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, OPOs, RHCs/FQHCs. *Guidance is pending and will be updated in future release.*

E-0027

(Rev.)

§494.62(b)(8) Condition for Coverage:

[(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years*.] At a minimum, the policies and procedures must address the following:]

(8) How emergency medical system assistance can be obtained when needed.

Interpretive Guidelines for §494.62(b)(8).

ESRD facilities must include in its emergency plan, policies and procedures for obtaining emergency medical assistance when needed. Medical system assistance can be considered but not limited to, outside assistance such as from a nearby hospital. Additionally, this can mean assistance from other ESRD facilities including personnel to assist during a single-facility disaster.

Survey Procedures

- Verify the ESRD facility has included in its emergency plan, policies and procedures for obtaining emergency medical assistance when needed.

E-0028

(Rev.)

§494.62(b)(9) Condition for Coverage:

[(b) Policies and procedures. The dialysis facility must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years*.] At a minimum, the policies and procedures must address the following:]

(9) A process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, are on the premises at all times and immediately available.

Interpretive Guidelines for §494.62(b)(9).

ESRD facilities must include policies and procedures in its emergency plan that address a process that confirms that the specific requirements listed under this standard are on the premises at all times and immediately available in the event of an emergency. The process must be in writing. It is the facilities responsibility to determine what equipment is should on the premises and available during an emergency to assist patients in an emergency. Additionally, it is the responsibility of the facility to ensure that all necessary equipment identified in this area, should-be in working order at all times in accordance with the manufacturer instructions. Emergency drugs should not be out of date and should be stored and maintained based on the manufacturer instructions. The facility is in the best position to determine what emergency equipment it needs to have available. In addition, dialysis facilities need to be able to manage care-related emergencies during an emergency when other assistance, emergency medical services systems, may not be immediately available to them.

Survey Procedures

- Verify the dialysis facility has a process in place by which its staff can confirm that emergency equipment is on the premises and immediately available.
- Verify that the process includes at least the listed emergency equipment within its emergency plan by asking to see a copy of the written processes/ policy on emergency equipment and medications.
- Check to see that all of the above equipment is available and in working order. Ask to see procedures/checklist for ensuring equipment is checked
- Check to see that all emergency drugs are not out of date.

PACE - NON-CITABLE (No assigned tags)

Reference Only (PACE)

(Rev.)

§460.84(b)(10) Requirement:

[(b) Policies and procedures. The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least *every 2 years.*]

The policies and procedures must address management of medical and non-medical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or

safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at *every 2 years*. At a minimum, the policies and procedures must address the following:

- (10)(i) Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs.
- (ii) Staff who know how to use the equipment must be on the premises of every center at all times and be immediately available.
- (iii) A documented plan to obtain emergency medical assistance from outside sources when needed.

Interpretive Guidelines for §460.84(b)(10).

Guidance is pending and will be updated in future release.

E-0029

(Rev.)

§403.748(c), §416.54(c), §418.113(c), §441.184(c), §460.84(c), §482.15(c), §483.73(c), §483.475(c), §484.102(c), §485.68(c), §485.625(c), §485.727(c), §485.920(c), §486.360(c), §491.12(c), §494.62(c).

(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least *every 2 years (annually for LTC)*.

Interpretive Guidelines applies to: §403.748(c), §416.54(c), §418.113(c), §441.184(c), §460.84(c), §482.15(c), §483.73(c), §483.475(c), §484.102(c), §485.68(c), §485.625(c), §485.727(c), §485.920(c), §486.360(c), §491.12(c), §494.62(c).

NOTE: This does not apply to Transplant *Programs*.

Guidance is pending and will be updated in future release.

E-0030

(Rev.)

§403.748(c)(1), §416.54(c)(1), §418.113(c)(1), §441.184(c)(1), §460.84(c)(1), §482.15(c)(1), §483.73(c)(1), §483.475(c)(1), §484.102(c)(1), §485.68(c)(1), §485.625(c)(1), §485.727(c)(1), §485.920(c)(1), §486.360(c)(1), §491.12(c)(1), §494.62(c)(1).

[(c) The [facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least *every 2 years (annually for LTC)*.] The communication plan must include all of the following:]

- (1) Names and contact information for the following:
 - (i) Staff.

- (ii) Entities providing services under arrangement.**
- (iii) Patients' physicians**
- (iv) Other [facilities].**
- (v) Volunteers.**

***[For Hospitals at §482.15(c) and CAHs at §485.625(c)] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Patients' physicians**
 - (iv) Other [hospitals and CAHs].**
 - (v) Volunteers.**

***[For RNHCIs at §403.748(c):] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Next of kin, guardian, or custodian.**
 - (iv) Other RNHCIs.**
 - (v) Volunteers.**

***[For ASCs at §416.45(c):] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Patients' physicians.**
 - (iv) Volunteers.**

***[For Hospices at §418.113(c):] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Hospice employees.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Patients' physicians.**
 - (iv) Other hospices.**

***[For HHAs at §484.102(c):] The communication plan must include all of the following:**

- (1) Names and contact information for the following:**
 - (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Patients' physicians.**
 - (iv) Volunteers.**

***[For OPOs at §486.360(c):] The communication plan must include all of the following:**

- (2) Names and contact information for the following:**
 - (i) Staff.**
 - (ii) Entities providing services under arrangement.**
 - (iii) Volunteers.**
 - (iv) Other OPOs.**
 - (v) Transplant and donor hospitals in the OPO's Donation Service Area (DSA).**

Interpretive Guidelines applies to: §403.748(c)(1), §416.54(c)(1), §418.113(c)(1), §441.184(c)(1), §460.84(c)(1), §482.15(c)(1), §483.73(c)(1), §483.475(c)(1), §484.102(c)(1), §485.68(c)(1), §485.625(c)(1), §485.727(c)(1), §485.920(c)(1), §486.360(c)(1), §491.12(c)(1), §494.62(c)(1).

NOTE: This does not apply to Transplant *Programs*.
Guidance is pending and will be updated in future release.

E-0031

(Rev.)

§403.748(c)(2), §416.54(c)(2), §418.113(c)(2), §441.184(c)(2), §460.84(c)(2), §482.15(c)(2), §483.73(c)(2), §483.475(c)(2), §484.102(c)(2), §485.68(c)(2), §485.625(c)(2), §485.727(c)(2), §485.920(c)(2), §486.360(c)(2), §491.12(c)(2), §494.62(c)(2).

[(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least *every 2 years (annually for LTC)*.] The communication plan must include all of the following:

- (2) Contact information for the following:**
 - (i) Federal, State, tribal, regional, and local emergency preparedness staff.**
 - (ii) Other sources of assistance.**

***[For LTC Facilities at §483.73(c):] (2) Contact information for the following:**

- (i) Federal, State, tribal, regional, and local emergency preparedness staff.**
- (ii) The State Licensing and Certification Agency.**
- (iii) The Office of the State Long-Term Care Ombudsman.**
- (iv) Other sources of assistance.**

***[For ICF/IIDs at §483.475(c):] (2) Contact information for the following:**

- (i) Federal, State, tribal, regional, and local emergency preparedness staff.**
- (ii) Other sources of assistance.**
- (iii) The State Licensing and Certification Agency.**

(iv) The State Protection and Advocacy Agency.

Interpretive Guidelines applies to: §403.748(c)(2), §416.54(c)(2), §418.113(c)(2), §441.184(c)(2), §460.84(c)(2), §482.15(c)(2), §483.73(c)(2), §483.475(c)(2), §484.102(c)(2), §485.68(c)(2), §485.625(c)(2), §485.727(c)(2), §485.920(c)(2), §486.360(c)(2), §491.12(c)(2), §494.62(c)(2).

NOTE: This does not apply to Transplant *Programs*.
Guidance is pending and will be updated in future release.

E-0032

(Rev.)

§403.748(c)(3), §416.54(c)(3), §418.113(c)(3), §441.184(c)(3), §460.84(c)(3), §482.15(c)(3), §483.73(c)(3), §483.475(c)(3), §484.102(c)(3), §485.68(c)(3), §485.625(c)(3), §485.727(c)(3), §485.920(c)(3), §486.360(c)(3), §491.12(c)(3), §494.62(c)(3).

[(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least *every 2 years (annually for LTC)*.] The communication plan must include all of the following:

- (3) Primary and alternate means for communicating with the following:**
- (i) [Facility] staff.**
 - (ii) Federal, State, tribal, regional, and local emergency management agencies.**

***[For ICF/IIDs at §483.475(c):] (3) Primary and alternate means for communicating with the ICF/IID's staff, Federal, State, tribal, regional, and local emergency management agencies.**

Interpretive Guidelines applies to: §403.748(c)(3), §416.54(c)(3), §418.113(c)(3), §441.184(c)(3), §460.84(c)(3), §482.15(c)(3), §483.73(c)(3), §483.475(c)(3), §484.102(c)(3), §485.68(c)(3), §485.625(c)(3), §485.727(c)(3), §485.920(c)(3), §486.360(c)(3), §491.12(c)(3), §494.62(c)(3).

NOTE: This does not apply to Transplant *Programs*.
Guidance is pending and will be updated in future release.

E-0033

(Rev.)

§403.748(c)(4)-(6), §416.54(c)(4)-(6), §418.113(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §482.15(c)(4)-(6),

§483.73(c)(4)-(6), §483.475(c)(4)-(6), §484.102(c)(4)-(5), §485.68(c)(4), §485.625(c)(4)-(6), §485.727(c)(4), §485.920(c)(4)-(6), §491.12(c)(4), §494.62(c)(4)-(6).

[(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least *every 2 years (annually for LTC).*] The communication plan must include all of the following:

(4) A method for sharing information and medical documentation for patients under the [facility's] care, as necessary, with other health providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii). [This provision is not required for HHAs under §484.102(c), CORFs under §485.68(c)]

(6) [(4) or (5)]A means of providing information about the general condition and location of patients under the [facility's] care as permitted under 45 CFR 164.510(b)(4).

***[For RNHCIs at §403.748(c):] (4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to maintain the continuity of care, based on the written election statement made by the patient or his or her legal representative.**

***[For RHCs/FQHCs at §491.12(c):] (4) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).**

Interpretive Guidelines applies to: §403.748(c)(4)-(6), §416.54(c)(4)-(6), §418.113(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §482.15(c)(4)-(6), §441.184(c)(4)-(6), §460.84(c)(4)-(6), §483.73(c)(4)-(6), §483.475(c)(4)-(6), §484.102(c)(4)-(5), §485.68(c)(4), §485.625(c)(4)-(6), §485.727(c)(4), §485.920(c)(4)-(6), §491.12(c)(4), §494.62(c)(4)-(6).

NOTE: For RHCs/FQHC's the regulatory language differs under (c)(4). Additionally, a method for sharing information and medical documentation for patients under the RHC/FQHC's care, as necessary, with other health providers to maintain the continuity of care and a means of providing information about the general condition and location of patients does not apply.

NOTE: This does not apply to Transplant *Programs*.
Guidance is pending and will be updated in future release.

E-0034
(Rev.)

§403.748(c)(7), §416.54(c)(7), §418.113(c)(7) §441.184(c)(7), §482.15(c)(7), §460.84(c)(7), §483.73(c)(7), §483.475(c)(7), §484.102(c)(6), §485.68(c)(5), §485.68(c)(5), §485.727(c)(5), §485.625(c)(7), §485.920(c)(7), §491.12(c)(5), §494.62(c)(7).

[(c) The [facility] must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least *every 2 years (annually for LTC).*] The communication plan must include all of the following:

(7) [(5) or (6)] A means of providing information about the [facility's] occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

***[For ASCs at 416.54(c): (7) A means of providing information about the ASC's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.**

***[For Inpatient Hospice at §418.113(c):] (7) A means of providing information about the hospice's inpatient occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.**

Interpretive Guidelines applies to: §403.748(c)(7), §416.54(c)(7), §418.113(c)(7), §441.184(c)(7), §460.84(c)(7), §482.15(c)(7), §483.73(c)(7); §483.475(c)(7); §484.102(c)(6); §485.68(c)(5), §485.625(c)(7); §485.727(c)(5); §485.920(c)(7); §491.12 (c)(5), §494.62(c)(7).

**NOTE: This does not apply to outpatient hospices or Transplant *Programs*.
*Guidance is pending and will be updated in future release.***

**E-0035
(Rev.)**

§483.73(c)(8); §483.475(c)(8)

****[For ICF/IIDs at §483.475(c):]***

[(c) The ICF/IID must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be reviewed and updated at least every 2 years.] The communication plan must include all of the following:

****[For LTC Facilities at §483.73(c):]***

[(c) The LTC facility must develop and maintain an emergency preparedness communication plan that complies with Federal, State and local laws and must be

reviewed and updated at least annually.] The communication plan must include all of the following:

(8) A method for sharing information from the emergency plan, that the facility has determined is appropriate, with residents [or clients] and their families or representatives.

Interpretive Guidelines for §483.73(c)(8) and §483.475(c)(8).

NOTE: This ONLY applies to LTC Facilities and ICF/IIDs.

Guidance is pending and will be updated in future release.

E-0036

(Rev.)

§403.748(d), §416.54(d), §418.113(d), §441.184(d), §460.84(d), §482.15(d), §483.73(d), §483.475(d), §484.102(d), §485.68(d), §485.625(d), §485.727(d), §485.920(d), §486.360(d), §491.12(d), §494.62(d).

**[For RNCHIs at §403.748, ASCs at §416.54, Hospice at §418.113, PRTFs at §441.184, PACE at §460.84, Hospitals at §482.15, HHAs at §484.102, CORFs at §485.68, CAHs at §486.625, “Organizations” under 485.727, CMHCs at §485.920, OPOs at §486.360, RHC/FHQs at §491.12:]*

(d) Training and testing. The [facility] must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

[For LTC at §483.73(d):]* **(d) Training and testing. The LTC facility must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

[For ICF/IIDs at §483.475(d):]* **Training and testing. The ICF/IID must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least *every 2 years*. The ICF/IID must meet the requirements for evacuation drills and training at §483.470(i).

*[For ESRD Facilities at §494.62(d):] **Training, testing, and orientation.** The dialysis facility must develop and maintain an emergency preparedness training, testing and patient orientation program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training, testing and orientation program must be *evaluated* and updated at *every 2 years*.

Interpretive Guidelines applies to: §403.748(d), §416.54(d), §418.113(d), §441.184(d), §482.15(d), §460.84(d), §483.73(d), §483.475(d), §484.102(d), §485.68(d), §485.625(d), §485.727(d), §485.920(d), §486.360(d), §491.12(d), §494.62(d).

NOTE: This does not apply to Transplant *Programs*.
Guidance is pending and will be updated in future release.

E-0037

(Rev.)

§403.748(d)(1), §416.54(d)(1), §418.113(d)(1), §441.184(d)(1), §460.84(d)(1), §482.15(d)(1), §483.73(d)(1), §483.475(d)(1), §484.102(d)(1), §485.68(d)(1), §485.625(d)(1), §485.727(d)(1), §485.920(d)(1), §486.360(d)(1), §491.12(d)(1).

**[For RNCHIs at §403.748, ASCs at §416.54, Hospitals at §482.15, ICF/IIDs at §483.475, HHAs at §484.102, “Organizations” under §485.727, OPOs at §486.360, RHC/FQHCs at §491.12:]*

(1) Training program. The [facility] must do all of the following:

- (i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.*
- (ii) Provide emergency preparedness training at least every 2 years.*
- (iii) Maintain documentation of all emergency preparedness training.*
- (iv) Demonstrate staff knowledge of emergency procedures.*
- (v) If the emergency preparedness policies and procedures are significantly updated, the [facility] must conduct training on the updated policies and procedures.*

*[For Hospices at §418.113(d):] **(1) Training.** The hospice must do all of the following:

- (i) Initial training in emergency preparedness policies and procedures to all new and existing hospice employees, and individuals providing services under arrangement, consistent with their expected roles.**
- (ii) Demonstrate staff knowledge of emergency procedures.**
- (iii) Provide emergency preparedness training at least *every 2 years*.**
- (iv) Periodically review and rehearse its emergency preparedness plan with hospice employees (including nonemployee staff), with special emphasis**

placed on carrying out the procedures necessary to protect patients and others.

(v) Maintain documentation of all emergency preparedness training.

(vi) If the emergency preparedness policies and procedures are significantly updated, the hospice must conduct training on the updated policies and procedures.

*[For PRTFs at §441.184(d):] **(1) Training program.** The PRTF must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) After initial training, provide emergency preparedness training *every 2 years*.

(iii) Demonstrate staff knowledge of emergency procedures.

(iv) Maintain documentation of all emergency preparedness training.

(v) If the emergency preparedness policies and procedures are significantly updated, the PRTF must conduct training on the updated policies and procedures.

*[For PACE at §460.84(d):] **(1) The PACE organization must do all of the following:**

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least *every 2 years*.

(iii) Demonstrate staff knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.

(iv) Maintain documentation of all training.

(v) If the emergency preparedness policies and procedures are significantly updated, the PACE must conduct training on the updated policies and procedures.

[For LTC Facilities at §483.73(d):] **(1) Training Program. The LTC facility must do all of the following:*

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

*[For CORFs at §485.68(d):]**(1) Training.** The CORF must do all of the following:

- (i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.
- (ii) Provide emergency preparedness training at least *every 2 years*.
- (iii) Maintain documentation of the training.
- (iv) Demonstrate staff knowledge of emergency procedures. All new personnel must be oriented and assigned specific responsibilities regarding the CORF's emergency plan within 2 weeks of their first workday. The training program must include instruction in the location and use of alarm systems and signals and firefighting equipment.
- (v) *If the emergency preparedness policies and procedures are significantly updated, the CORF must conduct training on the updated policies and procedures.*

*[For CAHs at §485.625(d):] (1) Training program. The CAH must do all of the following:

- (i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.
- (ii) Provide emergency preparedness training at least *every 2 years*.
- (iii) Maintain documentation of the training.
- (iv) Demonstrate staff knowledge of emergency procedures.
- (v) *If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.*

*[For CMHCs at §485.920(d):] (1) Training. The CMHC must provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles, and maintain documentation of the training. The CMHC must demonstrate staff knowledge of emergency procedures. Thereafter, the CMHC must provide emergency preparedness training at least *every 2 years*.

Interpretive Guidelines applies to: §403.748(d)(1), §416.54(d)(1), §418.113(d)(1), §441.184(d)(1), §460.84(d)(1), §482.15(d)(1), §483.73(d)(1), §483.475(d)(1), §484.102(d)(1), §485.68(d)(1), §485.625(d)(1), §485.727(d)(1), §485.920(d)(1), §486.360(d)(1), §491.12(d)(1)

NOTE: This does not apply to Transplant *Programs* or ESRD facilities.
Guidance is pending and will be updated in future release.

E-0038
(Rev.)

§494.62(d)(1): Condition for Coverage:

(d)(1) Training program. The dialysis facility must do all of the following:

- (i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.**
- (ii) Provide emergency preparedness training at least *every 2 years*.**

Staff training must:

(iii) Demonstrate staff knowledge of emergency procedures, including informing patients of—

(A) What to do;

(B) Where to go, including instructions for occasions when the geographic area of the dialysis facility must be evacuated;

(C) Whom to contact if an emergency occurs while the patient is not in the dialysis facility. This contact information must include an alternate emergency phone number for the facility for instances when the dialysis facility is unable to receive phone calls due to an emergency situation (unless the facility has the ability to forward calls to a working phone number under such emergency conditions); and

(D) How to disconnect themselves from the dialysis machine if an emergency occurs.

(iv) Demonstrate that, at a minimum, its patient care staff maintains current CPR certification; and

(v) Properly train its nursing staff in the use of emergency equipment and emergency drugs.

(vi) Maintain documentation of the training.

(vii) If the emergency preparedness policies and procedures are significantly updated, the dialysis facility must conduct training on the updated policies and procedures.

Interpretive Guidelines for §494.62(d)(1).

Guidance is pending and will be updated in future release.

E-0039

(Rev.)

§416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2), §484.102(d)(2), §485.68(d)(2), §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §491.12(d)(2), §494.62(d)(2).

****[For RNCHI at §403.748, ASCs at §416.54, HHAs at §484.102, CORFs at §485.68, OPO, “Organizations” under §485.727, CMHC at §485.920, RHC/FQHC at §491.12, ESRD Facilities at §494.62]:***

(2) Testing. The [facility] must conduct exercises to test the emergency plan annually. The [facility] must do all of the following:

- (i) Participate in a full-scale exercise that is community-based *every 2 years*;
or
 - (A) When a community-based exercise is not accessible, *conduct a facility-based functional exercise every 2 years*; *or*
 - (B) If the [facility] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in *its next required* community-based or individual, facility-based *functional* exercise following the onset of the actual event.
- (ii) Conduct an additional exercise *at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted*, that may include, but is not limited to the following:
 - (A) A second full-scale exercise that is community-based or individual, facility-based *functional exercise*; *or*
 - (B) *A mock disaster drill*; *or*
 - (C) A tabletop exercise *or workshop* that *is* led by a facilitator *and includes a group discussion* using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.
- (iii) Analyze the [facility's] response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [facility's] emergency plan, as needed.

**[For Hospices at 418.113(d):]*

- (2) *Testing for hospices that provide care in the patient's home. The hospice must conduct exercises to test the emergency plan at least annually. The hospice must do the following:*
 - (i) *Participate in a full-scale exercise that is community based every 2 years; or*
 - (A) *When a community based exercise is not accessible, conduct an individual facility based functional exercise every 2 years; or*
 - (B) *If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full scale community-based exercise or individual facility-based functional exercise following the onset of the emergency event.*
 - (ii) *Conduct an additional exercise every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:*
 - (A) *A second full-scale exercise that is community-based or a facility based functional exercise; or*
 - (B) *A mock disaster drill; or*
 - (C) *A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.*

(3) Testing for hospices that provide inpatient care directly. The hospice must conduct exercises to test the emergency plan twice per year. The hospice must do the following:

- (i) Participate in an annual full-scale exercise that is community-based; or*
 - (A) When a community-based exercise is not accessible, conduct an annual individual facility-based functional exercise; or*
 - (B) If the hospice experiences a natural or man-made emergency that requires activation of the emergency plan, the hospice is exempt from engaging in its next required full-scale community based or facility-based functional exercise following the onset of the emergency event.*
- (ii) Conduct an additional annual exercise that may include, but is not limited to the following:*

- (A) A second full-scale exercise that is community-based or a facility based functional exercise; or*
 - (B) A mock disaster drill; or*
 - (C) A tabletop exercise or workshop led by a facilitator that includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.*
- (iii) Analyze the hospice's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the hospice's emergency plan, as needed.*

**[For PRFTs at §441.184(d), Hospitals at §482.15(d), CAHs at §485.625(d):]*

(2) Testing. The [PRTF, Hospital, CAH] must conduct exercises to test the emergency plan twice per year. The [PRTF, Hospital, CAH] must do the following:

- (i) Participate in an annual full-scale exercise that is community-based; or*
 - (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or*
 - (B) If the [PRTF, Hospital, CAH] experiences an actual natural or man-made emergency that requires activation of the emergency plan, the [facility] is exempt from engaging in its next required full-scale community based or individual, facility-based functional exercise following the onset of the emergency event.*
- (ii) Conduct an [additional] annual exercise or and that may include, but is not limited to the following:*

- (A) A second full-scale exercise that is community-based or individual, a facility-based functional exercise; or*
 - (B) A mock disaster drill; or*
 - (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.*
- (iii) Analyze the [facility's] response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the [facility's] emergency plan, as needed.*

**[For PACE at §460.84(d):]*

(2) Testing. The PACE organization must conduct exercises to test the emergency plan at least annually. The PACE organization must do the following:

- (i) Participate in an annual full-scale exercise that is community-based; or*
 - (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or*
 - (B) If the PACE experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE is exempt from engaging in its next required full-scale community based or individual, facility-based functional exercise following the onset of the emergency event.*
- (ii) Conduct an additional exercise every 2 years opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted that may include, but is not limited to the following:*
 - (A) A second full-scale exercise that is community-based or individual, a facility based functional exercise; or*
 - (B) A mock disaster drill; or*
 - (C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.*
- (iii) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.*

**[For LTC Facilities at §483.73(d):]*

(2) The [LTC facility] must conduct exercises to test the emergency plan at least twice per year, including unannounced staff drills using the emergency procedures. The [LTC facility, ICF/IID] must do the following:

- (i) Participate in an annual full-scale exercise that is community-based; or*
 - (A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise.*
 - (B) If the [LTC facility] facility experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LTC facility is exempt from engaging its next required a full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.*
- (ii) Conduct an additional annual exercise that may include, but is not limited to the following:*
 - (A) A second full-scale exercise that is community-based or an individual, facility based functional exercise; or*
 - (B) A mock disaster drill; or*
 - (C) A tabletop exercise or workshop that is led by a facilitator includes a group discussion, using a narrated, clinically-relevant emergency*

scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the [LTC facility] facility's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the [LTC facility] facility's emergency plan, as needed.

**[For ICF/IIDs at §483.475(d)]:*

(2) Testing. The ICF/IID must conduct exercises to test the emergency plan at least twice per year. The ICF/IID must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or
(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or.
(B) If the ICF/IID experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ICF/IID is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or
(B) A mock disaster drill; or
(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the ICF/IID's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the ICF/IID's emergency plan, as needed.

**[For OPOs at §486.360]*

(d)(2) Testing. The OPO must conduct exercises to test the emergency plan. The OPO must do the following:

(i) Conduct a paper-based, tabletop exercise *or workshop* at least annually. A tabletop exercise is led by a facilitator *and includes a group discussion*, using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. *If the OPO experiences an actual natural or man-made emergency that requires activation of the emergency plan, the OPO is exempt from engaging in its next required testing exercise following the onset of the emergency event.*

(ii) Analyze the OPO's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the [RNHCI's and OPO's] emergency plan, as needed.

Interpretive Guidelines applies to: §403.748(d)(2), §416.54(d)(2), §418.113(d)(2), §441.184(d)(2), §460.84(d)(2), §482.15(d)(2), §483.73(d)(2), §483.475(d)(2), §484.102(d)(2), §485.68(d)(2), §485.625(d)(2), §485.727(d)(2), §485.920(d)(2), §486.360(d)(2)§491.12(d)(2), §494.62(d)(2)

NOTE: This does not apply to Transplant *Programs*.
Guidance is pending and will be updated in future release.

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§482.15(g)

(g) Transplant hospitals. If a hospital has one or more transplant *programs* (as defined in § 482.70)—

(1) A representative from each transplant *program* must be included in the development and maintenance of the hospital's emergency preparedness program; and

(2) The hospital must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the hospital, each transplant *program*, and the OPO for the DSA where the hospital is situated, unless the hospital has been granted a waiver to work with another OPO, during an emergency.

Interpretive Guidelines for §482.15(g).

Hospitals which have transplant *programs* must include within their emergency planning and preparedness process one representative, at minimum, from the transplant *program*. If a hospital has multiple transplant *programs*, each center must have at least one representative who is involved in the development and maintenance of the hospital's emergency preparedness process. The hospital must include the transplant *program* in its emergency plan's policies and procedures, communication plans, as well as the training and testing programs.

The hospital must also collaborate with each OPO in its designated service area (DSA) or other OPO if the hospital was granted a waiver to develop policies and procedures (protocols) that address the duties and responsibilities of each entity during an emergency.

Both the hospital and the transplant *program* are required to demonstrate during a survey that they have collaborated in the planning and development of the emergency program. Both are required to have written documentation of the emergency preparedness plans. However, the transplant *program* is not individually responsible for the emergency preparedness requirements under §482.15 (see Tag E-005 at §482.78).

Survey Procedures

- Verify the hospital has written documentation to demonstrate that a representative of each transplant *program* participated in the development of the emergency program.
- Ask to see documentation of emergency protocols that address transplant protocols that include the hospital, the transplant *program* and the associated OPOs.