State Operations Manual
Appendix H - Guidance to Surveyors: End-Stage Renal Disease Facilities

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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

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§494.20 - Condition: Compliance with Federal, State, and local laws and regulations.

Interpretive Guidelines §494.20

This Condition emphasizes the Centers for Medicare & Medicaid Services' (CMS) role as a partner with State and local governments, as well as with other Federal agencies. The purpose of this Condition is to affirm the principle that Medicare reimbursement should be distributed to ESRD facilities that comply with local, State, and Federal laws and rules. This Condition is not intended to adjudicate laws and rules from other federal agencies, state, and local governmental agencies. This Condition should only be cited when a specific deficient practice has been completely adjudicated by the authority(ies) having jurisdiction in the area, and a final decision of noncompliance with the other entity's requirement has been reached.

Facilities are expected to comply fully with investigations conducted by public health, regulatory, or law enforcement authorities.

V101

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.20 - 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

This tag is intended for use in citing standard-level noncompliance.

Applicable laws and regulations of other Federal agencies which could be a basis for noncompliance with §494.20 include the Department of Health & Human Services' Office of Civil Rights (HHS OCR) for the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA), the Department of Justice Civil Rights Division for Title III related to public accommodations under the Americans with Disabilities Act (ADA); the Occupational Safety and Health Administration (OSHA) for regulations related to employee safety; and the Food and Drug Administration (FDA) for regulations related to the safety of drugs and medical devices. If a drug or device may have caused or contributed to a serious injury or illness, the facility must notify the manufacturer and the FDA using FDA's User Facility reporting requirements. Clusters of adverse events (infectious or non- infectious) should also be reported to the appropriate State or local public health department, as required by those authorities. Because these other Federal laws are complex, surveyors are not expected to be their enforcement mechanism. If noncompliance with the laws or rules of another Federal agency is suspected or noted, contact your CMS Location for guidance.

The Condition for Infection Control at V-145 addresses compliance with reporting communicable diseases. The Condition for Reuse at V-383 addresses compliance with FDA reporting requirements related to dialyzer/bloodline reuse. The Condition for Personnel Qualifications at V-681 addresses compliance with licensure and certification of facility staff.

Subpart B—Patient Safety

V110

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§494.30 - Condition: Infection control.

Interpretive Guidance §494.30

This Condition incorporates, as regulation, two documents from the Centers for Disease Control and Prevention (CDC) and also includes CMS-developed regulations. These infection control requirements apply to both the chronic dialysis in-center facility and any home dialysis program(s).

Survey of this Condition requires observations of care delivery, interviews with staff and patients, and review of medical records, facility logs, policies and procedures and quality assessment and performance improvement (QAPI) documentation. Direct care staff are observed and interviewed regarding their adherence to infection control practices. Administrative and supervisory staff, as well as the medical director, may be interviewed to clarify issues. Medical and administrative records must demonstrate recognition of any potential infection and the actions taken to prevent its transmission within the dialysis facility.

If deficient practices noted in infection control techniques are multiple, pervasive, or to an extent that present a risk to patient health and safety, condition-level noncompliance should be considered. Per 42 C.F.R. §488.24(b), condition level noncompliance should be considered when the deficiencies are of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients.

V111

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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

A sanitary environment is achieved through the implementation of cleanliness standards within the facility and treatment area to prevent the spread of infections. This includes adhering to "Standard Precautions" for all healthcare settings, as well as the more stringent precautions recommended by the CDC for hemodialysis units due to the increased potential for contamination with blood and pathogenic microorganisms. See the linked CDC report for guidance on infection control precautions recommended for outpatient hemodialysis units.

"Standard Precautions" apply to the care of all patients in any healthcare setting and include the use of gloves, gown, or mask whenever needed to prevent contact of the healthcare worker with blood, secretions, excretions, or contaminated items.

Standard Precautions are the CDC's recommended system of infection control precautions for all health care settings. Standard Precautions evolved from Universal Precautions (UP) and Body Substance Isolation (BSI), based on the principle that all blood, body fluids, secretions, and excretions (except sweat), non-intact skin, and

mucous membranes may contain transmissible infectious agents.

Dialysis facilities should adhere to Standard Precautions for all healthcare settings and the additional precautions recommended for hemodialysis facilities to ensure effective infection control. Infection control requirements apply to both the chronic dialysis in-center facility and any home dialysis program(s).

V112

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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)

The CDC "Recommendations for Preventing Transmission of Infections among Chronic Hemodialysis Patients" (MMWR, Vol. 50/No. RR-05), pages 18 to 28, including the "Recommended Infection Control Practices for Hemodialysis Units at a Glance," found at: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm *is incorporated by reference into the regulation and, thus, facilities must demonstrate that they follow standard infection control precautions by implementing its recommendations. For the purposes of these Conditions for Coverage, the portions of the CDC infection control recommendations incorporated by reference are mandatory and must be adhered to and demonstrated within the dialysis facility. When serving as Regulation text, the words of the CDC document are excerpted exactly as written. The entire CDC document includes background information and rationale for the CDC-recommended practices and can be used as an informational resource.*

Note: When words are inserted or altered in a direct quotation, square brackets—[ ]—are placed around the change. The brackets enclose words intended to explain the quote or to help integrate the quote into the guidance.

According to the CDC, "preventing transmission among chronic hemodialysis patients of blood-borne viruses and pathogenic bacteria from both recognized and unrecognized sources of infection requires implementation of a comprehensive infection control program. The components of such a program include infection control practices specifically designed for the hemodialysis setting, including routine serologic testing and immunization, surveillance, training and education."

CDC's components of a comprehensive infection control program to prevent transmission of infections among chronic hemodialysis patients include:

- *Infection control practices for hemodialysis units.*
- *Infection control precautions specifically designed to prevent transmission of bloodborne viruses and pathogenic bacteria among patients.*
- *Routine serologic testing for Hepatitis B virus infections.*
- *Vaccination of susceptible patients against Hepatitis B.*
- *Isolation of patients who test positive for Hepatitis B surface antigen.*
- *Surveillance for infections and other adverse events.*
- *Infection control training and education.*

The infection control practices recommended by CDC for hemodialysis units will reduce opportunities for patient-to-patient transmission of infectious agents, directly or indirectly through contaminated devices, equipment, and supplies, environmental surfaces, or hands of personnel. These practices should be carried out routinely for all patients in the chronic hemodialysis setting because of the increased potential for blood contamination during hemodialysis and because many patients are colonized or infected with pathogenic bacteria. These infection control practices include additional measures to prevent Hepatitis B Virus (HBV) transmission because of the high titer of HBV in each milliliter of infected blood and its ability to survive on environmental surfaces.

According to the CDC, for patients at increased risk for transmission of pathogenic bacteria, including antimicrobial-resistant strains, additional precautions might also be necessary. Patients with either an infected skin wound with drainage uncontrolled by dressings, or uncontrolled fecal incontinence or diarrhea, should be dialyzed at a station with as few adjacent stations as possible. Staff members treating the patient should wear a separate gown for patient care, and supplies and equipment (such as blood pressure cuffs) should not be shared between patients with uncontrolled draining wounds.

Surveillance for infections and other adverse events is necessary to monitor the effectiveness of infection control practices, as well as to train and educate both staff members and patients on appropriate infection control behaviors and techniques.

V113

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 and station.

Interpretive Guidance § 494.30(a)(1)(i)

According to the CDC, hand washing is the most effective measure to prevent the transmission of contaminants.

Because exposure to blood and potentially contaminated items can be routinely anticipated during hemodialysis, gloves are required whenever caring for a patient or touching the patient's equipment. To facilitate glove use, a supply of clean non-sterile gloves and waste receptacles should be readily accessible to each dialysis station and work area. Gloves should be changed frequently during patient care.

Examples of when gloves should be worn:

- *Staff members must wear gloves while performing procedures that have the potential for exposure to blood, dialysate, and other potentially infectious substances. This includes procedures such as caring for patients' vascular accesses or catheters, setting up reprocessed dialyzers pre dialysis treatment, inserting or removing the vascular access needles, connecting the dialysis blood lines to the vascular access needle lines or catheter lines, touching the dialysis blood lines, dialyzer, or machine during or after a dialysis treatment, administering intravenous medications, handling blood lines, dialyzers, dialysate tubing and machines post dialysis treatment, and cleaning and disinfecting the dialysis machine and chair post dialysis treatment.*
- *Gloves should be provided to patients and visitors if these individuals assist with procedures that risk exposure to blood or body fluids, such as self-cannulating or holding access sites post-treatment to achieve hemostasis.*
- *Chair-side computer keyboards/screens can easily become contaminated because of their proximity to the patient station. Hand hygiene is imperative after contact with the chair-side computer and before contact with the patient, regardless of whether contact with the computer occurred through gloved or ungloved hands.*

Examples of when gloves should be changed:

- *When soiled (e.g., with blood, dialysate, or other body fluids);*
- *When going from a "dirty" area or task to a "clean" area or task.*
  Note: A dirty area is defined as an area where there is a potential for contamination with blood or body fluids and areas where contaminated or used

supplies, equipment, blood supplies, or biohazard containers are stored or handled. A clean area is an area designated for clean and unused equipment, supplies, and medications.

- *When moving from a contaminated body site to a clean body site of the same patient, and,*
- *After touching one patient or their machine and before arriving to care for another patient or touch another patient's machine.*

In addition, gloves must be changed between each patient and station; accordingly, if there is a change in patient and/or station, a new pair of clean gloves must be used each time for access site care, vascular access cannulation, administration of parenteral medications or to perform invasive procedures. The intention is to ensure that clean gloves, which have not previously touched potentially contaminated surfaces, are in use whenever there is a risk for cross-contamination to a patient's bloodstream to occur.

"Hand hygiene" refers to either washing hands with soap and water or using a waterless, alcohol-based antiseptic hand rub with a 60-90% alcohol content. Hands should be washed with soap and water if visibly soiled. If not visibly soiled, hand hygiene with alcohol-based hand rub may be used. The CDC recommends that hand washing involve rubbing hands together "vigorously" for 15 seconds, and that the use of alcohol-based rubs involves covering all surfaces of hands and fingers until the hands are dry. According to the CDC, even with glove use, hand hygiene is necessary after glove removal because hands can become contaminated through small defects in gloves and from the outer surface of gloves during glove removal. Resources: Hand Hygiene Guidance; Hand Hygiene for Dialysis Care.

Examples of when hand hygiene should be performed:

- *After touching blood, body fluids, secretions, excretions, and potentially contaminated items;*
- *Before and after direct contact with patients;*
- *Before performing any invasive procedure such as vascular access cannulation or administration of parenteral medications;*
- *Immediately after gloves are removed;*
- *After contact with inanimate objects, including medical equipment or environmental surfaces at the patient station;*
- *Before entering and on exiting the patient treatment areas, and,*
- *When moving from a contaminated body site to a clean body site of the same patient.*

The CDC document, "Prevention of Intravascular Catheter-Related Infections" ("RR-10"), which is also incorporated into the applicable regulations, states that staff should wear clean or sterile gloves when changing the dressing on intravascular catheters. Staff must observe hand hygiene before and after palpating catheter insertion sites, as well as before and after accessing or dressing an intravascular catheter.

Hand hygiene is required after every direct contact with a patient and between patient contacts, even if the contact is casual. Gloves are not necessary for casual social contact

with a patient, for example, staff members may touch the patient's shoulder, take their arm, or shake hands without wearing gloves. However, gloves should always be worn anytime contact with blood or body fluids is anticipated.

Supplies of gloves should be strategically placed so that staff have adequate access for both routine and emergency use.

Physicians and non-physician practitioners, social workers and dietitians must follow these same requirements for glove use and hand hygiene if providing direct patient care or when in contact with patients.

V114

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

A "sufficient number" means that sinks are easily accessible and readily available in the patient treatment area and in other appropriate areas, such as the reuse room, medication area, home training room, and isolation area/room, to meet the needs of the staff and patients.
Sinks must be plumbed with both hot and cold water. If the flow of water is initiated through motion detection, adjustments to the system must ensure that warm water is available to encourage staff to wash their hands according to CDC recommendations (see V113).

Hand washing sinks should be dedicated only for hand washing purposes and should remain clean. Avoid placing, cleaning, or draining used items in hand-washing sinks. Used or contaminated items should be handled in designated utility sinks. The facility should have a sink available for patients to wash their access sites prior to treatment and their hands after treatment. This sink may also be used by staff for hand washing. Soap and a supply of paper towels protected from contamination must be available at each sink.

V115

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

In addition to wearing gloves, staff should wear personal protective equipment (PPE) appropriate to the anticipated potential exposure. Staff should wear PPE during the initiation and termination of dialysis treatment, manipulation of access needles or catheters, administration of medications through the extracorporeal circuit or by subcutaneous injection, the reprocessing of dialyzers, and cleaning and disinfecting of patient care supplies and equipment. Protective clothing or gear must be changed if it becomes soiled with blood, body fluids (including dialysate), secretions, or excretions.

Street clothes, scrub suits, or uniforms are sufficient attire within the dialysis unit, except during times when the spurting or spattering of blood, body fluids, potentially contaminated substances, or chemicals may occur. At those times, a cover garment that provides a fluid-resistant barrier must be worn. This could be a lab coat, a gown, or an apron that incorporates sleeves. The garment must be closed in front when used during patient care. The protective garment should fully cover the arms and torso from the neck area to the thigh/knee area. Aprons without sleeves are insufficient PPE for procedures that may result in blood spattering.

Physicians, advanced practice registered nurses, physician assistants, social workers and dietitians must wear a cover garment which provides a fluid resistant barrier with full coverage of arms and body front if they are providing service to any patient in the treatment area during a time of high risk for spurting or spattering of blood, as, for example, during initiation or termination of dialysis. The garment should be changed if it becomes soiled. Visitors should be provided with cover garments if they are in the treatment area during initiation or termination of dialysis.

Home patients do not have to wear gowns when they are caring for themselves. The partner or caregiver of a home patient should wear appropriate PPE, including gloves, and practice appropriate hand hygiene.

Separate PPE (gown, face shield, etc.) should be used in the isolation area/room and removed before leaving the isolation area/room. "Separate" refers to PPE that is dedicated for use in the isolation room for the particular patient. If a patient's family member or other visitors are accessing the isolation area, staff should provide these individuals with barrier PPE to be worn during the visit and removed when leaving.

The "treatment area" refers to the physical space where dialysis treatments are administered in the dialysis unit, including the reuse room and home training area. Staff must avoid any activity that could lead to self-contamination, such as applying lip balm or handling/inserting contact lenses in the treatment area. Patients may eat and drink at their dialysis stations, depending on facility policies. If non-disposable dishes are

provided by the facility, they should be cleaned in the usual manner; no special care is needed for these items.

V116

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

According to the CDC, any item taken to a patient's dialysis station could become contaminated with blood and other bodily fluids, serving as a vehicle of transmission to other patients either directly or through contamination from personnel's hands. Items taken to a patient's dialysis station include those placed on the top or sides (in baskets) of dialysis machines and on dialysis chairs.

After use, all equipment and supplies must be considered potentially blood-contaminated and should be separated, handled with caution, and either disinfected or discarded. If provided, linens should be removed after use, separated from clean items, and laundered. If blood pressure cuffs are used for multiple patients, the coverings must be disposable or able to be adequately disinfected.

If the facility provides linens or blankets for patient use, these items should be considered potentially contaminated with blood. If patients bring their own blankets, pillows, etc., they should be instructed to wash the linen they bring to treatment and use bleach to remove blood stains.

If the facility provides portable or cellular phones, remote controls, or individual televisions for patient use during treatment, these items must be properly cleaned and disinfected before use by another patient.

V117

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

CDC RR-05 as Adopted by Reference 42 CFR 494.30(a)(1)(i)

"Additional measures to prevent contamination of clean or sterile items include a) preparing medications in a room or area separated from the patient treatment area and designated only for medications; b) not handling or storing contaminated (i.e., used) supplies, equipment, blood samples, or biohazard containers in areas where medications and clean (i.e., unused) equipment and supplies are handled; and c) delivering medications separately to each patient. Common carts should not be used within the patient treatment area to prepare or distribute medications. If trays are used to distribute medications, clean them before using for a different patient."

Interpretive Guidance § 494.30(a)(1)(i)

According to the CDC, measures to prevent contamination of clean or sterile items include: a) preparing medications in a clean room or area separated or away from the patient treatment area and designated only for medications; b) not handling, cleaning, or storing potentially contaminated (i.e., used) supplies, equipment, blood samples, or biohazard containers in areas where medications and clean (i.e., unused) equipment and supplies are handled; and, c) delivering medications separately to each patient. Common medication carts must not be used to deliver medications.

It is acceptable for the medication prep area to be located within the treatment area, but the space should be separated from individual patient stations, and a clean area must be designated. Medications used in the home training area can be prepared in the same room where home training is conducted, provided a clean area is available for medication preparation.

The patient treatment area should have designated "clean" and "dirty" areas. A dirty area is considered to be an area where there is a potential for contamination with blood or body fluids and areas where contaminated or used supplies, equipment, blood supplies, or biohazard containers are stored or handled. A clean area is considered an area designated solely for clean and unused equipment, supplies, and medications. Staff must remain aware of the separation of clean and dirty areas to prevent cross-contamination.

Surveyors should recognize that smaller, older facilities may face challenges in achieving separate areas for clean and dirty equipment or tasks; the key is protecting clean areas and items from cross-contamination.

V118

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

According to the CDC, once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two or more vials should not be pooled into a single vial.

Single-use vials/ampules must be used for only one patient, should not be entered more than once, and if entered, may not be stored for future use.

Staff should only enter vials with a new sterile syringe and needle. If both vials are single-use and are discarded after the single entry into each, the same syringe may be used. If either vial is multi-use, a different syringe must be used for entry into each vial.

V119

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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.

Interpretive Guidance § 494.30(a)(1)(i)

According to the CDC, if a common supply cart is used, it must be kept in a designated area away from any areas where the spurting or spattering of blood or fluid may occur, and the cart should not be moved between stations.

Medication vials, patient care items, including gloves, syringes, alcohol swabs, and other supplies, should not be stored in pockets, inside fanny packs, or other similar locations.

V120

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

According to the CDC, external transducer protectors, which provide a protective barrier between dialysis bloodlines and the dialysis machine, should not be reused. "Wet" ("wet with blood or other fluid") external transducer protectors must be changed immediately, and the side of the external transducer protector that faces the machine should be inspected for visible fluid. If the external transducers are wetted with blood, the staff should inspect the wetted transducer to see if fluid has passed through. If fluid or blood is visible on the side of the transducer protector that faces the machine, the machine must be opened by qualified personnel after the dialysis treatment to allow the internal transducer to be inspected for contamination. This includes inspecting the internal pressure tubing set and pressure sensing port for possible blood contamination. Frequent blood pressure alarms or frequent requirements for adjusting the blood level in the drip chamber can be indicators of contamination of the internal transducer filter.

Recognize that some bloodlines do not have external transducer protectors; this requirement would not apply in those cases, except for changing the bloodlines between patients.

V121

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.30(a)(4) - And 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)

Potentially infectious waste and soiled laundry should be removed from the patient treatment area throughout the day as the containers are filled in order to maintain an

environment that enhances safe patient care. All disposable items should be placed in bags thick enough to prevent leakage.

Any waste contaminated with blood should be considered "infectious" and handled according to local, State, and Federal regulations governing medical waste disposal.

To help reduce the risk of injury or infection from sharps, the FDA recommends that healthcare facilities use FDA-cleared sharps disposal containers for the disposal of used needles and other sharps. FDA-cleared sharps disposal containers are made from rigid, puncture-resistant plastic or metal with leak-resistant sides and bottoms, and a tight-fitting, puncture-resistant lid with an opening that accommodates depositing a sharp object but is not large enough for a hand to enter. For information on sharps disposal at healthcare facilities, see "Sharps Disposal Containers in Health Care Facilities."

Biohazard waste containers should be clearly labeled and sealed when they are full. They should also be stored in an area protected from casual access and contamination of the water supply.

V122

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.30(a)(4) - And 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)

Failures in environmental cleaning and disinfection have led to transmission of blood-borne pathogens (e.g., Hepatitis B virus) and other infections from one patient to another in hemodialysis units. Correct cleaning and disinfection of environmental surfaces (including patient chair or bed surfaces, dialysis equipment surfaces, adjacent tables, and work surfaces) must be performed between patient uses to prevent transmission of dangerous pathogens.

A facility should establish written protocols for cleaning and disinfecting surfaces and equipment, including careful mechanical cleaning before any disinfection process. For guidance, refer to CDC RR-5 Table 2 below.

CDC Table 2. Disinfection procedures recommended for commonly used items or surfaces in hemodialysis units

Item or Surface	Low-Level Disinfection*	Intermediate-Level Disinfection*
Gross blood spills or items contaminated with visible blood		X
Hemodialyzer port caps		X
Interior pathways of dialysis machine		X
Water treatment and distribution system	X	X[†]
Scissors, hemostats, clamps, blood pressure cuffs, stethoscopes	X	X[§]
Environmental surfaces, including exterior surfaces of hemodialysis machines	X	

* Careful mechanical cleaning to remove debris should always be done before disinfection.

[†] Water treatment and distribution systems of dialysis fluid concentrates require more extensive disinfection if significant biofilm is present within the system.

[§] If item is visibly contaminated with blood, use a tuberculocidal disinfectant.

Any manufacturer's guidance for sterilizing or disinfecting an item should be followed, as well as guidance from the chemical sterilant or disinfectant manufacturer, including appropriate dilution and contact time.

At the end of each dialysis treatment, all surfaces without visible blood should be cleaned following the low-level disinfection protocol using soap, detergent or detergent germicide. Per CDC guidance, for visible blood, the intermediate-level disinfection protocol must be followed, which requires the area to be immediately cleaned with a cloth soaked in tuberculocidal disinfectant or a 1:100 dilution of bleach (300-600 mg/L free chlorine), following the manufacturer's directions for contact time. Gloves must be worn, and the used cloth placed into a leak-proof container. After cleaning up all visible blood, a disinfectant must be applied a second time using a new cloth or towel. No patient should be at the station during this time.

Blood spills in the treatment area and other areas, such as the waiting room and patient bathroom, need to be cleaned effectively and immediately, or as soon as possible, given the patient care situation. Cleaning and disinfection of a blood spill must be completed with a cloth soaked with a tuberculocidal disinfectant or a 1:100 or stronger dilution of bleach (300-600 mg/L free chlorine) (i.e., intermediate-level disinfection). After all visible blood is cleaned, staff should use a new cloth or towel to apply disinfectant a second time.

In hemodialysis units, cleaning and disinfection procedures during patient changeover are particularly prone to error and contribute to the risk of cross-contamination if correct procedures are not observed. A sufficient patient-free interval is necessary at each station to facilitate adequate cleaning and disinfection. Routine surface disinfection should not begin until the patient has left the station. Station disinfection includes the following equipment/surfaces: the dialysis machine, the purified water connection,

dialysate concentrate container(s) or connection(s), the wall-box, and the treatment chair.

According to current recommendations from the CDC, to prevent cross-contamination between patients, it is essential that the previous patient completely vacate the station before staff begin cleaning and disinfecting the station and setting up for the next patient. It is essential to note that all dialysis patients must be clinically stabilized (i.e., have stable blood pressure and vascular access hemostasis) following their dialysis treatments before being transferred from the dialysis station. If a patient is not sufficiently stable to be moved from the dialysis station, cleaning and disinfection of the equipment at the station, as well as preparations for the next patient, must be delayed until the patient can be safely moved outside the station. CDC has developed an audit tool and checklist to promote recommended practices for infection prevention in dialysis facilities. They are available for use by facility staff to help guide and assess their practice. These resources can be found here:

Dialysis Station Routine Disinfection Checklist
Dialysis Station Routine Disinfection Audit Tool

"Intermediate-level disinfection" kills bacteria and most viruses and is accomplished by using a tuberculocidal "hospital disinfectant" or a 1:100 dilution of bleach (300-600 mg/L free chlorine). "Low-level disinfection" kills most bacteria and is accomplished by using general-purpose disinfectants. Intermediate and low-level disinfectants are designed for use on environmental surfaces; they can also be used on non-critical medical devices, depending on the design and labeling claims. Reference https://www.cdc.gov/mmwr/pdf/rr/rr5005.pdf, page 15/46.

At the end of each patient treatment, the staff should clean and disinfect the dialysis station. Special attention should be given to cleaning control panels on dialysis machines, treatment chairs, and other frequently touched surfaces that may be contaminated with patients' blood. The staff should discard all fluids and clean and disinfect all surfaces of the containers associated with the prime waste (including containers attached to the machines) after each treatment.

After each treatment, the staff needs to clean and disinfect medical devices and equipment. Items such as scissors, hemostats, clamps, stethoscopes, and blood pressure cuffs need to be cleaned and disinfected between patient uses. If the item is visibly contaminated with blood, an intermediate-level disinfectant must be used.

Staff must clean and disinfect the internal circuits of the dialysis machines properly. Single-pass machines may be rinsed and disinfected at the beginning or end of each day, while batch-recirculating machines must be drained, rinsed, and disinfected after each use. If a blood leak occurs, follow the manufacturer's recommendations for additional disinfection.

A facility should document procedures for the dialysis machine disinfection, including testing for residual disinfectant.

No Tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.30(a)(3) Patient isolation procedures to minimize the spread of infectious agents and communicable diseases;

Interpretive Guidance § 494.30(a)(3)

This is an information tag. Isolation procedures required by the CDC are related to the care and treatment of HBV+ patients. For guidance and references to isolation, refer to the individual tags related to isolation, which are provided below in this section.

V124

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Clarification of terminology: "HBsAg positive" is used synonymously with "HBV+" meaning that an individual has tested positive for the presence of Hepatitis B surface antigen. "HBsAg negative" is used synonymously with "HBV-" meaning that the person does not have the Hepatitis B surface antigen. "HBV susceptible" means that the person does not have sufficient Hepatitis B surface antibody levels to achieve immunity to the virus. "HBV immune" means the person has sufficient Hepatitis B surface antibodies to achieve immunity to the virus.

According to the CDC, although the incidence of HBV infection is low among chronic hemodialysis patients, preventing transmission depends on timely detection of patients converting from HBsAg-negative to HBsAg-positive and rapid implementation of isolation procedures before cross-contamination can occur.

In order to prevent the transmission of Hepatitis B among ESRD patients, all new patients should be tested, and their HBV serologic status (i.e., HBsAg, total anti-HBc, and anti-HBs results) should be known prior to admission for treatment. If the results of this testing are not known at admission because of an emergency situation, the patient should be tested immediately upon intake and results known within 7 days of admission.

CDC's schedule for Hepatitis B testing is below:

Schedule for Routine Testing for Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) Infections

Patient Status	On Admission	Monthly	Semiannual	Annual
All patients	HBsAg,* Anti-HBc* (total), Anti-HBs,* Anti-HCV, ALT†			
HBV-susceptible, including nonresponders to vaccine		HBsAg		
Anti-HBs positive (≥10 mIU/mL), anti-HBc negative				Anti-HBs
Anti-HBs and anti-HBc positive		No additional HBV testing needed		
Anti-HCV negative		ALT	Anti-HCV	

* Results of HBV testing should be known before the patient begins dialysis.
† HBsAg=hepatitis B surface antigen; Anti-HBc=antibody to hepatitis B core antigen; Anti-HBs=antibody to hepatitis B surface antigen; Anti-HCV=antibody to hepatitis C virus; ALT=alanine aminotransferase.

HBV-Susceptible Patients: *Susceptible patients should begin receipt of Hepatitis B vaccine immediately upon admission. Test susceptible patients monthly for HBsAg, including those who a) have not yet received Hepatitis B vaccine, b) are in the process of being vaccinated, or c) have not adequately responded to vaccination. Note that, while the patient's anti-HBs level is <10 mIU/mL, they are considered susceptible to Hepatitis B and should be tested for HBsAg on a monthly basis.*

Follow-up of Vaccine Responders: *Retest patients who respond to the vaccine annually for anti-HBs antibodies.*

HBV-Infected Patient: *Chronically infected patients do not require routine follow-up testing for infection control. Annual testing for HBsAg is reasonable to detect the small percentage of HBV-infected patients who might lose their HBsAg.*

HBV-Immune Patients: *Annual anti-HBs testing of patients who are positive for anti-HBs (>10 mIU/mL) and negative for anti-HBc determines the need for booster doses of vaccine to ensure that protective levels of antibody are maintained. Follow-up testing after booster doses of vaccine are given is not recommended, nor is routine follow-up testing necessary for patients who are positive for both anti- HBs and anti-HBc.*

A facility should have systems in place for communicating these test results to other units or hospitals when patients are transferred for care.

V125

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

CDC RR-05 Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i)

Routine Testing for Hepatitis B: seroconversion

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.

Interpretive Guidance § 494.30(a)(1)(i)

According to the CDC, in patients newly infected with HBV, HBsAg often is the only serologic marker initially detected. HBsAg-positive seroconversions must be reported to the State or local health department as required by law or regulation. Patients with a positive HBsAg must be isolated. Patients newly identified with HBsAg-positive status should be evaluated for the need for counseling, medical evaluation, and vaccination of contacts. Repeat HBsAg testing should be conducted, and patient should be tested for anti-HBc (including IgM anti-HBc) 1–2 months later. Six months later, the facility should repeat HBsAg testing and test for anti-HBs to determine clinical outcome and need for counseling, medical evaluation, and referral of contacts for vaccination. Patients who become HBsAg negative are no longer infectious and can be removed from isolation.

If there have been any seroconversions since last survey, there should be documentation of actions taken in response. Recognize that seroconversions should be relatively rare, and each seroconversion should be carefully analyzed for any potential that transmission occurred within the dialysis unit.

V126
V126
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

According to the CDC, Hepatitis B vaccination is recommended for all susceptible chronic hemodialysis patients and staff members, regardless of whether the facility accepts patients with hepatitis B virus (HBV) infection. OSHA mandates that each facility provide the HBV vaccine to all susceptible staff members.

Hepatitis B vaccination is also recommended for patients with Stage 1-5 chronic kidney disease who are not yet on dialysis, as well as for those undergoing peritoneal dialysis (PD) and home hemodialysis (home HD), since they may require in-center hemodialysis. While not a requirement, best practice suggests that the home training nurse advise anyone assisting in the home hemodialysis treatment of an HBV+ patient to consult their physician about vaccinating against Hepatitis B.

The patient's physician should refer to the CDC recommendations or the vaccine literature for guidance in dosing. Higher doses of the vaccine are recommended for hemodialysis patients due to their immunocompromised state.

Since patients and staff have the right to refuse a vaccination, this rule is interpreted to mean that all susceptible patients and staff are "offered" an appropriate Hepatitis B vaccination schedule in an appropriate timeframe. "Appropriate timeframe" refers to the period during which vaccinations should be offered and initiated for employees and patients, and the course completed according to the timeline suggested by the vaccine manufacturer.

For employees, personnel files should demonstrate compliance with this regulation. OSHA requires facilities to maintain a record of their employees' Hepatitis B immunization history and to contact past employers to obtain vaccination records, if applicable. OSHA requires these records be maintained for 30 years after the person leaves employment. If the employee states they have been vaccinated, but the records are not obtainable, the personnel record should include a statement attesting to the employee having received the vaccine, along with the dates (or approximate dates) signed by the employee.

Patient medical and personnel records respectively must show whether susceptible patients and staff are offered Hepatitis B vaccination. There must be a system in place to track vaccination administration to ensure completion of the ordered course.

V127

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

CDC RR-05 Requirements as Adopted by Reference 42 CFR 494.30 (a)(1)(i)

Hepatitis B Screening: Patients and Staff

Test all vaccinees [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)

According to the CDC, all patients and staff must be tested for anti-HBs 1–2 months after the last primary vaccine dose to determine their response to the vaccine. Patients and staff members who do not respond to the primary vaccine series should be revaccinated with a full course of vaccine and retested for response. No additional doses of vaccine are warranted for those who do not respond to the second series. Patients who require a booster dose of the HBV vaccine should not be assigned to a staff member concurrently caring for HBV+ positive patients.

The CDC defines an adequate response to vaccination as a laboratory result of ≥10 mIU/mL anti-HBs. The laboratory performing the testing for anti-HBs must be able to define a 10 mIU/mL concentration.

Results should be reported as a numeric value; a result of "positive" or "negative" is not sufficient. Some manufacturers of anti-HBs assays consider a level of anti-HBs slightly higher than 10mIU/mL to be protective. For these assays, the higher level of titer considered to be protective by the kit manufacturer should be used to determine whether or not the patient or staff member is immune.

Primary non-responders to vaccination who are HBsAg negative should be considered susceptible to HBV infection.

Patients who respond to the vaccine should be retested annually for anti-HBs. If anti-HBs declines to <10 mIU/mL, these patients should receive a booster dose of Hepatitis B vaccine and continue to be retested for anti-HBs annually. Retesting immediately after the booster dose is not necessary.

For staff members who initially respond to the vaccine, neither booster doses of vaccine nor periodic serologic testing to monitor antibody concentrations are necessary.

The facility and the responsible physicians should consult the CDC recommendations on dosing and revaccination.

V128

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Beginning February 9, 2009, all new facilities have been required to have a separate isolation room unless the facility has obtained a waiver from CMS for this requirement. See V129 for the details of this requirement.

According to the CDC, HBV+ patients must dialyze in a separate isolation room during dialysis to prevent contact and transmission by contact with blood spills, splattering, or spurting of blood and other body fluids.

A separate room with a door is required to contain any spillage of blood, body fluids, and other contaminants, as well as to prevent cross-contamination that can occur due to environmental contamination. HBV is stable in the environment and can survive on surfaces (and remain infectious) for at least 1 week. Since Hepatitis B is not airborne, the walls of the room do not need to reach the ceiling, but they must extend to the floor to contain blood spills. The door must also be closed during times when blood spurting or spattering is possible, such as at the initiation and termination of treatment. The walls must allow for visual monitoring of the patients in the room (unless a staff member is continually present) and contain any potential blood or fluid spills.

A separate room is the safer and preferred method of isolation; however, "existing" facilities, meaning those facilities that were treating HBV+ patients as of the effective date of the regulations, i.e. October 14, 2008, and that were using a separate area rather than a separate room, may continue to use the separate "isolation" area, unless they are expanding the physical location, in which case they must add an isolation room or obtain a waiver of the requirement. If an existing facility uses a designated isolation area rather

than a room, the area used for HBV+ patients should be separated from other stations by a space at least equivalent to the width of one hemodialysis station. The "isolation" station could be an "end of row" station to facilitate the separation of the area from the mainstream of the dialysis facility's activities and to decrease the number of adjacent dialysis stations.

If there are current HBV+ patients on census, the isolation area/room and equipment cannot be used for HBV- patients on other shifts or days due to the risk of cross-contamination. When any HBV+ patients are no longer on census, the "isolation" area/room may be terminally cleaned, disinfected and used for HBV- patients.

Existing units, currently without HBV+ patients, that accept HBV+ patients after the effective date of these regulations may establish a separate area (as described above) for the care of these patients. Any facility that expands its physical capacity after February 9, 2009, must include an isolation room or secure a waiver. See V129.

Every facility must have the capacity to separate potentially HBV+ patients during treatment. Existing units that do not currently accept or treat HBV+ patients may have a transfer agreement with a local chronic facility that has capacity for isolation stations. If no local facility is available to accept such transfers, the existing facility must establish an isolation room or area for use with HBV+ patients.

If an HBV+ patient chooses home dialysis, precautions must be exercised during the training of that patient to prevent potential cross-contamination of the training environment and other home patients. These could include conducting the training in the patient's home, rather than at the dialysis facility, or limiting the use of the training space to the HBV+ patient until training is completed. Different precautions would be necessary depending on the modality: home HD vs. PD. Relatives or other individuals who assist with dialysis for an HBV+ patient should be instructed to ask their physician regarding vaccination against Hepatitis B infection.

V129

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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)

As of February 9, 2009, all new facilities must have an isolation room or have been granted a waiver for this requirement by CMS, demonstrating sufficient capacity in their geographic area for isolation rooms. Waiver requests, including information on the

geographical accessibility of isolation rooms, should be referred to the applicable CMS Location.

An on-site survey is not required to determine the approval or denial of an isolation room waiver request. A desk review may be conducted, and CMS should evaluate all materials submitted by the dialysis facility when reviewing and processing a waiver request. Reference State Operations Manual, Ch. 2, Section 2281A for additional information on the review of an isolation room waiver request.

V130

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Separate dedicated supplies and equipment, including blood glucose monitors, must be used to provide care to the HBV+ patient. All supplies used in the isolation room/area, such as clamps, blood-pressure cuffs, testing reagents, etc., should be labeled "isolation" and not routinely removed from the isolation room/area.

Refillable concentrate containers must be surface disinfected at the completion of each treatment. They may be kept in the isolation area and refilled at the door or removed for cleaning and disinfection. In the disinfection area, the "isolation" container(s) and pick-up tube(s) must be segregated in a dedicated, designated area away from all other containers and pick-up tubes. If the container/pick-up tube is to be rotated out of the isolation area, it must be bleached before subsequent use.

Separate gowns should be used in the isolation area and removed before leaving the isolation area/room. Anyone entering the isolation area/room during the patient's treatment must wear a protective gown.

HBV+ patients must undergo dialysis on dedicated machines. Due to the risk of cross-contamination, facilities should avoid switching equipment used for HBV+ patients for use with HBV- patients.

Equipment used by HBV+ patients should be reserved for them unless repair or maintenance is needed or until all HBV+ patients have been discharged.

Based on CDC guidance, dialyzers for HBV+ patients must not be reused. Refer to V301 under Reuse.

When the machine is no longer dedicated to an HBV+ patient, its internal pathways can be disinfected using conventional protocols, its external surfaces can be cleaned and disinfected, and it can be returned to general use.

V131

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

One staff person may care for one or more HBV+ patients and one or more immune patients simultaneously, but may not care for Hepatitis B susceptible patients at the same time. Hepatitis B status should be considered when assigning patients to stations nearest the isolation area. If a staff member assigned to care for an HBV+ patient must concurrently care for someone other than another HBV+ patient, the additional patient(s) must be HBV immune. Patients who require a booster dose of the HBV vaccine should not be assigned to a staff member concurrently caring for HBV+ positive patients. When possible, only HBV immune staff should be assigned to care for HBV+ patients.

V132

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Training and education in infection control rationales and practices appropriate to the responsibilities and task assignments of staff members at risk for occupational exposure to blood must be provided initially upon employment and at least annually. OSHA

mandates dialysis staff receive bloodborne pathogen training annually and CDC recommends infection control training initially on employment and annually.

Topics must include (but are not limited to):

- ***Proper hand hygiene technique.***
- ***Proper use of personal protective equipment (PPE).***
- ***Infection control practices recommended for hemodialysis units and differences from Standard Precautions.***
- ***Special precautions for HBsAg-positive patients.***
- ***Proper infection control techniques for initiation, care, and maintenance of access sites.***
- ***Modes of transmission for blood-borne viruses, pathogenic bacteria, and other microorganisms as appropriate.***
- ***Proper handling, preparation, and administration of parenteral medications, maintaining aseptic technique; and,***
- ***Proper methods to clean and disinfect equipment and environmental surfaces to minimize transmission of microorganisms.***
- ***Rationale for segregating HBsAg-positive patients with a separate room, machine, instruments, supplies, medications, and staff members; and,***
- ***Centralized record keeping to monitor and prevent complications, including routine serologic testing results for HBV and HCV, hepatitis B vaccine status, episodes of bacteremia and loss of access caused by infection, and other adverse events.***

V142

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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)

The facility should have written policies and procedures covering the infection control program and practices, including, but not limited to, emerging infectious diseases, isolation, and any additional precautions for patients with communicable diseases with different modes of transmission, such as tuberculosis (TB), influenza, and multidrug-resistant organisms. The facility must review practices and update policies and procedures as needed to ensure infection control practices are rigorously followed.

V143

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.30(b)(2) - Ensure that clinical staff demonstrate compliance with current aseptic techniques when dispensing and administering intravenous medications from vials and ampules; and

Interpretive Guidance § 494.30(b)(2)

Safe injection practices are critical to prevent transmission of infections in the dialysis setting. Medication administration from vials, ampules, and bags is common during dialysis and therefore increases the potential for unsafe and inappropriate injection practices.

Opened multiple-dose vials should be handled aseptically and used and discarded in accordance with the manufacturer's set time frames and/or other accepted standards for use (e.g., US Pharmacopeia). Staff preparing medications should clean the septum of any multi-use vial with alcohol before inserting the needle and the injection port before using the port to administer a medication.

Facilities may not fill syringes with saline from the single dose saline bag or IV tubing connected to the patient at the dialysis station.

When saline syringes are required for vascular access care or to flush medications, facilities should obtain syringes pre-filled with sterile saline from a manufacturer, Food and Drug Administration (FDA)- registered outsourcing facility, or pharmacy whenever possible.

If pre-filled syringes are not available and the facility needs to use alternative procedures to secure saline flushes, the following safe injection practices should be considered:

- ***Syringes with sterile saline for an individual patient are filled in a dedicated clean area removed from the patient treatment area. Although not required, a clean room separate from the patient treatment area is the preferred location.***
- ***Prepare syringes for an individual patient as close as possible to the time of administration to prevent compromised sterility or stability.***
- ***Use aseptic technique for disinfection of saline vials prior to entry and follow the suggested standards from the Association for Professionals in Infection Control and Epidemiology (APIC) and the Institute for Safe Medication Practices (ISMP) when preparing saline flushes, including:***
  - ***Medication containers labeled single-dose or single-use (e.g., saline bags, single dose vials, ampules) may not be used to prepare more than one syringe for vascular access care or to flush medications.***
  - ***Any unused saline in the opened single-dose or single-use container must be discarded and may not be stored for future use on the same patient.***
- ***If multi-dose vials are used to prepare saline flush syringes, they must be dated upon opening and discarded within 28 days unless the manufacturer specifies a different***

date for that vial. The beyond-use date should never exceed the manufacturer's expiration date.

The facility must have a mechanism in place to ensure expired medications are not available for use.

Resources: Medication Preparation; Medication Administration; FAQs for Single-dose/Single-use Vials; FAQs for Multi-dose vials; Injection Safety Checklist for Outpatient Settings.

V144

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.30(b)(3) - 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)

There should be a documented reporting mechanism for infection control issues. The nurse manager, administrator, and medical director should each be able to describe the infection control program and reporting mechanisms.

Infection control and patient safety issues should be continuously reported and discussed in QAPI meetings, and the response taken to address these issues should be documented. Records of tracking infections should be a part of the facility's QAPI program. Refer to V637.

V145

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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)

The reporting of incidences of communicable diseases should be documented and become a part of the QAPI record. Clusters of adverse events should be promptly reported to the appropriate State or local public health authority. The QAPI process does not preclude the need to report serious adverse events to public health authorities in a timely manner.

V146

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.30(a)(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)

It is the intention of the Conditions for Coverage to incorporate relevant guidance from the CDC "Guidelines for the Prevention of Intravascular Catheter-Related Infections," MMWR August 9, 2002/Vol. 51/No. RR-10, into the requirements for facility infection control practices. Much of the material in this referenced guideline is general or relates to catheter selection, insertion, and use in acute or relatively short-term situations. The elements of this guidance that are most relevant to hemodialysis facilities address the risks posed by intravascular catheters and the need for appropriate staff education, surveillance, vascular access care, and rigorous hand hygiene to reduce these risks.

For purposes of these Conditions for Coverage, the portions of this document that are incorporated by reference are mandatory and must be adhered to and demonstrated within the dialysis facility.

Note: When words are inserted or altered in a direct quotation, square brackets—[ ]—are placed around the change. The brackets enclose words intended to explain the quote or to help integrate the quote into the guidance.

The entire CDC document "Guidelines for the Prevention of Intravascular Catheter-Related Infections" includes background information and rationale for the CDC-recommended practices and can be used as an informational resource. For reference, the document may be found at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm.

V147

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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

1. Educate health-care workers regarding the … appropriate infection control measures to prevent intravascular catheter-related infections.
2. Assess knowledge of and adherence to guidelines periodically for all persons who … manage intravascular catheters.

II. Surveillance

- **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
Antibiotic lock solutions: Do not routinely use antibiotic lock solutions to prevent CRBSI (catheter related blood stream infections).

Interpretive Guidance § 494.30(a)(2)

According to the CDC, intravascular catheters solve the problem of attaining vascular access quickly when there is insufficient time for development of a longer-term internal access: ideally a fistula, or secondarily, a graft. Catheters also provide a solution of last resort when internal access site opportunities have been exhausted.

However, despite their expedience, these catheters pose a threat of infection with the potential for immediate and long-term morbidity and mortality consequences for the patient.

The use of catheters for hemodialysis is the most common factor contributing to bacteremia in dialysis patients and the relative risk for bacteremia in patients with dialysis catheters is seven times the risk for patients with primary arteriovenous fistulas. Staff must maintain aseptic technique for the care of all vascular accesses, including intravascular catheters.

The CDC lists the two most common routes of catheter infection as:

- *Migration of skin organisms through the insertion site and into the cutaneous catheter tract, resulting in colonization of the catheter tip; and,*

- *Contamination of the hub, resulting in intraluminal colonization of the catheter. The initiation and termination of the dialysis process, as well as manipulation and tension on the catheter, provide frequent opportunities for such contamination. Minimizing the use of intravascular catheters and protecting the insertion site and catheter hub from contamination through education and training on rigorous care is crucial in reducing catheter-related infections.*

Catheter insertion sites should be routinely assessed by staff at each treatment. Most catheter sites are covered with either transparent dressings or gauze. Patients with catheters should be instructed to replace the dressing if a catheter site has sufficient bleeding or drainage to dampen or soil the dressing between treatments.

The CDC advises that prophylactic antibiotic lock solutions be reserved for use only in special circumstances, e.g. in units where the rate of catheter-related bloodstream infection (CRBSI) has not decreased despite optimal maximal adherence to aseptic technique.

In addition to CDC recommendations for education, training, and infection control surveillance of intravascular catheters, dialysis facilities should adhere to current standards of practice for vascular access care. The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) has provided evidence-based clinical practice guidelines for a number of topics, including Clinical Practice Guideline for Vascular Access. As of 2019, NKF's KDOQI guidelines continue to recommend the use of aseptic technique and masks for patients and staff performing catheter connection and disconnection procedures to minimize the risk for infection.

Manufacturers' directions should be adhered to for the types of antiseptics recommended for safe cleaning of the skin and catheter.

The facility should have an initial and ongoing training program for infection control practices, which includes information on the prevention of intravascular catheter-related infections.

Facility policies should address the training and qualifications of staff who may access catheters, in accordance with any State licensure requirements, as well as the frequency for periodic practice audits, to verify staff knowledge and adherence to infection control guidelines for intravascular catheters.

V148

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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

- **Conduct surveillance … to determine CRBSI rates, monitor trends in those rates, and assist in identifying lapses in infection-control practices.**
- **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.**

Interpretive Guidance § 494.30(a)(2)

Citing noncompliance with this requirement should be considered if there is lack of evidence of surveillance for catheter-related infections.

A log or another tracking mechanism, such as the Dialysis Module of the National Healthcare Safety Network (NHSN), should be used. Both the surveillance log/database and the patient's individual medical records should contain detailed information on catheter infections and other adverse events, such as, but not limited to prolonged bleeding, stenosis/clotting, allergic reactions, pyrogenic reactions, cardiac arrests, hospitalizations, and deaths.

Refer to V637 under the Condition: Quality Assessment and Performance Improvement (QAPI).

V175

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.40 - Condition: Water and dialysate quality.

Interpretive Guidance § 494.40

This Condition incorporates the Association for the Advancement of Medical Instrumentation's (AAMI's) "American National Standard for Dialysate for Hemodialysis," 2004 (RD52:2004) into the regulation. This AAMI document references portions of their "American National Standard for Water Treatment Equipment for Hemodialysis Applications" (RD62:2001) as the specifications for various water treatment components. The referenced portions of RD62:2001 are also incorporated into the regulation by reference.

The V-tags associated with the water and dialysate quality requirements are divided into 3 parts: (1) the 2004 AAMI standard, (2) any related 2004 AAMI guidance that CMS identifies as relevant, and (3) "Additional Guidance" where CMS provides its additional suggestions on how to best comply with the AAMI guidance.

A survey of this Condition requires inspection of the water treatment and dialysate preparation equipment, as well as their distribution systems; an interview with personnel responsible for the day-to-day operation of those systems; and a review of the records of

operation and testing for those systems. Supervisory personnel may be interviewed to clarify issues or questions. Critical to ensuring patient safety is the expectation that every survey visit include direct observation of water testing for chlorine/chloramine.

Noncompliance at the Condition level should be considered if identified deficient practices are pervasive throughout the Standards included in this Condition, serious in nature, and/or a potential risk to patient health and safety.

Examples of potential Condition level noncompliance may include, but are not limited to:

- *Demonstrated lack of knowledge or training of staff assigned responsibility for the operation or monitoring of the water treatment or dialysate preparation systems;*

- *Failure to perform and document the test(s) for chlorine and chloramine accurately, including the use of testing strips or reagents that are expired or not sensitive to the required levels;*

- *Unsafe practices in the preparation, labeling, or delivery of dialysate; and,*
- *Failure to address out-of-range results for tests of water or dialysate (bacteria, endotoxin, or chemical analysis).*

V176

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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, 75000 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, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795.

Interpretive Guidance § 494.40(a)

The practice guideline of the Association for the Advancement of Medical Instrumentation (AAMI) for "Dialysate for hemodialysis" (ANSI/AAMI RD52:2004) is incorporated by reference at 42 CFR 494.40 and is reflected in the tags and the interpretative guidelines at V176 to V278. AAMI is a professional organization in which

committees composed of representatives of the industry, providers, and regulatory agencies develop voluntary guidelines for medical products and procedures.

Some explanatory language from ANSI/AAMI RD52:2004 and from the Annex to that document has been included below as guidance to surveyors.

Note: When words are inserted or altered in a direct quotation, square brackets—[ ]—are placed around the change. The brackets enclose words intended to explain the quote or to help integrate the quote into the guidance.

AAMI standards, to be fully understood, should be read in their entirety and anyone attempting to apply AAMI standards and recommended practices is encouraged to obtain the complete standard. AAMI disclaims responsibility for any characterization or explanation of its standards and recommended practices that were not developed and communicated in accordance with AAMI procedures for the official interpretation of technical documents.

Grouping of AAMI sections within a given tag may be non-consecutive based on its relevance to the standard being addressed. For example, tag V236 for additives incorporates sections 5.4.4.1 (concentration jugs), 5.4.5 (additives – labeling), and 6.4.2 (additives) from the RD52:2004 requirements.

V177

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52: 2004
4 Fluid quality
4.1 Water

The fluid quality requirements apply to the purified water as it enters the equipment used to prepare dialysate or concentrates from powder at a dialysis facility and apply to the water treatment system as a whole and collectively, and not to each of the devices that make up the system.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.4 Fluid quality
A.4.1.1 Maximum level of chemical contaminants in water

ANSI/AAMI RD62:2001 establishes maximum levels of chemical contaminants in three categories: chemicals known to have particular toxicity for hemodialysis patients, chemicals listed in the U.S. Environmental Protection Agency's Safe Drinking Water Act, and physiological substances that can adversely affect patients if present in the dialysate in excessive amounts.

Several chemicals have been clearly shown to be toxic to dialysis patients at concentrations that are not necessarily toxic to the general population. Those chemicals include aluminum, copper, chloramines, fluoride, nitrate, sulfate, and zinc.

Uptake of aluminum from the dialysate is associated with bone disease, anemia, and dialysis encephalopathy syndrome, which is usually fatal. The suggested maximum aluminum level has been specified to prevent the accumulation of this toxic metal in the patient. Aluminum is particularly likely to increase suddenly to high levels as a result of changing the method of water treatment to include aluminum-containing compounds.

Chloramines damage red blood cells by oxidizing hemoglobin to methemoglobin and by inhibiting antioxidant pathways. Their toxicity in hemodialysis patients is undisputed. Although the role of free chlorine in oxidative blood damage is unclear, its high oxidation potential and ability to form chloramines suggest that the use of highly chlorinated water in dialysate preparation should be avoided.

High levels (>20 ppm) of fluoride in the water used to prepare dialysate are clearly toxic to hemodialysis patients and have resulted in patient deaths. Such high levels of fluoride have resulted from accidental over fluoridation of a municipal water supply, as well as from deionizer exhaustion. The toxicity of fluoride in dialysis patients is questionable at the levels usually associated with fluoridated water (1 ppm). However, in the absence of a consensus on its role in uremic bone disease, the AAMI Renal Disease and Detoxification (RDD) Committee thought it prudent to restrict the fluoride level of dialysate.

Nitrates are a marker for bacterial contamination and fertilizer runoff and have been linked to cases of methemoglobinemia. Nitrates should be permitted only at very low levels. Sulfate at levels above 200 mg/L has been related to nausea, vomiting, and metabolic acidosis. The symptoms disappear when the level remains below 100 mg/L. Both copper and zinc toxicity have been demonstrated when those substances are present

in dialysate at levels below those permitted by the EPA standard. Hence, a lower level has been chosen.

The second group of chemical contaminants included in ANSI/AAMI RD62:2001 is based on the U.S. Environmental Protection Agency's Safe Drinking Water Act (see 2.6). The standard specifies maximum allowable limits for most contaminants in this group at 1/10 of the EPA maximum allowable limit. The lower levels were chosen because the volume of water used for dialysis far exceeds that used for drinking water, because protein binding of these solutes may occur in the blood, and because there is reduced renal excretion of these substances. Selenium and chromium levels were set at the "no-transfer" level. The no-transfer level was chosen, even though it exceeds the EPA limit for selenium and 28% of the EPA limit for chromium, because there is no need for a restriction below the level at which there is no passage from the dialysate to the blood.

The third group of substances included in ANSI/AAMI RD62:2001 consists of physiological substances that can adversely affect the patient if they are present in the dialysate in excessive amounts. Calcium, potassium, and sodium are examples of those substances.

The chemical contaminants regulated by ANSI/AAMI RD62:2001, as listed in Table 1, should not be considered a definitive list of harmful substances; they are only a partial listing of contaminants that might reasonably be expected to be present and have clinical implications. Iron is not included because it does not enter the patient's blood in sufficient quantities to cause toxicity. However, iron may cause fouling of water purification devices or dialysate proportioning systems. Furthermore, municipal water supplies are dynamic systems, which may change with the seasons or in response to new regulations from the EPA.

Additional Guidance:
Table 1 reflects the Standard adopted by CMS as regulation on April 15, 2008, 73FR20369. Individuals or groups of facilities may adopt newer, more stringent requirements by policy.

The medical director is ultimately responsible for the safety and quality of the water used for patient treatments. Each product water chemical analysis must be within the parameters listed in Table 1 at V177. If any values exceed those listed, facility staff must notify the medical director of the results, repeat testing, and take action to address any repeated high levels.

The medical director must be knowledgeable about the water treatment system installed and ensure that the system, as installed, will produce AAMI quality water. Ways to ensure this result would include analysis of the source water and consultation with experts in water treatment, as well as confirmation that the planned installation would be sufficient to produce AAMI quality water by the manufacturer or vendor of the water treatment equipment. For initial surveys, the facility should provide a copy of a chemical analysis with results within AAMI standards accomplished before starting any patient

treatment in the new facility. For resurveys, there must be evidence of ongoing monitoring of the chemical quality of the water, along with actions taken when levels exceed the AAMI standards.

The use of water outside of AAMI standards should be infrequent, considered only when no other option is available to provide desperately needed dialysis, and limited to one treatment per patient. An emergency "plan" that specifies the facility will use tap water or dechlorinated tap water is not acceptable without evidence that the source water has been found safe for such use (i.e., has levels below AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc, and other contaminants known to be toxic to dialysis patients). The medical director is ultimately responsible for this decision; in some instances, short-term exposure to contaminants limited to one treatment may be the optimal choice, rather than not receiving the dialysis treatment at all. Refer to V182.

If the water supply utility has notified the city that the source water is highly chlorinated due to a water main break, flooding, or bacterial contamination of the municipal system, the dialysis facility must conduct more frequent monitoring of chlorine/chloramines (i.e., every 30-60 minutes).

For frequency of monitoring water for chemical contaminants, refer to V201 for Reverse Osmosis (RO) systems and to V206 for Deionization (DI) systems.

V178

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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 levels for the total viable microbial count in the product water shall be 50 CFU/mL, and for the endotoxin concentration, 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)

AAMI Rationale for the Development and Provision of This Recommended Practice
A.4.1.2 Bacteriology of water

When ANSI/AAMI RD5:1981 was initially developed, it was generally considered that the water used to prepare dialysate did not require sterilization. Studies have demonstrated that the incidence of pyrogenic reactions is directly related to the number of bacteria in dialysate. It is also known that a dialysate delivery system can amplify the level of

bacteria in the water used to supply the system. Those studies provided the rationale for setting a recommended maximum concentration of 200 bacteria per mL in the water used to prepare dialysate.

Several groups of investigators have convincingly demonstrated that pyrogenic reactions are caused by lipopolysaccharides, also known as endotoxins, associated with Gram-negative bacteria. Gram-negative water bacteria can multiply rapidly in the chemically pure water used to supply hemodialysis systems. It has also been demonstrated clearly that endotoxins and endotoxin fragments can cross both low-flux and high-flux hemodialysis membranes.

Because 48 hours can elapse between sampling water to determine microbial contamination and receiving results, and because bacterial proliferation can be rapid, action levels for microbial counts and endotoxin concentrations are included in these regulations. Those action levels allow the user to initiate corrective action before levels exceed the recommended maximum levels. Unlike cultures, endotoxin testing does not require extended incubation times. Endotoxin testing, when performed in the dialysis facility, can yield results in approximately 1 hour, thereby eliminating the long delay between sampling and obtaining a result.

During the development of this recommended practice, the AAMI RDD Committee was tasked with recommending levels of bacteria and endotoxins above which the water should not be used for dialysis applications. In making the recommendations outlined in ANSI/AAMI RD52:2004, Section 4.1.2, the AAMI RDD Committee understood that dialysis would continue at contaminant levels above the action level but below the recommended maximum level. Establishing a recommended maximum level of contamination at which dialysis should be stopped immediately is difficult because the risk of adverse events, such as pyrogenic reactions, must be balanced against the risks of uremia if a patient is not dialyzed. The balance between these two risks will depend on the level of contamination, the time of exposure, and the patient's medical condition. Because this balance will almost certainly vary from circumstance to circumstance, the AAMI RDD Committee felt that there was insufficient data on which to base levels of bacteria and endotoxins above which dialysis should not be performed. The final decision of whether to discontinue dialysis rests with the medical director of a facility. Whatever decision is made, the AAMI RDD Committee recommends that the water treatment and distribution system be disinfected promptly any time the levels of bacteria or endotoxins exceed the action levels recommended in AAMI 4.1.2. Additionally, it may be prudent to discontinue dialyzer reuse if the levels of bacteria or endotoxins exceed the recommended maximum levels outlined in AAMI 4.1.2, as the water is introduced directly into the blood compartment of the dialyzer.

Additional Guidance:

If the facility reaches the "action" level, remedial action is required. Action could be to repeat a culture, particularly if only one in a set of cultures was above the action limit. Action could also include disinfecting the system and repeating cultures at several sites.

Some states require this testing to be done in a laboratory approved for the analysis of potable water.

V179

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ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a)

4.1.2 Bacteriology of water
The manufacturer or supplier of a complete water treatment and distribution system [must] demonstrate that the complete water treatment, storage, and distribution system is capable of meeting these requirements at the time of installation.

Following the installation of a water treatment, storage, and distribution system, the user is responsible for continued monitoring of the water bacteriology within the system and for complying with the requirements of this standard, including those related to action levels.

Interpretive Guidance § 494.40(a)

While this standard is primarily addressed to the manufacturer of equipment, each dialysis facility's medical director is responsible for the quality of medical care provided to patients. The medical director oversees the installation and monitoring of the water treatment and distribution system. Their failure to evaluate and validate the environment where devices and equipment will be used may result in non-compliance with this requirement.

Existing facilities must monitor AAMI water chemical analysis and microbial testing and take action if the results fall outside AAMI standards. If culture results exceed the action levels, the facility may need to repeat cultures or disinfect the system and repeat cultures (depending on the number of positive cultures, etc.) and continue treatment while awaiting the results.

AAMI recommendations at 4.1.1, Table 1, recommend maximum levels of contaminants above which corrective measures should be taken. Testing should occur initially upon installation, and at annual intervals thereafter. If the water supply for the facility is from a private well, an annual analysis of the product water quality may not be sufficient to ensure that the feed water requirements of the water treatment system in use are continuously met. The quality of water from the well may change over time, and private wells are not routinely monitored. More frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. When more frequent than annual testing is performed by the dialysis facility, testing may be limited to specific contaminants that are known to be of concern.

Frequency and methods for monitoring water bacteriology are addressed at V252 & V255.

V180

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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)

ANSI/AAMI RD52:2004

AAMI Rationale for the Development and Provision of This Recommended Practice
A.4.3.2.1 Bacteriology of conventional dialysate
It is now clear that endotoxins, endotoxin fragments, or other bacterial products cross at least some dialysis membranes under some operating conditions.

In addition to the risk of acute pyrogenic reactions, indirect evidence increasingly shows that chronic exposure to low amounts of endotoxin may play a role in some of the long-term complications of hemodialysis therapy. Patients treated with ultrafiltered dialysate have demonstrated a decrease in serum β2-microglobulin concentrations, a decrease in markers of inflammation, and an increased responsiveness to erythropoietin. In longer-term studies, use of microbiologically ultrapure dialysate has been associated with a decreased incidence of β2-microglobulin-associated amyloidosis, better preservation of residual renal function, and improved nutritional status. For those reasons, the AAMI RDD Committee reduced the recommended maximum microbial count in the dialysate to 200 CFU/mL and added a recommendation that the endotoxin concentration not exceed 2 EU/mL. The values are the same as those for water used to prepare the dialysate (ANSI/AAMI RD62:2001), implying that the dialysate proportioning system should not add significantly to the microbiological burden in the water. Although the AAMI RDD Committee did not review supporting data, it considered contemporary dialysate delivery systems to be fully capable of performing at this level, provided that the user followed the manufacturer's instructions on cleaning and disinfecting the system, including

disinfection of the line between the water distribution system and the concentrate mixing chambers of the dialysate proportioning system.

Additional Guidance:

Conventional dialysate refers to the dialysate typically used for hemodialysis in the U.S., as opposed to "ultrapure dialysate." Recognize that the purity of dialysate is essential, in that "reverse" ultrafiltration can occur, allowing dialysate to cross the dialyzer membrane and enter the patient's bloodstream. This can occur with most dialyzers, especially high-flux dialyzers at the distal end of the dialyzer, and especially if the patient does not have much fluid weight to remove (allowing less ultrafiltration pressure to be used). A minimum ultrafiltration rate (UFR), as per the dialysis machine manufacturer's DFU, should be maintained to prevent reverse ultrafiltration.

It is not expected that concentrates would be cultured or tested for endotoxin levels. Machine cultures (of dialysate) are used as evidence to determine if this requirement is met.

"Promptly" may be met if action is taken within 48 hours of receiving the results of testing. One example of a corrective measure is to repeat cultures, particularly in cases where one of several cultures exceeds the action level, or to disinfect the system and repeat cultures. Action should also include notifying the medical director of the results.

V181

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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 to an acceptable range. The user is responsible for monitoring the dialysate bacteriology of the system following installation. It is the user's responsibility to establish a regular monitoring routine.

Interpretive Guidance § 494.40(a)

AAMI Rationale for the Development and Provision of This Recommended Practice
A.4.3.2.2 Bacteriology of ultrapure dialysate

Ultrapure dialysate is defined as one having a bacterial content of less than 0.1 CFU/mL and an endotoxin content of less than 0.03 EU/mL. This definition is now widely accepted, particularly in Europe, and the use of ultrapure dialysate is considered a requirement for on-line convective therapies (see AAMI A.4.3.2.3).

Ultrapure dialysate is prepared by sequential ultrafiltration of dialysate prepared from purified water meeting the requirements of AAMI 4.1 and concentrates. Dry powder cartridges are frequently used for the online preparation of bicarbonate concentrate to minimize the potential for the concentrate to contribute high levels of bacteria and endotoxin to the dialysate.

Additional Guidance:

The sensitivity and specificity of the test assay significantly impact the accuracy and subsequent interpretation of test results. Users should select assays that are sensitive to the test being performed.

At the time of publication of these regulations (April 15, 2008, 73 FR 20369), most dialysis facilities in the U.S. were using conventional dialysate, rather than ultrapure dialysate. The use of conventional or ultrapure dialysate is a clinical decision made by the ordering physician. There is no Federal requirement to use ultrapure dialysate.

V182

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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 the failure of a critical component of the water purification and distribution system.

Interpretive Guidance § 494.40(a)

ANSI/AAMI RD52:2004

5 Equipment
5.1 General

This section on equipment provides a brief description of the different components that may be included in a water purification and distribution system used for hemodialysis applications. Since feed water quality and product water requirements may vary from facility to facility, not all of the components described will be necessary in every purification and distribution system.

Routine dialysis requires a well-functioning water purification and distribution system, since dialysis cannot be performed without an adequate supply of water. In addition, specific components of the water purification and distribution system are critical to its operation. An example of such a critical component is the circulating pump in an indirect feed system.

Additional Guidance:

An emergency or contingency "plan" that specifies the facility will use tap water or de-chlorinated tap water may include evidence that the water intended for use has been found safe for such use (i.e., has levels below AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc and other contaminates known to be toxic to dialysis patients). Refer also to the requirements for emergency policies and procedures found under the Condition for Physical Environment at V408.

No tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 the 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)

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5 Equipment
A.5.2 Water purification systems

Devices marketed to purify water for hemodialysis are also subject to the U.S. Food and Drug Administration's (FDA) 510(k) approval process. The FDA has published guidelines for water purification devices used in hemodialysis (Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for

Hemodialysis). Water purification devices marketed for use in hemodialysis applications must be approved by the FDA, and users should ensure that devices obtained from vendors have been approved by the FDA.

Design and instrumentation of individual purification devices may vary from these general descriptions. For example, softeners may be configured as a single resin bed that is regenerated outside the regular operating hours of the dialysis unit, or they may have a dual-bed configuration that allows one bed to be regenerated. At the same time, the other is used to provide water for normal dialysis operations.

Depending on the feed water quality and product water requirements, not every component may be required in a given facility. Likewise, additional components may be required in certain circumstances. For example, carbon adsorption may not provide adequate chloramine removal if the water contains substances, such as polyphosphates, that mask the reactive sites on the carbon particles. In those circumstances, other processes, such as infusion of sodium metabisulfite, may be required to achieve product water that meets these requirements.

Users are encouraged to obtain detailed descriptions of all purification processes, together with operating manuals and maintenance procedures, from the manufacturer or the vendor providing the water purification and distribution system.

Additional Guidance:

This is an informational tag; specific requirements for various water treatment components and deficient practices should be cited under the applicable component tags.

Under FDA regulations at the time these regulations were published (April 15, 73FR20369), all water treatment devices and systems installed after May 30, 1997 must meet review requirements under section 510(k) of the Food, Drug, and Cosmetic Act (21 U.S.C. sec. 360(k)) as described in Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis. If a facility is found to be using water treatment devices installed after 1997 that have not been approved by the FDA, they may be found out of compliance with 42 C.F.R. §494.20. Equipment installed prior to 1997 is not required to have evidence of FDA 510(k) approval. Regardless of when a water purification system was installed, the system must yield water and dialysate that meets these AAMI standards and must be monitored and maintained in accordance with the ANSI/AAMI RD52 guidelines, as incorporated by reference in these regulations.

Each piece of water treatment equipment described below is not required for every system, and determinations of necessary equipment will be made by the facility based on a number of factors such as feed water analysis and geographical considerations. The water treatment system must be designed to process the local source water into AAMI quality water. All facilities should have primary and secondary carbon tanks to remove chlorine/chloramines, and reverse osmosis (RO) or deionization (DI) treatment systems.

Any component in use should meet the requirements specified in these rules for that component.

V184

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a) 8Environment

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 minimizing 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)

To ensure access is restricted to authorized users only, the delivery doors/loading dock must not be left unlocked, open and unattended. Unauthorized users are considered to be individuals that are not involved in the monitoring and maintenance of the water treatment system, such as visitors and non-dialysis staff. Many water systems are in the same room as stored treatment supplies. Staff members that need access to supplies stored in the same room as the water treatment system should have access into that area to retrieve supplies.

Hospital based chronic outpatient units may share the water room with an acute unit; staff designated as authorized users from each unit would be expected to have access to the equipment.

V185

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a) 8Environment (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)

ANSI/AAMI RD52:2004
8 Environment
An area for processing samples and performing on-site tests is also recommended.

Additional Guidance:

Occasionally, systems may be located in an area with limited space, Regardless of the layout of the water purification system, provision must be made to allow staff immediate access all equipment, ports, etc. to operate and monitor the system. In all cases, the operator should be able to describe and identify the various components and the distribution system.

V186

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a) 8Environment (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)

Responsible staff members must be able to test the alarms to validate they can be heard in the treatment area. If alarms normally sound during certain events during the treatment day, documenting that these are heard in the treatment area will suffice for testing. Updated guidance from AAMI RD62:2001 recommend that alarms in the patient treatment area and water treatment rooms should be loud enough to be heard while patients are on dialysis, and should not be muted for more than 3 minutes.

V187

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a) 8Environment (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)

The use of text labels, such as "RO Water," and color-coded "arrow tape" provide a convenient means of identifying pipe content and flow direction.

An example of labeling for a regenerable softener is given below.

WATER SOFTENER: System protects RO membrane by removing calcium and magnesium "hardness ions," adding sodium ions in their place.

- Using sample port #4 [varies from system to system], test water hardness at end of each treatment day. Result must be 1 grain/gallon or less.
- Check brine tank daily to be sure the tank is at least half filled with salt, adding salt pellets if necessary. Water may become "hard" if salt pellet level is low.
- Check timer daily to verify that it shows the correct time of day. Incorrect timer settings may cause the softener to regenerate during dialysis and can result in automatic shutdown of the RO.
- Notify charge nurse and facility technician if hardness test is greater than 1 grain/gallon or if timer does not show correct time of day.

Additional Guidance:

There must be a schematic diagram which allows the staff to follow the flow of the water through the components and each component and the piping must be labeled as described in the recommended practice for the Environment where the water purification and storage system is located.

V188

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

5.2.2 Sediment filters

Permanent, back-washable sediment filters, also known as "bed filters," are frequently located at or near the beginning of hemodialysis water treatment systems and are intended to remove relatively coarse particulate materials from incoming water. Although a single filtration medium may be used, bed filters known as multimedia filters are more commonly selected. These units contain multiple layers, each layer retaining progressively smaller particles. In this way, the bed is used to its fullest extent; the largest particles are removed in the first layer contacted by the water, and the smallest in the final layer.

As the bed accumulates particulate material, open passages begin to clog, and resistance to the water flowing through the filter increases. Ultimately, the increased resistance to flow will result in a reduction of water supply to downstream components. To prevent this situation from occurring, bed filters are cleaned by periodic backwashing, which is accomplished either manually or by using a timer-activated control valve.

Bed filters should be fitted with gauges to measure the hydrostatic pressure at the filters' inlet and outlet. These values can be used to determine the dynamic pressure drop across the filter (delta pressure or ΔP), which serves as an index of resistance to flow and provides a basis for setting the frequency of backwashing.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include:

- *For sediment filters, monitor the pressure drop across the filter daily, looking for a pressure drop of less than a number determined by facility policy.*
- *For the sediment filter backwashing cycle, monitor the backwash cycle timer setting daily at the beginning of the day, looking for the backwash clock set to the time determined by facility policy.*

Additional Guidance:

Sediment filters are not required in every facility; instead, the source water should determine the necessary water treatment components. If sediment filters are in use, the facility must follow these requirements.

If a water treatment system includes multiple components that backwash, the "time" set on each timer may need to be staggered to allow sufficient water to be available for the backwashing. This may result in some timers being set an hour or two different from the correct time. If so, there should be a posted notice to that effect.

Pressure readings should be taken while the equipment is running. To determine the pressure drop (or delta P), observe the pressure readings on the gauges before and after the filter. If the gauge before the filter reads 70 mmHg and the gauge after the filter reads 50 mmHg, the pressure drop or "Delta P (ΔP)" is 20. The ΔP must be within the facility set limits; a result higher than the limits indicates that the filter needs to be backwashed or replaced.

V189

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.2.3 Cartridge filters

Cartridge filters consist of a cylindrical cartridge of the filter medium with a central drainage core. Although cartridge filters may be installed at the inlet to a water system, their usual application is as a final filtration step before reverse osmosis.

As the cartridge accumulates particulate material, resistance to flow through the filter increases, as indicated by an increase in ΔP.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include:
For cartridge filters: monitor for pressure drop across the filter daily, looking for a pressure drop less than a number determined by facility policy. Since some values are system-specific, the facility should define an acceptable operating range for monitoring pressure drops based on the manufacturer's instructions or measurements of system performance.

Additional Guidance:
Cartridge filters are not required in every facility; the source water should determine the necessary water treatment components. If cartridge filters are in use, the facility must follow these requirements.

A marked decrease in ΔP could indicate that there is no filter in the container.

V190

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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.

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)

ANSI/AAMI RD52:2004
5.2.4 Softeners
Water containing calcium or magnesium can form relatively hard deposits and is referred to as "hard water." Water that has had these elements replaced by sodium ion exchange is called "soft water," hence, the term "softener." Softeners also remove other polyvalent cations, most notably iron and manganese, although they are somewhat limited in their effectiveness in this regard. The primary use of softeners in hemodialysis water systems is to prevent hard water deposits from damaging sensitive reverse osmosis membranes.

A softener is a cylinder or vessel that contains insoluble spheres or beads, called "resin," to which sodium ions are attached. During operation, exchangeable sodium ions in the resin are progressively replaced by calcium and magnesium ions. When all the sodium ions have been used, the resin bed has reached a condition referred to as "exhaustion." Softeners that automatically regenerate also include a brine tank, from which saturated sodium chloride solution is drawn during regeneration, and a control valve that regulates regeneration and service cycles.

Additional Guidance:

Softeners are not required in every facility; instead, the source water should determine the necessary water treatment components. If softeners are in use, the facility must follow these requirements.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include:
For the water softener regeneration cycle, monitor the regeneration cycle timer setting daily at the beginning of the day to ensure the softener timer is set to the correct time. Alternatively, verify that the timer is set by the facility to allow multiple tanks to backwash in sequence, rather than all at once.

Automatically regenerated water softeners shall be fitted with a mechanism to prevent water containing high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration. The requirement to prevent water with a high concentration of sodium from entering the product water line is essential when a facility offers nocturnal dialysis, as regeneration cycles for most components are set for nighttime.

The face of the timers used to control the regeneration cycle should be visible to the user. The timer box cover should have a clear window allowing the timers to be seen, or the cover should be removed when timers need to be viewed. Facility policy should define the expected level of salt in the brine tank, with a minimum requirement that salt pellets fill at least half of the tank.

Rarely are dual bed softeners used. These allow one bed to function while the other bed regenerates. If used, the facility is responsible for the correct installation of the dual bed softeners to ensure that the effluent from the regenerating bed goes to drain, rather than

downstream to other water treatment components, or that regeneration occurs when the RO is not in use.

V191

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

6.2.4 Softeners
Softener monitoring, which should be performed daily, involves testing effluent water for total hardness to ensure that the limits established by the reverse osmosis machine manufacturer are not exceeded. In the case of automatically regenerating softeners, monitoring also includes verification that the brine tank contains a sufficient supply of undissolved sodium chloride and that the control valve timer, when present, indicates the correct time of day.

Testing for hardness should be performed using an ethylenediaminetetracetic acid (EDTA) titration test, with "dip and read" test strips, or a similar method.

The hardness test conducted at the end of the day will indicate the overall effectiveness of the water softener under worst-case conditions and ensure that the softener is sized correctly—that is, it has sufficient capacity, expressed in grains of calcium carbonate.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include:
For softeners: monitor product water softness daily at the end of the treatment day for hardness as calcium carbonate, <l grain/gal, unless otherwise specified by the manufacturer of the reverse osmosis equipment.

Additional Guidance:
The water softener log may be incorporated as a part of another log kept for the water treatment system. For hardness tests requiring color differentiation, the person performing the analysis should be capable of correctly interpreting the results, including

the ability to distinguish and accurately identify any colorimetric or other readings. If the person cannot differentiate these colors, an automated meter should be used.

V192

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

5.2.5 Carbon adsorption

Carbon adsorption systems, often referred to as carbon filters, are the principal means of removing both free chlorine and chloramine.

Removal of free chlorine to a maximum level of 0.5 mg/L and chloramine to a maximum level of <0.1 mg/L is necessary to protect hemodialysis patients from red cell hemolysis. In addition, free chlorine may also degrade some reverse osmosis membranes, depending on the membrane material.

AAMI Rationale for the Development and Provision of This Practice

A.5.2.5 Carbon adsorption

Although treatment of water by carbon adsorption is the method usually used to meet these requirements for chloramines, the AAMI RDD Committee recognized that in certain situations, carbon adsorption might not adequately remove chloramines. Inadequate removal of chloramines may occur when the chloramines are in the form of naturally occurring N-chloramines or when practices such as the use of high pH or the inclusion of orthophosphate or polyphosphates are used (by the supplier's water treatment plant) to comply with the EPA's lead and copper rule. In such circumstances, other strategies for chloramine removal may be needed to supplement carbon adsorption. The AAMI RDD Committee is aware that adding sodium metabisulfite prior to the reverse osmosis system has been successful in eliminating chloramine in hemodialysis applications.

Other means of removing chloramines, such as redox alloy media and ultraviolet irradiation at 185 nm, are used in the pharmaceutical and electronics industries. These processes are currently being evaluated for hemodialysis applications. The final choice of a system for chloramine removal in hemodialysis settings will depend on local conditions and may require the inclusion of more than one of the processes outlined above.

Additional Guidance: *If a facility has employed supplemental strategies for chlorine removal, these should be in addition to the use of at least two carbon tanks that hold the carbon beds. The medical director and the chief technician should be able to discuss the rationale for the use of supplemental strategies. Facility records should document the systems in place to protect patients from exposure to chlorine and chloramine, and these systems should be monitored according to the manufacturer's directions.*

V193

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Carbon beds may be plumbed in two ways:

- *Tanks/beds connected consecutively, so that all of the water flows through both tanks/beds; or*
- *"Parallel" so that approximately half of the water flows through each set of tanks/beds*

In the case of parallel plumbing (#2), each tank/bed can vary in size, as several smaller tanks would be in use to provide the required empty bed contact time (EBCT). For parallel-connected tanks/beds, there must be sample ports, as addressed at V192, for each set of tanks/banks, as testing of one set of tanks/beds is irrelevant to the function of the other set of tanks/beds.

If block carbon is used to supply dechlorinated water to a portable RO unit, there must be one dual block carbon system (two block carbon or one block carbon and one granular activated carbon tank) per portable RO, and each portable RO must supply one hemodialysis machine, per the manufacturer's directions.

V194

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD62:2001

4.3.9 Carbon adsorption media

For example, when testing between the beds shows that the first bed is exhausted, the second bed should be moved into the first position, the second bed replaced with a new bed, and the exhausted bed discarded.

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.

ANSI/AAMI RD52

5.2.5 Carbon adsorption

Some granular activated carbon contains aluminum, which can elute from the carbon and add to the burden of aluminum to be removed by reverse osmosis or ion exchange. The use of acid-washed carbon minimizes this source of aluminum in the water.

Additional Guidance:

Facilities using an exchange tank system should establish a schedule for replacing the exhausted carbon adsorption media based on their experience with these tanks to prevent interruptions to patient services. The date of exchange of tanks should be documented on the tank and in the appropriate log. Facilities using back-washable carbon systems should establish a schedule for back-washing the tanks and document the system's function. Back-washing does NOT regenerate the carbon; it rearranges the carbon in the tank, exposing sites that have not yet been used to adsorb chlorine or chloramine. Back-washable systems do exhaust; the responsible staff member should be able to describe how they will replace the carbon when indicated. A "schedule" could refer to "every X months" rather than a specific date or month and should be based on past experience at the facility. Carbon in the tanks can be removed and replaced ("rebedding") on site when the tanks are offline.

Granulated activated carbon (GAC) with a minimum iodine number of 900 must be specified when replacement carbon is ordered. Acid-washed carbon is recommended, as it will protect the RO from exposure to excess aluminum, but is not required as the RO would still protect the patient.

V195

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a)

5.2.5 Carbon adsorption: (10 minute EBCT)

When granular activated carbon is used as the [adsorption] media, it shall have a minimum iodine number of 900, and each bed shall have a minimum empty bed contact time of 5 minutes at the maximum flow rate through the bed.

Interpretive Guidance § 494.40(a)

The empty bed contact time (EBCT) of the granulated activated carbon (GAC) system should be periodically calculated for the maximum water flow through the carbon tanks. The facility determines the frequency of monitoring based on the manufacturer's directions for use. Specific facility conditions may warrant more frequent monitoring, such as chlorine disinfection practices for source water. Water flow rates may vary, altering the need for more or less GAC to achieve the 10-minute total EBCT (for 2 beds). If additional patient treatments or shifts are added, the resultant increased water demand should prompt the medical director and technical staff to consider adding more carbon in order to maintain the minimum EBCT. "Each adsorption bed" refers to the primary tank

or tanks as one adsorption bed and the secondary tank or tanks as another adsorption bed.

V196

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

5.2.5 Carbon adsorption

In addition to removing free chlorine and chloramine, carbon also adsorbs a wide variety of other substances, including both naturally occurring and synthetic organic compounds. The capacity of carbon to remove free chlorine and chloramine may be reduced when other substances "mask" reactive sites on the carbon media. Additionally, the efficiency of free chlorine and chloramine removal is reduced as the pH increases or the temperature decreases. The net effect of those variables is that the finite capacity of carbon beds to remove free chlorine and chloramine cannot be predicted with any certainty. Therefore, their performance needs to be monitored frequently.

6.2.5 Carbon adsorption

Carbon adsorption performance is monitored by measuring free chlorine and/or chloramine concentrations in the water exiting the first carbon bed of a series-connected pair. It should be noted that sampling for total chlorine (the sum of free chlorine and chloramine), allowing a maximum level of 0.1 mg/L of total chlorine, is often simpler than analyzing for free chlorine and chloramine separately.

More frequent monitoring may be appropriate during temporary operation with a single carbon bed, which can occur following breakthrough of the first bed. In such instances, testing is performed on water exiting the second carbon bed in a series-connected pair. The decision to increase the frequency of monitoring should be based on the system's past performance and whether changes in feed water quality have occurred.

AAMI Rationale for the Development and Provision of This Recommended Practice A.6 Monitoring

A.6.2.5 Carbon adsorption

Intensive monitoring of carbon adsorption beds is recommended due to the long history of adverse events associated with chloramine contamination of dialysate. Chloramine concentrations in municipal water can fluctuate from day to day, and the capacity of carbon adsorption beds to remove chloramine can vary depending on the pH and temperature of the water, the nature of the chloramine compounds present, and the presence of other substances in the water. The dependence of chloramine removal on multiple factors makes the performance of carbon adsorption beds unpredictable. Patient safety can only be ensured by intensively monitoring the performance of the carbon adsorption bed. Configuring carbon adsorption beds in series and sampling from a port located between the two beds provides one margin of protection against chloramine breakthrough. When chloramine is first detected in the effluent from the first adsorption bed, essentially the full capacity of the second bed remains available for chloramine removal. This reserve capacity allows the user to conveniently replace the exhausted bed without risk to patients. The exhausted bed is discarded, the second bed is moved into the first position, and a new bed is placed in the second position. A new bed of virgin carbon shall be used for replacement. Carbon cannot be regenerated in a dialysis facility, and the use of regenerated carbon is prohibited by ANSI/AAMI RD62:2001 (see 2.3 in that AAMI document). Backwashing of carbon beds does not regenerate the carbon, although it may allow more efficient use of the bed's capacity by removing channels that can form in the bed during routine operation.

AAMI Rationale for the Development and Provision of This Recommended Practice A.6.2.5 Carbon adsorption

The recommendation that the water purification system operate for at least 15 minutes before sampling is to guard against inadvertently drawing water that has been in the bed for an extended period.

Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4, include:

For carbon adsorption beds, monitor the product water levels of free chlorine and/or total chlorine between the beds prior to beginning each patient shift. The expected result is less than or equal to 0.1 mg/L of total chlorine.

Additional Guidance:

For parallel-connected tanks/beds, testing must be performed for each set of tanks/beds each time testing is conducted.

Test strips with color comparison charts that indicate a low-level reading of zero and a first "number" of 0.5 are not sufficiently sensitive to detect levels as low as 0.1 and should not be used for testing product water for safe levels of chlorine/chloramine. An indication of "0" on the comparison charts does not suffice to demonstrate that the strips are sensitive to "0." Consult the manufacturer's guidance or contact the manufacturer if there are any questions regarding the sensitivity of specific test strips. When deciding whether to use a "quantitative" or "qualitative" test methodology, it is essential to recognize that determining low levels of chlorine (i.e., <0.1 ppm) requires the use of the quantitative method.

If an online chlorine/chloramines monitor is in use that incorporates an automated alarm, particular testing times are not required. Facility policy and practice should follow the manufacturer's guidance regarding any required comparison testing and calibration of the monitor.

The ability to discern colors is a crucial job function for individuals responsible for interpreting colorimetric tests. Depending on the test method used, staff assigned this responsibility must be capable of properly interpreting the results and accurately distinguishing and identifying any colorimetric results; alternatively, a digital meter must be used. If a digital meter is used, it should be calibrated to zero before testing to ensure accurate measurements.

For deficient practices with exceeding the acceptable level of chlorine or chloramine refer to V270-273 of this section.

V197

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.2.5 Carbon adsorption

The AAMI RDD Committee recognized that it might not be practical to rotate the bed positions in installations that use large, backwashable carbon beds. However, there was concern that the capacity of the second bed might decrease unpredictably and no longer provide adequate backup if a breakthrough occurred in the first bed. For this reason, the AAMI RDD Committee recommended replacing both beds if bed rotation was not possible.

Additional Guidance:
When facilities operate with one exhausted carbon bed for up to 72 hours, the log of testing should include the actual times testing was done rather than indicating "1st, 2nd, or 3rd" shift.

A "negative" sample is interpreted as a total chlorine (the sum of free chlorine and chloramine) level less than or equal to 0.1mg/L. A "positive" sample is interpreted as a total chlorine level above 0.1mg/L.

Note: When separately analyzing the removal of free chlorine and chloramines, a maximum level for free chlorine removal is 0.5 mg/L, and removal of chloramine to a maximum level of 0.1mg/L is necessary to protect hemodialysis patients from red cell hemolysis.

V198

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a)
5.2.5 Carbon adsorption

In some circumstances, carbon adsorption may not adequately remove chloramines from water. High pH of feed water, the occurrence of N-chloramines, and the use of orthophosphate or polyphosphate for corrosion control have been associated with a

decrease in the removal of chloramines by carbon adsorption. In those situations, carbon adsorption may need to be supplemented with other methods of chloramine removal.

5.2.6 Chemical injection systems

Chemical injection systems may be used in the pretreatment section of a water purification system to supplement the physical purification processes described in the previous clauses. Applications of chemical injection include the addition of sodium metabisulfite to remove chloramines and the addition of acid to adjust pH.

Organic acids may act as nutrients, allowing bacteria to proliferate.

AAMI Rationale for the Development and Provision of This Recommended Practice A.5.2.6 Chemical injection systems

The AAMI RDD Committee expressed reservations about adding chemicals to the water. However, it recognized that the addition of chemicals may be necessary in some circumstances if a facility is to meet the maximum contaminant levels set forth in AAMI 4.1.1. For example, if the municipal water contains high levels of N-chloramines or chloramine in the presence of orthophosphate or polyphosphate, injection of sodium metabisulfite may be one of the few options available for chloramine removal.

If chemical injection is used in the pretreatment cascade, users should ensure that the addition of the chemical does not interfere with the operation of subsequent purification processes, including the primary purification process. For example, the performance of thin-film composite reverse osmosis membranes may be affected by the pH of the feed water. At pH levels below 7, the rejection of fluoride may be substantially reduced compared to its rejection at a pH of 8.
Suggested monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For chemical injection systems, monitor the level of chemical in the reservoir, injector function, and value of the controlling parameter (pH) daily. Results should indicate that the chemical level in the reservoir is greater than or equal to the facility's set value, and the controlling parameter is within the range of the facility's set values.

Additional Guidance:

There are other chemicals that may be injected to address problems with excessive chlorination or pH levels. If chemical injection is in use, facility policy must address this and reflect the manufacturer's direction in the use of any system. If the acid is being used to lower pH, a monitor including an audible alarm in the treatment area should be used. If a flocculant is being injected to address excessive organic matter, an alarm will not be needed.

If the facility has designed its own system, the medical director should be cognizant of the risks and benefits of the system and is expected to have participated in the decision to install it. Verification of the function and safety of a self-designed chemical injection

system must be completed prior to placing the system online during active patient treatment.

Labels must be updated at least every time a solution for use in the system is prepared.

The requirement for "testing of each batch" could be met by using a test specified by the manufacturer of the chemical or the injection device, such as pH or conductivity. "Verification that the test results meet all applicable criteria" means the person doing the test compares the test result with the expected result to ensure the test result is within the expected range(s). If the test result does not match the expected range, that batch of chemical must not be used. Policy should direct the next steps, including options such as mixing another batch and retesting, and notifying supervisory staff for direction.

The Hazard Communication Standard (HCS) (OSHA, 29 CFR 1910.1200(g)), revised in 2012, requires that the chemical manufacturer… provide Safety Data Sheets (SDSs) (formerly MSDSs or Material Safety Data Sheets) for each hazardous chemical to downstream users to communicate information on these hazards. Staff must follow the manufacturer provided SDS and implement protective measures related protective gear and ventilation necessary for preparation of chemicals for injection.

Chemical injection systems are not required in every facility; the source water should determine the water treatment components needed. If chemical injection is in use, the facility must follow these requirements.

V199

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

5.2.7 Reverse osmosis

Reverse osmosis (RO) systems have become widely used in hemodialysis water purification systems, largely because these devices remove dissolved inorganic solutes as well as bacteria and bacterial endotoxins.

The RO membrane separation process components are a semipermeable membrane, typically in a spiral-wound configuration, a pump, and various flow and pressure controls to direct the flow of water through the system. In operation, feed water is pressurized by the RO pump and is then directed along the surface of the semi-permeable membrane. A portion of the water is forced through the membrane, a process that removes inorganic salts, bacteria, and bacterial endotoxins. The remainder of the water continues along the membrane surface and is directed to drain. Water passing through the membrane is referred to as "product water" or "permeate." The water that flows along the membrane surface and to the drain is known as "reject water" or "concentrate." This flow configuration, known as "cross-flow filtration," prevents a progressive build-up of materials on the membrane surface that would eventually lead to fouling and membrane failure. In some reverse osmosis systems, a portion of the reject water stream is recycled to the feed water stream. This recycling enables higher velocities across the membrane surface, which may help reduce membrane fouling, while also allowing for a higher overall use of water. RO systems usually operate in a single-stage configuration.

However, if a higher level of purification is required, a two-stage RO can be used. In a two-stage RO, the product water from the first stage acts as the feed water for the second stage.

Depending on membrane configuration and materials of construction, RO systems are sensitive to various feed water conditions that may lead to diminished performance or premature failure.

Additional Guidance:

The facility should have documentation of the RO manufacturer's DFU of feed water and monitoring, and facility procedures must reflect them. The RO parameters must be recorded and monitored each day the facility is operating. The medical director, nurse manager and chief technician should be able to describe how trends in the RO function are monitored to detect problems.

V200

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

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. ***[Requirements for reverse osmosis systems in ANSI/AAMI RD52:2004 directs users to ANSI/AAMI RD62:2001, subclause 4.3.7].***

5.2.7 Reverse osmosis:

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. ***[Requirements for reverse osmosis systems in ANSI/AAMI RD52:2004 directs users to ANSI/AAMI RD62:2001, subclause 4.3.7].***

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)

ANSI/AAMI RD52:2004

5.2.7 Reverse osmosis
RO systems should be fitted with a variety of sensors to monitor the system's performance. Conductivity or total dissolved solids (TDS) sensors in the feed water and product water streams are used to monitor the membrane's ability to remove dissolved inorganic solutes. Flow meters, usually in the product water and reject water streams, are used to monitor the output of the RO system. RO systems are also equipped with gauges to monitor pressure at various points throughout the system. Although not indicative of treated water quality, monitoring flow rates and pressures can help ensure the system is operating within the manufacturer's specifications, thereby ensuring RO reliability.

6.2.7 Reverse osmosis

Other parameters that must be measured daily include product and reject stream flow rates and various internal pressures to the extent permitted by RO instrumentation. Although these parameters are not directly indicative of treated water quality, monitoring them can help ensure that the system is operating within the manufacturer's specifications, and thus will aid in maintaining the performance of the RO membranes.

The measurements can be used to calculate rejection of solutes by the RO membrane and provide a measure of equipment performance.

Percent rejection is calculated using the following formula:
Rejection (%) = Feed water conductivity-permeate conductivity x 100 Feed water conductivity

Newer RO systems may have a direct reading for percent rejection.

Flow rates can be used to calculate the percent recovery of the RO using the following formula:
Recovery (%) = Permeate water flow rate x 100 Permeate water flow rate + Reject water flow rate

NOTE: The percent recovery is also known as the "water conversion factor." The terms are equivalent if none of the reject water stream is recycled to the feed water stream (see AAMI 5.2.7). If some of the reject water stream is recycled, the equation given above provides a measure of overall water utilization by the reverse osmosis system, rather than the recovery of water during a single pass through the membrane module.

Suggested reverse osmosis monitoring guidelines from ANSI/AAMI RD52, Table 4 include:

- *Monitor the product water conductivity, total dissolved solids (TDS), or resistivity and calculated rejection rate according to the manufacturer's recommendations (continuous monitors) with a result showing a rejection rate greater than or equal to the facility set parameter percentage;*
- *Monitor the product and reject flow rates, and calculate recovery daily (continuous monitors), with a result showing product water flow rate greater than a facility set number of gallons per minute (gpm); and recovery rate in the facility set % range.*

Additional Guidance:

Not all manufacturers incorporate a preset limit that activates an audible alarm when the quality of the product water diminishes, but all do offer a process for the user to follow in determining a suitable limit. The medical director and the chief technician should be able to discuss how the set point was determined. The response should address the requirement that product water meet these requirements for chemical contaminants. Different criteria would apply if the RO is followed by DI polishing.

The conductivity or TDS of the product water is an important monitoring parameter. There may be a lower percent rejection in areas where the feed water is fairly pure (e.g., it has a low TDS).

Determining rejection rates may require staff to calculate this from the displayed data. If the RO does not display rejection rates, expect any staff member assigned responsibility for monitoring the water treatment system to be able to calculate the percent rejection. Normal ranges should be known to the operator.

In the absence of an automatic divert to drain valve for the RO, facility staff should demonstrate knowledge of the requirement to manually stop water flow to the dialysis machines and other dialysis related equipment (e.g., concentrate mixing stations, reprocessing equipment) should the water quality alarm sound.

V201

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

If your State has more stringent requirements, those must be followed to avoid potential noncompliance with 42 C.F.R. § 494.20..Accordingly, facilities who fail to comply with state and local laws would be cited at V100 or V101.

V202

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

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. ***[Guidance for deionization systems monitoring in ANSI/AAMI RD52:2004 directs users to ANSI/AAMI RD62:2001; Section 4.3.6]***

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 Guidance § 494.40(a)

ANSI/AAMI RD52:2004

5.2.8 Deionization

Deionization (DI) is an ion exchange process that removes both anions (negatively charged ions) and cations (positively charged ions) from water. During the exchange process, hydroxyl ions replace other feed water anions, and hydrogen ions replace other feed water cations; the hydroxyl and hydrogen ions then combine to form pure water.

Water treated by DI may be very high quality with regard to the absence of ionized contaminants, but the process does not remove nonionized substances, including bacteria and bacterial endotoxins. DI systems may contain anion and cation resin in separate vessels, known as "dual-bed systems," or may have both resin types mixed together in a single vessel, known as "mixed-bed" or "unibed systems."

AAMI Rationale for the Development and Provision of this Recommended Practice A.5.2.8 Deionization

Deionizers are an effective means of removing ionic contaminants from water. However, they do not remove nonionic species (such as bacteria), and they may contribute bacterial contaminants to the water rather than remove them. The inability of deionizers to remove nonionic contaminants may limit the removal of aluminum by deionization. Deionizers have a finite capacity for contaminant removal. Once the deionizer is depleted of hydrogen and hydroxyl ions, the next least avidly bound ions will be displaced by more avidly bound ions. For example, once the hydroxyl ions are depleted, anionic contaminants in the water will displace fluoride ions from the anion exchange resin.

This phenomenon has led to high levels of fluoride in the product water, with subsequent patient injury and/or death. For the above reasons, the use of deionization as the primary means of purification is strongly discouraged. 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.

Deionizers offer a large surface area for bacterial proliferation and deionizers generally contribute to the bioburden in the water. The tendency for deionizers to contribute bacterial contaminants to the water is greater when deionizers are kept as a backup for a reverse osmosis system, particularly if there is no flow through the deionizers. Some facilities counter this tendency by connecting the deionizers in parallel to the main water line and by maintaining a low flow through them. An alternative approach is to contract with a local vendor to provide backup deionizers on demand.

Suggested deionizer monitoring guidelines from ANSI/AAMI RD52, Table 4 include: Product water resistivity must be continuously monitored, with a result of resistivity >1 megohm-cm.

Additional Guidance:

If DI tanks are available for back-up use, the facility should take action to counter the tendency of DI to contribute bacterial contaminants to the water. This may be accomplished by either storing the tanks dry, placing the tanks on line post-RO so that there is a low flow of water through them, or flushing the DI tanks daily. DI tanks should not be stored "wet," i.e., filled with stagnant water.

Exhausted DI tanks (<1.0 megohm-cm) present a serious risk to patients, and use of exhausted DI tanks have resulted in deaths. If the water system uses DI as primary purification or as a polish, the system must be closely monitored by knowledgeable staff. Pure water has a resistivity of 18.3 megohms. Documentation of a reading greater than 18.3 megohms would indicate some error. Exhausted DI tanks should be returned to the vendor for recharging. The date of exchange should be posted on the tank(s) and recorded in a log.

Deionization is not required in every facility; the source water should determine the water treatment components needed. If deionization is in use, the facility must follow these requirements.

V203

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a)

5.2.8 Deionization (alarms/divert to drain)

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. [ANSI/AAMI RD52:2004 guidance directs users to RD62:2001, Section 4.3.6]

ANSI/AAMI RD52:2004

5.2.8 Deionization

Specifically, 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)

ANSI/AAMI RD52:2004

5.2.8 Deionization
DI has a finite capacity that, when exceeded, will cause dangerously high levels of contaminants in the product water. Fortunately, the quality of product water from DI is easily monitored by resistivity monitors that, when used as specified (e.g., minimum resistivity 1 megohm-cm or greater), can prevent inadvertent operation of an exhausted deionization system.

Additional Guidance:

Except for home patients, there must be capability for either an automatic divert-to-drain system or other means to prevent product water from entering the distribution system for any DI system in use. DI has a very limited capacity that, when exceeded, will cause dangerously high levels of contaminants in the product water. Due to the increased risk to patient health and safety with the use of water from an exhausted DI tank, manually stopping the flow before the RO product water reaches the patient may not be as sufficient as the use of an automated protection system, such as a divert-to-drain valve.

V204

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

5.2.8 Deionization

Refer to RD62:2001, 4.3.6 Deionization: Feed water for deionization systems should be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.

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.

5.2.9 Ultrafiltration

Endotoxin-retentive ultrafilters should be placed in dialysis water systems in locations downstream of deionization, if deionization is the last process in a water treatment system.

Additional guidance:

Endotoxin-reducing devices and endotoxin-reducing ultrafilters may be used interchangeably in these applications. The typical range of micron filter size is .001

V205

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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.

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)

ANSI/AAMI RD52:2004
5.2.8 Deionization
The most common configuration for DI is to have two mixed beds in series, with resistivity monitors being placed downstream of each bed. Upon exhaustion of the first bed, reliance for water of sufficiently high resistivity shifts to the second bed, and dialysis operations may be continued for a short time (up to 72 hours) until a replacement bed is installed.

V206

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Samples for chemical analysis should be drawn after the last treatment component; if the water treatment system includes DI as primary or polish, the routine chemical analysis samples should be taken after the DI. Taking the sample from the last patient treatment station would also meet this requirement.

Note: requirements for preconfigured systems, which may include DI, are given at V276.

V207

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 [should] 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)

ANSI/AAMI RD52:2004

5.2.9 Ultrafiltration
Ultrafilters are membrane-based separation devices that may be used to remove particles as small as 1,000 daltons and are thus well suited to remove both bacteria and endotoxins.

If bacterial proliferation is not controlled, bacteria may "grow through" the membrane and contaminate the product water compartment of the filter.

6.2.9 Ultrafiltration

Such monitoring will indicate when membrane fouling has progressed to the point that membrane replacement or cleaning is needed.

Monitoring is also necessary to ensure that the device is being operated in accordance with the manufacturer's instructions.

Monitoring guidelines from ANSI/AAMI RD52, Table 4 include: For ultrafilters, monitor pressure drops across the filter daily for pressure drop less than a value set by the facility.

Additional Guidance:

Test results drawn pre and post ultrafilter should be used to determine if the concentrations of bacteria and endotoxin are reduced as stated by the manufacturer's label. These samples can be drawn at usual testing points: e.g., the post RO sample would function as the pre-UF sample, and the sample from the first water distribution outlet would serve as the post-UF sample. Such testing should be performed whenever an UF is originally installed, and whenever the specific type of UF is changed. Low levels of bacteria and endotoxin in the feed water to the ultrafilter may prevent the user from being able to show the manufacturer's specified level of reduction; an acceptable test result should be defined by facility policy, and in all cases must be within the AAMI standards for microbial contamination.

Disposable ultrafilters do not require disinfection when used within the manufacturer's parameters and pressure monitored to detect fouling.

Every filter has an initial pressure drop when installed new. Users should monitor the change in pressure and validate the acceptable pressure change each time the filter is replaced.

Ultrafilters are not required in every facility; the source water should determine the water treatment components needed. As referenced in V204, an ultrafilter is required if DI is the last water treatment component in the system. If ultrafilters are in use, the facility must follow these requirements. The typical range of micron filter size is .001 to .05 microns.

V208

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

5.3 Water storage and distribution
5.3.1 General

The function of the water storage and distribution system is to distribute product water from the purification cascade to its points of use, including individual hemodialysis

machines, hemodialyzer reprocessing equipment, and concentrate preparation systems. A water storage and distribution system typically contains a large volume of water exposed to a large surface area of piping and storage tank walls. Because chlorine and chloramines are removed in the purification process, the water does not contain a bacteriostatic agent. This combination of circumstances predisposes wetted surfaces to bacterial proliferation and biofilm formation.

5.3.3 Water distribution systems

Two types of water distribution systems are used: direct feed systems and indirect feed systems. In a direct feed system, water flows directly from the last stage of the purification cascade to the points of use. In an indirect feed system, water flows from the end of the purification cascade to a storage tank. From there, it is distributed to the points of use. In general, direct feed systems offer the least favorable environment for bacterial proliferation. However, with a direct feed system the purification cascade must be sized to provide sufficient water to meet the peak demand, and the system must have sufficient pressure at the end of the purification cascade to distribute the water to the points of use. Those two requirements often preclude the use of a direct feed system.

AAMI Rationale for the Development and Provision of This Recommended Practice A.5.3 Water storage and distribution

Direct feed water distribution systems typically return unused water to the feed side of the reverse osmosis unit. If the pressure at the end of the distribution loop decreases to a value below the water pressure at the inlet to the reverse osmosis pressurizing pump, retrograde flow of non-purified water into the distribution loop can occur. To minimize this risk, the AAMI RDD Committee recommends that dual check valves be used to prevent retrograde flow and that the pressure at the end of the distribution loop be monitored.

V209

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.3.2 Water storage
Internal spray mechanisms can facilitate effective disinfection and rinsing of a storage tank.

7 Strategies for bacterial control

7.1 General

A storage tank in the distribution system greatly increases the volume of fluid and surface area available and can serve as a niche for water bacteria. It may be necessary for the user to scrub the sides of the tank to remove bacterial biofilm if the tank design and maintenance are not adequate to prevent bacterial proliferation.

Additional Guidance:

If existing facilities with older storage tanks can demonstrate a history of water and dialysate cultures being below action levels, replacement of the existing tanks is not required. AAMI recommendation at 7.1 notes that the frequency of disinfection will vary with the design of the system, but disinfection should be performed monthly. In order to demonstrate a history of effective disinfection procedures, the facility is expected to demonstrate acceptable results for the most recent 3 months of water and dialysate cultures.

Bacterial control device(s) in use following the storage tank may include an ultrafilter or individual filters in the water supply line in each patient's dialysis machine.

If manufacturer instructions contain disinfection procedures for the storage tank, this should be followed. Tanks which fill from the top and drain from the bottom may, in fact, drain several times a day. The goal is to not have stagnant water. A properly designed and functional storage tank replaces its total volume throughout the day as part of the normal operation and does not require manual or frequent draining of the tank.

V210
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Additional Guidance:

Suggested water storage tank monitoring guidelines from ANSI/AAMI RD52, Table 4 include:
Measure bacterial growth and pyrogens, weekly, until a pattern of consistent compliance can be demonstrated. Action levels for bacterial growth are 50 CFU/mL; for endotoxin 1 EU/mL. Expect action to be taken for levels above 50 CFU/mL and above 1 EU/mL.

A "pattern of consistent compliance" could be demonstrated by showing results within these limits on weekly cultures for at least four weeks in a row. Laboratory generated reports are an acceptable alternative to recording results on a log if the laboratory provides an aggregate report allowing multiple monthly reports to be easily compared for trends.

V211

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)

ANSI/AAMI RD52:2004

5.3.3 Water distribution systems
A multistage centrifugal pump is preferred for this purpose.

7 Strategies for bacterial control
7.1 General

Other measures can also help protect pipes from contamination.

Additional Guidance:
It is not the intent of this regulation to dictate the type of pump used for this purpose, other than that the pump be made of inert material.

It is not intended that surveyors would measure flow rates; responsible staff (i.e., the chief technician) should be able to describe how the system is monitored to ensure at least minimum flow, i.e. constant flow passing through the piping system, during operation.

The facility must identify and remove any potential dead-end pipes. For example, if the facility has discontinued reprocessing dialyzers, any unused piping should be removed to prevent stagnant water or trapping of disinfectant.

V212
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

5.3.3 Water distribution systems

The choice of materials used for a water distribution system will also depend on the proposed method of disinfection. Whatever material is used, care should be taken to select a product with properties that provide the least favorable environment for bacterial proliferation, such as smooth internal surface. [See table below.]

Table 2—Compatibility of common disinfectants with piping materials used in water distribution systems

Material	Bleach	Peracetic acid	Formaldehyde	Hot water	Ozone
PVC	X	X	X		
CPVC	X	X	X		X
PVDF	X	X	X	X	X
PEX	X	X	X	X	
SS		X	X	X	X
PP	X	X	X	X	
PE	X	X	X		
ABS		X			
PTFE	X	X	X	X	X
Glass	X	X	X	X	X

PVC = polyvinylchloride, CPVC = chlorinated polyvinylchloride, PVDF = polyvinylidene fluoride, PEX = cross-linked polyethylene, SS = stainless steel, PP = polypropylene, PE = polyethylene, ABS = acrylonitrile butadiene styrene, PTFE = polytetrafluoroethylene.

NOTE—Table 2 is not intended as an exhaustive compilation of all possible compatible combinations of piping material and disinfectant. Users should verify compatibility between a given germicide and the materials of a piping system with the supplier of that piping system before using the germicide. Considerations of compatibility should include any joint materials and pipe fittings, as well as the actual piping material. The concentration of germicide and the duration and frequency of exposure also should be taken into account.

Additional Guidance:

In the event a facility is using piping in the water distribution system which is not indicated as compatible with the disinfectant in use per Table 2, responsible staff (medical director, chief technician) should provide evidence that the disinfectant in use has been verified by the manufacturer of the disinfectant or the 510(k) licensed disinfection device as compatible with their distribution piping.

V213

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Recommendations 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)

ANSI/AAMI RD52:2004

7.2 Microbial monitoring methods
7.2.1 General
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.

Suggested water distribution piping system monitoring guidelines from ANSI/AAMI RD52 6.1, Table 4 include:
Measure bacterial growth and pyrogens, weekly, until a pattern of consistent compliance can be demonstrated, then monthly. Action levels for bacterial growth are >50 CFU/mL; for endotoxin >1 EU/mL.

Additional Guidance:

An example of a change to the existing system would be changes to the RO membranes or installation of a new storage tank. Changes to the pre-treatment components (e.g., sediment filters, cartridge filters, softener, or carbon tanks) do not require a period of more frequent testing.

The sites listed should be cultured routinely, with additional sites considered if the results of routine test sites indicate a problem.

The bacteria and endotoxin results log, referred to in 6.3.3: Water distribution systems, could be graphic reports or documents generated by the laboratory, or created by staff from laboratory data, in order to include results from multiple months to allow identification of trends.

V252 should be used when routine cultures/endotoxin testing is not done at least monthly. Use this tag if more frequent testing is not done when indicated (e.g., for new facilities, when a major change has been made to an existing water system, or when monthly cultures taken from several sites are repeatedly positive).

Note: refer to V276 for requirements for preconfigured systems.

V214

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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

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. [ANSI/AAMI RD52:2004 requirements for UV irradiators intended for use in hemodialysis applications directs users to RD62:2001, Section 4.3.13]

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)

ANSI/AAMI RD52:2004

5.3.4 Bacterial control devices
5.3.4.1 Ultraviolet irradiators

[Equipment]

The recommendations provided in this clause concern UV irradiators used specifically for bacterial control.

Ultraviolet irradiators (also known as UV lights) may be used to control bacterial proliferation in purified water storage and distribution systems. UV irradiators contain a low-pressure mercury lamp that emits ultraviolet light at a wavelength of 254 nm. The lamp is housed in a transparent quartz sleeve that isolates it from direct contact with the water. If the irradiator is not fitted with a calibrated ultraviolet intensity meter that is filtered to restrict its sensitivity to the disinfection spectrum and that is installed in the wall of the disinfection chamber at the point of greatest water depth from the lamp, the dose of radiant energy provided by the lamp shall be at least 30 milliwatt-sec/cm2.

6.3.4 Bacterial control devices
6.3.4.1 Ultraviolet irradiators

[Monitoring]

UV irradiators are available equipped with radiant energy intensity sensors. A visual alarm or an output meter is acceptable for determining if the UV lamp is emitting sufficient radiant energy.

Because the radiant energy decreases with time, annual lamp replacement is typically required. Periodic cleaning of the quartz sleeve may also be required, depending on the water quality.

Additional Guidance:

Monitoring may be accomplished by any of the following options: use of a meter to monitor intensity of the lamp, use of an on-line monitor that activates an alarm, or replacement on a predetermined schedule.

The use of a UV irradiator in a bicarbonate distribution system may have a totally different role. If ozone is used to disinfect that system, the UV irradiator may be used to break down the ozone. If the UV irradiator is part of the bicarbonate distribution system, responsible staff must be able to describe the intended purpose of the UV in that application. Monitoring of the irradiator is still required, but there is no need to follow an irradiator used in the bicarbonate distribution system with an ultrafilter or other endotoxin-retentive device.

V215

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a)
5.3.4.1 Ultraviolet irradiators (filter)

UV irradiators should 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)

ANSI/AAMI RD52:2004
5.3.4.1 Ultraviolet irradiators

Ultraviolet irradiation also can be used to control bacteria in the pretreatment section of a water purification system, such as following carbon adsorption beds to reduce the bacterial burden presented to a reverse osmosis unit. Because using UV irradiation to kill bacteria increases the level of endotoxins in the water, UV irradiators should be followed by a means of reducing endotoxin concentrations, such as an ultrafilter in the purified water system or reverse osmosis in the pretreatment cascade.

Additional Guidance:
An ultrafilter or other endotoxin-retentive device may be used. If an RO follows the UV, the RO functions as an ultrafilter. This requirement is not intended to apply to UV irradiators placed in some bicarbonate distribution systems.

V216

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 should 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)

ANSI/AAMI RD52:2004
5.3.4.2 Ozone generators

Ozone may be used to control bacterial proliferation in water storage and distribution systems. Ozone may also degrade endotoxins. Therefore, ozone can be used for bacterial control only in systems constructed from ozone-resistant materials. Ozone generators convert oxygen in air to ozone using a corona discharge or ultraviolet irradiation. The ozonated air is then injected into the water stream. An ozone concentration of 0.2 mg/L to 0.5 mg/L, combined with a contact time of 10 minutes, is capable of killing bacteria, bacterial spores, and viruses in water. Destruction of established biofilm may require longer exposure times and/or higher concentrations of ozone.

Ozone may degrade many plastic materials, including PVC and elastomeric O-rings and seals.

Additional Guidance:

Ozone exposure may have a harmful and destructive effect on some plastic or metal materials. Therefore, it is not recommended for disinfection of many of the water distribution loop materials. Refer to Table 2 at V212.

The manufacturer of an ozone disinfection system is typically responsible for validating the recommended operating conditions to demonstrate that the system provides adequate reduction in bacterial and endotoxin levels. Refer to the manufacturer's guidance for required concentrations, contact time, and disclosure on the effectiveness of the system in killing bacteria and endotoxins.

The presence of ozone in product water may be harmful to patients. Staff must monitor the system disinfection to ensure that (1) the generator delivers ozone at the concentration and exposure time specified by the manufacturer and (2) there is a mechanism in place to detect ozone in the area of the ozone generator when ozone disinfection systems are used. Facility policy must define the frequency for "periodic basis" for testing the levels of ozone in ambient air. This policy should reflect the manufacturer's guidance and OSHA requirements for exposure limits.

V217

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 should 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)

ANSI/AAMI RD52:2004

5.3.4.3 Hot water disinfection systems
Hot water (≥80°C) may be used to control bacterial proliferation in water storage and distribution systems. Bacterial kill studies are not required.

Additional Guidance:
See Table 2 at V212 for acceptable heat-resistant materials.

V218

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Records of use of hot water disinfection systems should include logs or recorded evidence to verify that the specified water temperature was maintained for the specified period of time in order to accomplish the intended disinfection.

V219

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

7 Strategies for bacterial control

7.1 General

The strategy for controlling the proliferation of microorganisms in hemodialysis systems primarily involves proper system design and operation, and regular disinfection of water treatment system and hemodialysis machines. A key concept in ensuring compliance with water bacteriology standards is that disinfection schedules should be designed to prevent bacterial proliferation, rather than being designed to eliminate bacteria once they have proliferated to an unacceptable level (i.e., above the action level). With this strategy, monitoring levels of bacteria and endotoxins serves to demonstrate that the disinfection program is effective, not to indicate when disinfection should be performed. Gram-negative water bacteria, their associated lipopolysaccharides (bacterial endotoxins), and nontuberculous mycobacteria (NTM) most frequently come from the community water supply, and levels of those bacteria can be amplified depending on the water treatment system, dialysate distribution system, type of dialysis machine, and method of disinfection.

Two components of hemodialysis water distribution systems—pipes and storage tanks—can serve as reservoirs of microbial contamination. Hemodialysis systems frequently use pipes that are of larger diameter and longer than are needed to handle the required flow. Oversized piping slows the fluid velocity and increases both the total fluid volume and the wetted surface area of the system. Gram-negative bacteria in fluids remaining in pipes overnight multiply rapidly and colonize the wet surfaces, thus producing bacterial populations and endotoxin quantities in proportion to the volume and surface area. Such colonization results in the formation of protective biofilm that is difficult to remove once formed and that provides a barrier between the bacteria and germicide during disinfection.

Biofilms are communities of microorganisms attached to surfaces. They form just about anywhere a nonsterile fluid flows over the surface. Biofilm increases the ability of microorganisms to compete for nutrients and other resources. The complexity of biofilm depends on the degree of water or fluid movement and the availability of nutrients. Thicker biofilm, and usually a greater diversity of microorganisms, will form in slower-moving waters; in faster-moving waters, it is harder for microorganisms to become (and remain) attached to the surface, so biofilm formation takes longer. Organisms living within biofilm are shielded by an extracellular polymer or glycocalyx. This glycocalyx provides the bacteria with some protection from the action of disinfectants. Biofilm may exist throughout a hemodialysis distribution system. Once established in a distribution system or dialysis machine, biofilm can be difficult to eradicate. Bleach and ozone are generally the most effective agents for biofilm removal, and their use may be more efficacious if the pipes are treated first with a descaling agent. However, in some cases, complete or partial replacement of the distribution system may be the only way to eliminate biofilm.

Additional Guidance:
In order to minimize the risk of development of biofilm, every dialysis facility must disinfect their water distribution system at least monthly.

Delineation of what constitutes sufficient contact time of an EPA-registered disinfectant is typically determined by the manufacturer. All surfaces in the water distribution system must have sufficient contact, as instructed by the manufacturer, time with the disinfectant prior to its being rinsed from the system.

V220

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

7 Strategies for bacterial control
7.1 General
For most dialysis machines, routine disinfection with hot water or with a chemical germicide connected to a disinfection port on the machine does not disinfect the line between the outlet from the water distribution system and the back of the dialysis machine. One approach is to rinse the dialysis machines with water containing germicide or hot water when the water distribution loop is disinfected. If this procedure is used with a chemical germicide, each dialysis machine should be rinsed and tested for the absence of residual germicide following disinfection.

Additional Guidance:
The line between the outlet from the water distribution system and the back of the dialysis machine is commonly referred to as the machine supply line. It is a hose that connects the dialysis machine to the treated water outlet. This hose should be disinfected at the same frequency as the water distribution loop is disinfected, i.e., monthly.

No tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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.

Systems have recently been introduced 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 also the responsibility of the user.

Bicarbonate concentrate can be supplied by the manufacturer in one of three ways:

- **in gallon containers,**
- **as packaged powder that is mixed with purified water at the dialysis facility, and**
- **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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

5.4 Concentrate preparation
5.4.1 General

Acid concentrates supplied in 55-gallon drums or gallon containers by the manufacturer are the responsibility of that manufacturer (see AAMI 2.4). In some cases, the manufacturer will pump the acid concentrate from the 55-gallon drums into a holding tank at the dialysis facility. If the acid concentrate is pumped into a bulk storage tank at the dialysis facility, the user is responsible for maintaining the concentrate in its original state and to ensure that the correct formula is used according to the patient's prescription.

Additional Guidance:
Acid concentrates supplied in 55 gallon drums or gallon containers are the responsibility of the manufacturer until delivered; proper handling after delivery is the responsibility of the dialysis facility. If an inlet opening to the acid concentrate storage system is located on the outside of the building, the inlets should be secure and labeled.

V223
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.4.4.1 Mixing systems
For example, ventilation and personal protective equipment should be used to handle any residual dust introduced into the atmosphere when powdered concentrates are added to the system, as well as to manage any additional heat generated by the device.

V226

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. 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)

There must be a log or other method of recording the preparation of concentrates, to include the number of bags or weight of the powder and the amount of water used. See also the requirements for records of mixing detailed at V229.

The facility must have records of the manufacturer's instructions for the sanitizing, maintenance and monitoring of the mixing system.

Individuals assigned responsibility for mixing concentrates or for preventative maintenance of these systems must demonstrate competency in following the manufacturer's DFU.

V227

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

If a facility designs its own mixing systems, there must be documentation of the verification testing available for review.

V228

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.4.4.1 Mixing systems

Requirements for [labeling strategies that permit] such positive identification will vary among facilities, depending on the differences between concentrate formulations used and on whether single or multiple dialysate proportioning ratios are used. (The use of multiple dialysate proportioning ratios [e.g., 35X and 45X] in a single facility is strongly discouraged.)

Mixing tanks: Using a photocopy of the concentrate manufacturer's package label provides a convenient and comprehensive means of identifying the chemical composition or formulation of the concentrate; however, the lot number and expiration date should be marked out because they apply only to the dry powder.

As with mixing tanks, bulk storage/dispensing tank labeling can be conveniently accomplished by affixing a copy of the concentrate manufacturer's package label.

Concentrate jugs are typically non-disposable vessels provided by hemodialysis machine manufacturers and having a capacity sufficient for one or two hemodialysis sessions. The extent of labeling for these containers depends on the variety of concentrate formulations used and on whether the facility uses dialysis machines with different proportioning ratios (a practice that is strongly discouraged).

Additional Guidance:

If multiple dialysate proportioning ratios are in use, applicable staff and the medical director should be able to describe safeguards in place to prevent mismatching dialysate components/machines. There should be no incidents of ratio mismatch, for example, 35X acid used with a machine set for 45X. Labels made by the facility are acceptable as long as the required information is included. Labels should be used to alert staff when bleach or ozone is in a tank or concentrate jug during disinfection. If a group of jugs are being disinfected at once, a process control (such as a label or sign marking the area in use) could be used rather than individual labels for each jug.

V229

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
6.4.1 Mixing systems

Although not required, some manufacturers may provide allowable ranges for either the conductivity or the specific gravity of concentrates prepared from their powder. The use of pH as an indicator of proper dissolution is inappropriate for both acid and bicarbonate concentrates, because large variations in concentration do not produce significant changes in pH.

Additional Guidance:

The mixing logs should demonstrate complete documentation of this required information. Test results may include conductivity or specific gravity. Facility policy must stipulate the expected ranges for the test(s) used to verify correct mixing. Standards used to calibrate the instrument used to measure conductivity should encompass the expected results; for example, it would be unacceptable to use a "14" standard for an expected result of "70." "Verifying mixing and test results" means the staff member performing this task checks the results against the expected ranges for the test and does not release mixtures for use that test outside those ranges.

V230

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 the standards related to allowable bacterial and endotoxin levels].

The *mixing and* disinfection data should be recorded for each *mix and* disinfection cycle using a dedicated log.

Interpretive Guidance § 494.40(a)

The disinfection log may be kept electronically or on paper and may be for only this purpose or inclusive of other operations. Mixing and disinfection data may be maintained separately or jointly. Guidance for recordkeeping of mixing systems and maintenance of the mixing log is found at V229.

Standards related to allowable bacterial and endotoxin levels, i.e. bacteriology of conventional dialysate, is found at V180.

V231

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.4.4.2 Acid concentrate mixing systems

Use of a tank with a sloping bottom that drains from the lowest point is one means of facilitating this process.

Additional Guidance:
Facility policy and practice must ensure the tank is completely emptied between mixing batches of concentrate.

Facilities should maintain the system clean and free of spills of concentrate to reduce the potential of corrosion.

V232

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.4.4.3 Bicarbonate concentrate mixing systems

Bicarbonate concentrate mixing tanks should be designed to drain completely; for example, [bicarbonate mixing tanks] should have a sloping bottom and a drain at the lowest point. High- and low-level alarms can prevent overfilling and air damage to the pump.

A translucent tank allows users to see the liquid level; the use of sight tubes is not recommended because of the potential for microbial growth, such as bacteria, algae, and fungi.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.4.4.3 Bicarbonate concentrate mixing systems

Bicarbonate concentrates have been shown to support bacterial growth and to provide another source of initial bioburden capable of rapidly increasing after dilution. . . Therefore, additional precautions should be taken when preparing and handling bicarbonate concentrate to avoid excess growth of haloduric organisms. Also, prompt use of bicarbonate concentrates prepared in dialysis facilities from powder and purified water is strongly recommended.

Additional Guidance:

High and low-level alarms are not required. Facilities should maintain the system clean and free of spills of concentrate to reduce the potential of corrosion. Expect that systems will have little to no build-up of precipitate.

V233

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Bicarbonate concentrates should be used or discarded within the manufacturer's timelines, if these are available. If bicarbonate concentrates are mixed, the maximum allowable time of the older concentrate would supersede that of the fresh concentrate, after which the batch would either need to be used or discarded. If facility staff members combine bicarbonate concentrate from partially used jugs, there should be some system to ensure the concentrate is not kept past the maximum storage time of the oldest portion. Facilities that allow carryover of unused concentrate, e.g. unused mixed bicarbonate concentrates are stored for more than one day, should ensure that the leftover concentrate does not remain past the time specified by the manufacturer.

Central delivery systems should be cleared of bicarbonate solution at some point during the treatment day and rinsed clear. Generally this is done at the end of the treatment day.

V234

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provision of This Recommended Practice
5.4.4.3 Bicarbonate concentrate mixing systems

Over-agitation or mixing of bicarbonate concentrate may result in loss of CO2 from the solution. Loss of CO2 results in an increase in pH and favors the formation of carbonate that can lead to precipitation of calcium and magnesium carbonate in the fluid pathways of the dialysis machine following dialysate proportioning.

Additional Guidance:
There should be a system to prevent over-mixing of bicarbonate. This could include a timer integrated into the mixing system for automatic cut-off, or a policy to require staff to monitor the mixer and cut it off immediately when the time period for mixing is completed. Use of over-mixed bicarbonate concentrate can result in a low calcium level in the dialysate and a concomitant drop in patients' serum calcium levels.

V235

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.4.5 Additives

Manufacturers provide acid concentrates with a wide range of electrolyte compositions for different proportioning ratios. Most typical dialysate prescriptions can be obtained by using one or more of these commercially available concentrates. If particular formulations are not available, manufacturers provide additives that can be used to adjust the level of potassium or calcium in the dialysate. These additives are commonly referred to as "spikes."

6.4.2 Additives

When additives are used to increase concentrations of specific electrolytes in the acid concentrate, mixing procedures shall be followed as specified by the additive manufacturer.

Additional Guidance:
Depending on State law which will vary from State to State, the nurse practice act must be considered in determining the appropriateness of the staff being allowed to use a "spike" to change the concentration of electrolytes in the acid concentrate. Since the concentrate is a prescription medication, many states require a licensed nurse to perform this task. When facility policy allows use of "spikes," appropriate additives should be accurately mixed according to manufacturer's directions, labeled as required by these rules, and should be documented in the patient record to accurately reflect the composition of the dialysate used for treatment.

V236

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a)

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.

5.4.5 Additives (labeling)
Containers should be labeled to indicate the final concentration of the added electrolyte, *the date and time mixed, and the person mixing the concentrate.* 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)

Spiked jugs should be clearly labeled with this required information. If the jug is prepared for a specific patient, the label should include the name of the patient as well as the other required information.

V237

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.5.2 System configurations

Concentrate may be distributed from a central preparation point using reusable concentrate jugs that contain sufficient concentrate for one to two treatments, or it may be distributed through a piping system that provides concentrate connections at each treatment station. A combination of these two systems may also be used, with some concentrates distributed by concentrate jug and others through a piping system. Two common configurations used for distributing concentrate through a piping system are gravity feed and pressurized. Gravity feed systems require an elevated tank; pressurized systems deliver the concentrate using a pump and motor and do not require an elevated tank. The maximum allowable concentrate delivery pressure is specified by the manufacturer of the dialysate delivery machine and should not be exceeded.

Additional Guidance:

System configuration will vary based on the facility dynamic. When elevated tanks are used, they are usually smaller than those used for preparing concentrates.

V239

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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

***[*B*/*icarbonate 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 *standards*].**

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:
***It is recommended that the* interval between disinfection*s* 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)

ANSI/AAMI RD52:2004
5.5.4 Bicarbonate concentrate distribution systems

Bicarbonate concentrates provide excellent media for bacterial proliferation. The manufacturer's instructions can provide an initial disinfection schedule. However, this schedule may need to be adjusted on the basis of the user's bacteriological monitoring.

All chemical disinfectants (e.g., bleach and peracetic acid products) that are compatible with dialysis machines can be used to disinfect bicarbonate concentrate delivery systems. However, some disinfectants attack biofilm better than others.

In the event that precipitation or salt build-up impedes flow through a piping system, cleaning with a 1:34 solution of 5% acetic acid (e.g., distilled white vinegar) is recommended. Some manufacturers supply bicarbonate concentrate systems with UV irradiation or ozone systems for bacterial control.

Additional Guidance:
Alternatively, a 5% citric acid solution may be used instead of acetic acid if the manufacturer allows. It is not expected that concentrates would be cultured or tested for endotoxin levels. Bicarbonate concentrates are monitored via dialysate cultures.

V240

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

This requirement applies to UV irradiators used in the bicarbonate delivery system, rather than to an UV irradiator used in the water treatment/distribution system. A facility may have an UV irradiator in one system, and not in the other. The UV irradiator in the bicarbonate delivery system may also be used to help breakdown the ozone used to disinfect the bicarbonate delivery system.

V241

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004

6.5 Concentrate distribution
Because acid concentrate distribution systems have been shown not to be subject to bacterial proliferation, it is not necessary to perform bacteria and endotoxin testing on those systems.

Additional Guidance:
Whenever use of a new bicarbonate distribution system is initiated, weekly monitoring of dialysate should occur for at least four consecutive weekly reports of acceptable levels. Evaluation of positive culture or endotoxin reports should also consider the number of positives in relationship to the number of samples taken. For example, if one sample out of 10 has a count of 53, while the other 9 have no growth, repeating the culture of one or more sites may be the first action taken. The medical director should be involved in any decisions for determining the appropriate action(s) to address abnormal culture or endotoxin results, i.e., growth exceeds permissible standards.

V243

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Pick-up tubes are the tubes which go into the concentrate jugs to take up the concentrate. These look like large straws and are usually attached to the lids of the jugs.

V244

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
7 Strategies for bacterial control
7.1 General

Facilities that reuse concentrate jugs for bicarbonate concentrate should disinfect the jugs at least weekly. Bicarbonate concentrate can support prolific growth of microorganisms. Jugs can be disinfected with household bleach solutions (300 mg to 600 mg free chlorine, or 30 mL to 60 mL of 6.15% household bleach per gallon of water) with a contact time of about 30 minutes or another EPA-registered disinfectant according to the manufacturer's instructions.

Additional Guidance:

A 1:100 solution of household bleach: treated water may be used, which yields about 500-615 ppm available chloride. If the facility uses less contact time than 30 minutes, there must be evidence of the use of dialysate culture results to determine the needed disinfectant contact time. In all cases, the bicarbonate container disinfection process must result in compliance with the allowable dialysate microbiological levels of <200 cfu and <2 EU.

V245

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.5.3 Acid concentrate distribution systems
Acid concentrate is not susceptible to bacteria contamination, but every effort should be made to keep the system closed to prevent nonbacterial contamination and evaporation.

Additional Guidance:
If more than one acid is centrally delivered to treatment stations, outlets must be clearly labeled with the acid type.

V246

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
5.5.5 Concentrate outlets

For piped concentrate distribution systems, each treatment station is equipped with a concentrate outlet for bicarbonate, one or more outlets for acid concentrate, and a product water outlet for connection to the inlet line of the dialysis machine.

V248

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a)

5.6 Dialysate proportioning

/T/he 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)

ANSI/AAMI RD52:2004

5.6 Dialysate proportioning

Essentially, all dialysate is produced with three fluid streams: water, acid concentrate, and bicarbonate concentrate. This three-stream combination produces a highly buffered dialysate with a pH between 6.9 and 7.6. Dialysate can also be prepared from a single concentrate that contains acetate to provide a dialysate in which buffer is provided to the patient in the form of acetate, which is subsequently metabolized to yield bicarbonate. However, acetate containing dialysate is now rarely used in clinical practice.

Different manufacturers of dialysis machines use different methods of controlling the proportions of the concentrates. These can be generally grouped into two categories: "fixed proportioning" and "servo control." With both methods, the operator can select a desired sodium and bicarbonate level, and the machine will make the necessary adjustments to achieve the selected levels. Both types use a redundant system of controls and monitoring. With fixed proportioning systems, the pumps are set to established volumes, and the final conductivity is verified. With servo control machines, the individual concentrates are added until the conductivity achieves the expected value. A final redundant conductivity monitor verifies the mixture. Some machines may also monitor the pH of the dialysate as an additional safeguard against gross errors in dialysate formulation.

Generally, bicarbonate is available in one or two forms for each proportioning type (in liquid, cartridge, or dry powder, and in various sizes). Each proportioning type has numerous acid concentrate formulations ("codes") with different amounts of potassium, calcium, and magnesium ions, plus dextrose. To help differentiate between concentrates of different proportioning types, AAMI recommends that the manufacturer include a geometric symbol on the labels along with acid/base color coding.

Table 3- Symbols and color coding for different concentrate proportioning ratios

Concentrate type	*Acid proportioning ratio (Red color coding)*	*Geometric symbol*	*Bicarbonate Concentrate (Blue color coding)*	*Comments*
35X	*1:34*	*Square*	*Dry, liquid or cartridge*	
36.83X	*1:35.83*	*Circle*	*Dry or liquid*	*Bicarbonate concentrate contains some NaCl*
45X	*1:44*	*Triangle*	*Dry, liquid or cartridge*	
36.1X	*1:35.1*	*Hexagon*	*Cartridge*	*Power cartridges may be used for other proportioning ratios, except for 36.83X, in which the bicarbonate concentrate also contains NaCl*

Note 1 – The acid proportioning ratio refers to acid concentrate, water + bicarbonate concentrate

Note 2 – Acetate- containing concentrate is color -coded white

AAMI Rationale for the Development and Provision of This Recommended Practice
A.5.6 Dialysate proportioning
Dialysate is usually prepared by a proportioning system that sequentially adds acid concentrate and bicarbonate concentrate to purified water. These systems produce a buffered physiologic dialysate with a pH between 6.9 and 7.6. More recently, systems have been developed that use three concentrates (bicarbonate, sodium chloride, and an acid concentrate containing the remaining electrolytes) to allow more sophisticated variation of the dialysate composition during dialysis.

V249

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)
/C/hanging from one proportioning ratio to another requires recalibration for some models of dialysis machines. Thus, 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)

ANSI/AAMI RD52:2004
5.6 Dialysate proportioning

Some models of dialysis machines can use concentrates of only one type of proportioning ratio, but others may be set up or calibrated for use with concentrates of more than one proportioning type.

Additional Guidance:

The medical director and responsible staff should be knowledgeable of the mixing ratio the machines are set up to use and all dialysate supplies in the facility must match that ratio.

Rarely, a facility may have machines set for different ratios; this is a risky practice and would require very close monitoring to prevent a mismatch of supplies and machines. If machines are available for different ratios in the same facility, each machine should be clearly labeled for the applicable ratio and supplies for the different ratios should be segregated and labeled clearly to avoid mismatch. The medical director should be aware of this practice and be involved in quality control to avoid any patient consequence from potential mismatch of supplies and machines.

If machines are changed from one ratio to another, responsible staff members should be able to describe how they verified the machine functioned correctly after the change was made and how they monitored the dialysate electrolyte values.

V250

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD52:2004 Requirements as Adopted by Reference 42 CFR 494.40(a)

5.6 Dialysate proportioning (dialysate conductivity and pH measurement)

/I/t 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)

ANSI/AAMI RD52:2004

5.6 Dialysate proportioning

Injuries related to improper dialysate are rare, but they can and do happen when all procedures are not followed. Frequently, when the error occurs, several patients have been exposed before the facility recognizes the mistake. For example, because one of the concentrates is quite acidic and the other is basic, connecting the wrong concentrates to the machine could result in dialysate that could harm the patient.

Even though a single concentrate is used to prepare acetate dialysate, conductivity and pH should be checked, because certain mix-ups involving acid concentrate and other chemicals can result in an acceptable conductivity and very low pH.

Additional Guidance:

Each machine must be tested for pH using a handheld meter or other appropriate testing device (i.e., adequately sensitive testing strips) before every dialysis treatment and whenever a different composition of acid concentrate is used. If the dialysis machine manufacturer requires testing of conductivity, this must also be tested using an independent testing device prior to each treatment and before using a different composition of acid concentrate during the same treatment. The facility must have set limits for the allowable variability of the handheld values from the machine readings. As new technology evolves, the manufacturer's guidance related to this requirement should be followed.

No tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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.

ANSI/AAMI RD52:2004

6 Monitoring
6.1 General

Table 4—Monitoring guidelines for water purification equipment and distribution systems and dialysate

NOTE—Refer to note below the table for an explanation of the use of Xs in the Specification column.

Item to monitor	What to monitor	Special interval	Normal interval	Specification
Sediment filter	Pressure drop across the filter	NA	Daily	Pressure drop less than XXXX
Sediment filter backwashing cycle	Backwash cycle timer setting	NA	Daily—beginning of the day	Backwash clock set to XX:XX
Cartridge filter	Pressure drop across the filter	NA	Daily	Pressure drop less than XXXX
Water softener	Product water softness	NA	Daily—end of the day	Hardness as calcium carbonate less than 1 grain/gal, unless otherwise specified by the manufacturer of the reverse osmosis equipment
Water softener brine tank	Level of undissolved salt in tank	NA	Daily—end of the day	Salt level at XXX
Water softener regeneration cycle	Regeneration cycle timer setting	NA	Daily—beginning of the day	Softener timer set to XX:XX
Carbon adsorption beds	Product water free chlorine and/or total chlorine between the beds	NA	Prior to beginning each patient shift	< 0.1 mg/L of total chlorine
Chemical injection system	Level of chemical in the reservoir, injector function, value of the controlling parameter (e.g., pH)	NA	Daily	Chemical level in reservoir ≥ XXX; controlling parameter in range XX–XX
Reverse osmosis	Product water conductivity, total dissolved solids (TDS), or resistivity and calculated	NA	According to the manufacturer's recommendations (continuous monitors)	Rejection ≥ XX%

Item to monitor	*What to monitor*	*Special interval*	*Normal interval*	*Specification*
	rejection			
Reverse osmosis	*Product and reject flow rates, and calculated recovery*	*NA*	*Daily (continuous monitors)*	*Product water flow rate > X.X gpm; recovery in the range XX–XX %*
Deionizers	*Product water resistivity*	*NA*	*Continuous*	*Resistivity > 1 megohm-cm*
Ultrafilters	*Pressure drop across the filter*	*NA*	*Daily*	*Pressure drop less than XXXX*
Water storage Tanks	*Bacterial growth and pyrogens*	*Weekly, until a pattern of consistent compliance with limits can be demonstrated*	*NA*	*Bacterial count ≤ 50 CFU/mL; endotoxin ≤ 1 EU/mL*
Water distribution piping system	*Bacterial growth and pyrogens*	*Weekly, until a pattern of consistent compliance with limits can be demonstrated*	*Monthly*	*Bacterial count ≤ 50 CFU/mL; endotoxin ≤ 1 EU/mL*
UV light sources	*Energy output*	*NA*	*Monthly*	*Light output > XXX*
Ozone generators	*Concentration in the water*	*NA*	*During each disinfection*	*Ozone concentration > XXX*
Hot water disinfection systems	*Temperature and time of exposure of the system to hot water*	*NA*	*During each disinfection*	*Temperature not less than XX °C; minimum exposure time at temperature ≥ XX minutes*
Dialysate	*Bacterial growth and endotoxin in the dialysate*	*NA*	*Monthly, rotated among machines so that at least two machines are tested each month and so that each machine is tested at least once per year*	*Bacterial growth ≤50 CFU/mL; endotoxin ≤ 1 EU/mL*
Dialysate	*Conductivity and pH*	*NA*	*Each treatment*	*Conductivity within ± 5% of the nominal machine value; pH in the range 6.9–7.6*

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 the manufacturer's instructions or measurements of system performance.

V252

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
7.2.2 Sample collection

All new sterile plastic ware is endotoxin-free because of the high temperatures involved in the manufacturing process.

Additional Guidance:

Bacterial colony counts may be done by an outside lab (thus the reference to direct plate counts) or by the use of dip samplers, as described at V256. If a pattern of results greater than the accepted limits is identified, the frequency of cultures (and subsequent disinfection) should be increased to reach a frequency that ensures the system is being maintained below the allowed contamination level between scheduled sampling. Refer to V255.

V253

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 … *dialysis* 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)

ANSI/AAMI RD52:2004
7.2.2 Sample collection

In some newer dialysis machines, dialysate flow stops when the effluent line is disconnected from the port. In these instances, the machines are equipped with dialysate sampling ports that can be accessed using a syringe. These sample ports may be disinfected with alcohol and allowed to air dry. A 30 mL sterile syringe should then be used to aspirate dialysate out of and into the port before filling the syringe. The filled syringe should be discarded, and a fresh sample of dialysate collected using a new sterile syringe.

Additional Guidance:

Facilities may take samples of dialysate using a "clean catch" technique of the effluent from the Hansen connectors into sterile endotoxin-free collection containers, use a needleless system to access the port on the dialysate line, or use a syringe and needle to aspirate a sample from the port on the dialysate line.

A flow chart which gives suggestions for evaluating dialysate culture results and initiating corrective actions can be found in the original AAMI RD52:2004 document at Figure 1.

V254

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Samples must be collected before sanitation and disinfection procedures begin, since these procedures can impact and interfere with the results of the microbial tests. If repeat cultures are performed after sanitation and disinfection, the system should be flushed completely before collecting samples.

If the microbial testing is performed by an outside laboratory, logistics for the timely receipt of evaluating culture results should be considered, i.e., sample collection time, transit time, receipt of sample during lab operating days/hours, etc. Samples sent to labs must arrive during the lab's hours of operation. If disinfection is scheduled for Sunday, for example, samples may need to be collected on Wednesday or Thursday to allow transit time and arrival before the lab closes on Friday.

V255

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Responsible staff members must be able to describe what is done when bacterial counts exceed action levels.

V256

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
7.2.3 Heterotrophic plate count

This method is an indicator of water quality only and is not to be confused with total heterotrophic plate counts, which require much longer incubation times at 28° C.

If a more accurate count from plates containing fewer than 30 or more than 300 colonies is desired, larger or smaller volumes may be cultured. Smaller volumes can be obtained by making 1:10 serial dilutions in sterile phosphate buffer. If larger volumes are required, the membrane filtration method should generally be used.

Erratic colony counts . . . may indicate the presence of biofilm since sloughing of biofilm may occur with release of bacteria into the water. [W]hen contamination persists in spite of frequent and aggressive disinfection, it may be necessary to determine if biofilm is present in the system.

Additional Guidance:
Facilities that use dip samplers must send duplicate samples to a laboratory at least annually to evaluate the accuracy of the testing done with the dip samplers.

V257

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
7.2.3 Heterotrophic plate count

The reference method for culturing is the membrane filtration technique. With this method, a known volume of sample or diluted sample is filtered through a 0.45 µm membrane filter and the membrane filter is aseptically transferred to the surface of an agar plate. Trypticase soy agar (TSA, a soybean casein digest agar) is the medium of choice for culturing water and dialysate; other acceptable media include standard methods agar and plate count agar (also known as TGYE). Blood and chocolate agars are not appropriate for this test. The spread plate technique may also be used. With this method, an inoculum of at least 0.5 mL of sample is spread equally over the surface of the agar plate.

AAMI Rationale for the Development and Provision of This Recommended Practice
A.7 Strategies for bacterial control
A.7.2.3 Heterotrophic plate count

Sensitive culturing methods must be used to measure the low total viable microbial counts permitted for water used for hemodialysis applications under the provisions of ANSI/AAMI RD62:2001 and recommended for dialysate in this recommended practice. The membrane filter technique is particularly suited for this application because it permits large volumes of water to be assayed. Because the membrane filter technique may not be readily available in clinical laboratories, the spread plate assay can be used as an alternative.

However, if the spread plate assay is used, a calibrated loop shall not be used to apply sample to the plate. The sensitivity of an assay performed with a calibrated loop is low. A

standard calibrated loop transfers 0.001 mL of sample to the culture medium, so that the minimum sensitivity of the assay is 1,000 CFU/mL. This sensitivity is unacceptable when the maximum allowable limit for microorganisms is 200 CFU/mL. Therefore, when the spread plate method is used, a pipette should be used to place 0.1 mL to 0.5 mL of water on the culture medium.

Additional Guidance:
Responsible staff must be knowledgeable of the culture methods in use and must inform any outside labs that the samples are water and dialysate and that use of a calibrated loop to inoculate the culture plate is not acceptable.

V258

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD52:2004
7.2.4 Bacterial endotoxin test

Bacterial endotoxin testing is done using the Limulus amoebocyte lysate (LAL) assay. Two basic types of assay can be performed. The first is a kinetic assay, which is available in a colorimetric or turbidimetric format, and the second is a gel-clot assay.

The kinetic LAL assay uses control standard endotoxin to generate a standard curve to which unknowns are compared and concentrations are determined using linear regression. The kinetic assays employed in laboratories generally use a computer-driven spectrophotometer that automatically calculates the amount of endotoxin on the basis of color development or onset times for gel formation.

The gel-clot LAL assay is not as sensitive as the kinetic assay and provides only a positive or negative result; that is, it shows if endotoxin is present—or not—at a particular concentration. Single tube gel-clot tubes are available from several commercial sources, and kits with the following sensitivities are currently available: 0.015 EU, 0.03 EU, 0.06 EU, 0.125 EU, 0.25 EU, and 0.5 EU. Please note that these availabilities are subject to change, as technologies for testing sensitivities advance with time.

Positive control tubes are available from the suppliers of commercial LAL assays. More sophisticated testing protocols involving reagent controls may also be used (see 2.7), but their use is optional in this application.

Additional Guidance:
Technology for endotoxin testing is evolving and these regulations are not meant to prevent the use of a newer testing methodology, once such methodology is approved by FDA.

V259
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 requirements

Interpretive Guidance § 494.40(a)

The operators of the water/dialysate system equipment are typically trained by the manufacturer of the equipment, or the training is conducted from materials provided by the manufacturer. Water treatment service vendors may do the training using materials from the manufacturer.

The facility defines the frequency of audits to evaluate the operators' compliance: these should include actual observation of the work: e.g., collecting samples, performing water testing. Audits should be done at least annually and more frequently if problems are identified.

This tag addresses the content of the training for personnel responsible for the water and dialysate systems, and audits for compliance with procedures. Whether the personnel responsible for the water treatment system have been trained is addressed in the Condition for Personnel qualifications, at V696.

No Tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

These requirements are duplicative of requirements in AAMI RD52:2004, adopted by reference.

For (b)(1): Refer to V192 for the failure to have primary and secondary carbon tanks for removing chlorine/chloramines.

For (b)(2)(i): Refer to V197 for the failure to test after the secondary method of removing chlorine/chloramines when the test results after the primary method indicate breakthrough.

V270

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

"Corrective action" here could include backwashing carbon tanks, rebedding or replacement of the tanks, or addition of an adjunct system such as chemical injection to address an extremely high chlorine or chloramine load from the municipal supplier. In any case, testing must confirm acceptable levels of chlorine/chloramine before dialysis treatments can resume. It could be necessary to reschedule patient treatments, or for patients to be transferred to another facility for one or more treatments.

V271

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

If the system includes a holding tank and the water in that tank tests safe for chlorine and chloramine, that water may be used for patient treatment. Responsible staff must know how to prevent the water treatment system from continuing to make product water, thus adding water containing unsafe levels of chlorine to the storage or holding tank. Water produced by exhausted carbon tanks must not be used for treatment.

V272

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

Policy and practice must demonstrate this requirement is met. These policies must include notifying the medical director as an immediate action taken by the responsible staff member(s) in the event of a chlorine or chloramine breakthrough. Documentation of this notification should be evidenced in the facility's record/logs for chlorine or chloramine testing.

V273

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

"Corrective action" in this context would include a root cause analysis to determine the cause of the chlorine and chloramine breakthrough, and development and implementation of a corrective action plan to address the identified cause.

V274

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

Facility policy must include requirements to develop and implement a corrective action plan that ensures patient safety when water testing results exceed acceptable limits or action levels.

A corrective action plan must be developed and implemented to ensure patient safety if any of the results of water chemical analysis or microbial and endotoxin testing for water and dialysate exceed the AAMI action levels or fall outside the AAMI standards. Water and dialysate monitoring must be reported in the QAPI materials, and the medical director must be involved in analyzing and addressing test results outside of expected parameters.

V275

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

Responsible staff (nurses and patient care technicians) must be familiar with symptoms which might indicate a patient is having a reaction related to water or dialysate and must be able to describe appropriate actions to take in the event a patient or group of patients experiences such symptoms.

Facility or patient medical records (as appropriate) must demonstrate that any adverse incidents (such as fever, chills, or infection) were identified by staff and that appropriate actions were taken.

The medical director must develop standard protocols that require the collection of blood and dialysate cultures and endotoxin levels in the event of a patient's adverse reaction(s) during or following dialysis treatment.

Responsible staff (i.e., the nurse manager, charge nurses, water treatment technicians, chief technician and medical director) must demonstrate recognition of the need to evaluate the water system in the event of patient adverse reaction(s) during or following dialysis treatment and to take the indicated corrective action.

V276

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.40(e) - In-center use of preconfigured hemodialysis system. 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)

At the time of publishing these regulations (April 15, 2008, 73FR20369), several different preconfigured hemodialysis systems were available. These included conventional water treatment components and single-pass (conventional) dialysis machines; integrated systems which incorporated water treatment and dialysate preparation and delivery into one system; and sorbent-based systems which utilized columns (cartridges) of chemicals to regenerate the used dialysate for recirculation through the dialyzer. Although primarily used for home therapies, a preconfigured hemodialysis system may be used in-center. Such use might be for training a home patient, for back-up treatment of home patients, or for routine in-center treatment. In all cases, the system's FDA-approved labeling must be followed for machine use and monitoring of the water and dialysate quality.

Following the rationale established in AAMI 4.1: Water and 6.2.7 for achieving product water quality, if the preconfigured hemodialysis system incorporates a water treatment system, analysis of the water quality must be performed to ensure contaminants do not exceed maximum level of chemical contaminants listed at AAMI 4.1.1 (Table 1). A chemical analysis of the product water must be done at least annually near the end of the usability of any disposable component, or when any modifications are made to the treatment components (other than the replacement of disposable components). When any repairs are made to water treatment equipment, the impact on water quality should be evaluated and a chemical analysis performed if the repairs resulted in any modifications to the treatment components.

Chlorine/chloramine levels must be tested prior to the start of each treatment (or before use of each new batch of dialysate) in accordance with AAMI guidance and the manufacturer's recommendations/instructions for that test method. An appropriate volume of water for the testing method in use should be tested for the presence of chlorine/chloramine. The minimum volume of water required for testing is typically specified by the manufacturer or laboratory conducting the test. For batch systems (integrated systems which prepare enough dialysate for multiple treatments), the chlorine/chloramine testing must be performed at the worst case scenario, i.e., after the preparation of each batch of dialysate, but before use of that batch. If the test results exceed AAMI's maximum allowable level, the user must discard the batch, replace any applicable components, prepare a new batch of dialysate, and retest.

Systems that use sorbent technology do not produce water; the product of the sorbent cartridge is dialysate, thus, the requirements for the chemical, bacteriological and endotoxin testing of water do not apply. With sorbent technology, due to the low volume of exposure of patients to water (i.e., 6 liters per treatment) and the capacity of the single use sorbent cartridge to remove chlorine and chloramine, testing for chlorines and chloramine is not required. Sorbent system users are expected to perform bacteriological and endotoxin testing on dialysate.

Monitoring of the system must be in accordance with the FDA-approved labeling, which includes the manufacturers' directions for use (DFU). The facility should have the manufacturers' DFUs on file, and facility procedures should reflect those DFUs.

V277

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.40(e) - …The facility must meet all AAMI RD52:2004 requirements for water and dialysate…

Interpretive Guidance § 494.40(e)

If the facility is using a preconfigured FDA-approved hemodialysis system for in-center treatments, the facility must meet the requirements of ANSI/AAMI RD52:2004 in the use of that system.

V278

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.40(e) - …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)

Preconfigured systems used for in-center treatments must be tested at least quarterly for bacteria and endotoxins. Testing should occur more frequently when needed.

V300

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.50 - Condition: Reuse of hemodialyzers and bloodlines.

Interpretive Guidance § 494.50

This Condition applies only if the facility reuses hemodialyzers or bloodlines. The AAMI "Reuse of Hemodialyzers," third edition, ANSI/AAMI RD47:2002/A1:2003 is incorporated by reference to regulation as part of this Condition (V304-V368).

The observation of the actual practice of reprocessing and reuse is critical to surveying this Condition, as are interviews with the staff responsible for reprocessing and reuse. Additionally, records of the reprocessing process and medical records of patients included in the reuse program must be reviewed. Surveys of facilities that participate in centralized reprocessing programs require onsite visits at the reprocessing site, on a rotating basis, as part of the survey process.
Deficiencies identified at the centralized reprocessing site apply to all user facilities.

Condition-level citation should be considered if there are major deficient practices that have affected, or could potentially affect patient health and safety. Examples would include, but are not limited to:

- *Staff members assigned responsibility do not demonstrate competency;*
- *Less than sufficient concentration of germicide is in use;*
- *Direct care staff do not test for residual levels of germicide prior to reusing a dialyzer or the testing methods in use are not sufficiently sensitive;*
- *Reprocessing a dialyzer of a HBV+ patient.*

V301

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.50(a) - 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)

Note that, in the Interpretive Guidance, the term "reprocessing" refers to the processes of cleaning and the installation of germicide into a dialyzer, and the term "reuse" refers to the clinical use of a reprocessed dialyzer for hemodialysis.

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Hepatitis B positive (HBV+) patients must be excluded from any reprocessing/reuse program. Facilities must provide single-use dialyzers and bloodlines for patients who are HBV+.

If the facility reuses dialyzers and/or bloodlines for Hepatitis B positive patients, this requirement is not met. This practice may impact the health and safety of the other patients whose dialyzers are reprocessed and should be considered as Condition level non- compliance.

No tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.50(a)(2) – 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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.50(a)(3) - 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)

Any dialyzer included in the reprocessing/reuse program must be labeled by the manufacturer for multiple use and must have a manufacturer's label indicating the dialyzer may be used multiple times.

V304

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.50(b) - 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)

The AAMI "Reuse of Hemodialyzers," third edition, ANSI/AAMI RD47:2002/A1:2003 is incorporated by reference. The recommendations are provided in the "Regulation" column and carry the full weight of regulation. Explanatory language from the AAMI recommendations and portions of the AAMI rationale for the development and provisions of the recommended practice are provided in the "Interpretive Guidance" column as an aid to understanding the regulation. In some cases, the AAMI identification numbers may appear out of order, as they have been rearranged for better flow with the survey process. While exact language from the AAMI document has been incorporated as regulation, the language in the "Interpretive Guidance" column has been edited for clarity, brevity, and to minimize redundancy.

Note: When words are inserted or altered in a direct quotation, square brackets—[ ]—are placed around the change. The brackets enclose words intended to explain the quote or to help integrate the quote into the guidance.

AAMI RD47:2002/A1:2003
11 Reprocessing

The multiple use of a dialyzer begins with the labeling of the new dialyzer (see AAMI section 10) and then continues with the reprocessing procedures described in this section. Preparation of the reprocessed dialyzer for the next dialysis is described in

AAMI section 12. The cycle is repeated after the next use of the dialyzer until the dialyzer does not meet the criteria for continued use. The results of the tests and the signature or other unique means of identifying the person performing each step should be maintained in a permanent record (see AAMI section 4.2). Completion of all reprocessing steps, tests, and inspections should be documented in the reprocessing record, accompanied by the signature or other unique means of identification of the person completing them. When appropriate for the reprocessing procedure in use, all dialyzer manufacturer's instructions regarding reuse should be carefully followed.

V305

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Reprocessing records must be complete, legible and protected from unauthorized access. The record of use of a dialyzer may be included in the patient record, in computer listings, and in separate records of reprocessing. The history of each dialyzer from first use to discard must be clear. Staff may use computer entries to "sign" as completing various steps of the process.

V306

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.4 Records

Documentation is essential to a safe, effective hemodialyzer reprocessing program. The overall dialyzer reuse procedure documentation includes reference materials, procedures, and policies, some of which may be distributed in the facility for operating purposes. The other records serve to document aspects of the reuse procedure for each dialyzer, along with QC and QA measures, so that a complete history of the reprocessing of each dialyzer and QC/QA procedures exists.

Allowance is made for keeping the reprocessing record data in the reprocessing log, the patient's chart, or a combination of the two, because both of them are traceable, permanent records, and it may be inconvenient to record all of the information in one location.

Additional Guidance:

The reprocessing manual must be complete for the reprocessing method, germicide, and system in use. The manual must address test procedures, maintenance and calibration of the reprocessing equipment and training and competency testing of personnel. The manual may be separate or combined with the general policy and procedure manual. The manufacturer's "labeling" of a dialyzer includes the package insert, usually found in the shipping container for multiple dialyzers of the same type, and contains the dialyzer manufacturer's directions for use. If a specific dialyzer in use requires special consideration, the reprocessing manual should reflect the manufacturer's guidance.

V307

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002/A1:2003

5 Personnel qualifications and training

New personnel range in experience from those with no medical background who are fully trained by the facility, to licensed practitioners with extensive medical background.

Additional Guidance:

The reuse education provided must be sufficient to ensure patient safety and an effective and safe reprocessing/reuse program.

V308

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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:

- **the facility's specific reprocessing procedure, including a rationale for each step;**
- **basic documentation requirements of the program;**
- **the operation and maintenance of the facility's specific equipment for reprocessing hemodialyzers and, if appropriate, the dialysis systems and components;**
- **microbiology with respect to aseptic technique, the collection and handling of samples, and personnel safety precautions for infectious hazards;**
- **the risks and hazards of multiple use of hemodialyzers;**
- **the consequences of not performing tasks properly;**
- **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;**
- **the use and location of protective eyewear, respirators, masks, and special clothing;**
- **emergency procedures as required by the facility; and**
- **the principles of dialysis, emphasizing the characteristics of the hemodialyzer and the effect of reuse on these characteristics.**

Interpretive Guidance § 494.50(b)(1)

Available training materials must include all required topics and be congruent with the processes observed.

V309

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Facilities may cross-train staff from other positions, such as hemodialysis technicians or clerical staff, to perform reprocessing. Each person assigned to dialyzer reprocessing must complete all components of the training and demonstrate competency.

Personnel files should include:

- *Evidence that the medical director/designee has certified each of the reprocessing personnel who have successfully completed the required training;*
- *Annual competence review and applicable retraining;*
- *Retraining for any major change in the reuse program (e.g., a change in equipment or germicide).*

V310

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Health screening of personnel is dependent on the germicide in use. Specific requirements may be found on the OSHA material safety data sheets (MSDS) on file in each facility for applicable germicides.
Personnel files of reprocessing personnel should reflect the results of any required testing. Specific requirements for testing may be obtained from www.osha.gov and www.cdc.gov/niosh/.

V311

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002/A1:2003

6 Patient considerations
6.1 Medical issues

Dialyzers should not be reprocessed from patients who have tested positive with Hepatitis B surface antigens.

AAMI Rationale for the Development and Provisions of this Recommended Practice

A.6 Patient considerations
A.6.1 Medical issues

The AAMI Renal Disease and Detoxification (RDD) Committee's primary objective was not to recommend medical indications for reprocessing or evaluate the medical or economic implications of reprocessing but to provide recommendations for safe reuse practice.

At the time of this writing, the Centers for Disease Control and Prevention (CDC) does not object to reprocessing and reusing dialyzers from patients with Hepatitis C or patients with known HIV infection because of the low viral burden and transmission efficiencies. The AAMI RDD Committee recommends, however, that standard precautions be used in the reprocessing of all dialyzers.

These precautions include the use of gowns, masks, and gloves. Each facility should be aware of the hazards of infection and set policies accordingly.

Additional Guidance:
Dialyzers of patients who are positive for Hepatitis B must not be reprocessed. Refer to V301.

Facilities may also opt to exclude patients with other conditions from their reuse program. Facility reuse policies must specify which patients would be excluded.

There should be evidence in policy or in the minutes of the governing body that the medical director has made the decision to reprocess dialyzers. Additionally, physician orders for dialysis therapy must include whether the patient is participating in the reuse program. If a patient has shown sensitivity to the materials used in reprocessing, this problem must be addressed in the patient assessment and plan of care.

Standard precautions must be followed in all reprocessing/reuse activities: PPE appropriate to the task must be worn; and, all blood spills must be immediately cleaned. While it is not expected that reprocessing staff would change gloves between handling separate dialyzers during routine tasks, gloves that are visibly soiled with blood, as would occur during header cleaning, must be changed between dialyzers, as well as when reprocessing staff switch from performing a "dirty" task to a "clean" task, with appropriate hand hygiene performed prior to donning fresh gloves.

V312

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.6.2 Informed consent

Establishing QA practices such as those recommended here and sharing information with patients may aid in solutions to these problems.

The National Kidney Foundation and the American Association of Kidney Patients recommend that patient consent for dialyzer reuse be obtained.

Additional Guidance:
CMS does not require specific written patient consent, but does require that patients be informed that the facility does reprocess dialyzers and be informed about that process. Refer to V460 under the Condition for Patients' rights.

V313

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.7 Equipment

Types of reprocessing systems vary from sophisticated microprocessor-controlled systems to hand-operated valving systems.

It is particularly important that appropriate equipment is used properly to ensure all water that comes into contact with the fluid pathways for blood or dialysate is of AAMI quality, because the blood side of the dialyzer might take up endotoxins that could be released into the circulation system during the subsequent dialysis.

V314

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

The product water chemical and microbiological requirements outlined in this section are the same as those in ANSI/AAMI RD52:2004, incorporated by reference in these regulations under the Condition for water and dialysate quality.

Water samples for microbial and endotoxin testing must be routinely taken each month from the water supplying each reprocessing system, as close as possible to the point where the dialyzer would be connected to the system. If more than one automated reprocessing system is in use, the water supply to each system must be monitored monthly.

New facilities or facilities which add dialyzer reprocessing should validate the safety of the water supply to the reprocessing system by testing for bacteria (microbial content) and pyrogens (endotoxins) weekly for at least 3 months, and at least monthly thereafter. The sites to be tested include the water supply to the sinks used for rinsing dialyzers, to outlets used for mixing germicide, and to each reprocessing system.

Note: If water quality samples do not consistently meet AAMI standards, i.e., at least 3 consecutive months of testing results that meet required levels, the water quality testing is expected to be performed more frequent than monthly.

V315

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

In the reprocessing area, there must be sufficient drains to accommodate the reprocessing systems, air ventilation equipment to minimize exposure to germicide vapors (as listed in AAMI 8.1 "Reprocessing area and ventilation"), and an adequate number of electrical outlets for the equipment in use.

The pressure of the water used for reprocessing should be monitored. There should be a pressure gauge in the water line of any sink used for dialyzer rinsing, with defined parameters for the accepted pressures to use during that procedure. Dialyzer manufacturers specify maximum pressures for rinsing; exceeding those pressures can result in rupture of the dialyzer membranes and potential blood leaks. Use this tag if there is no pressure gauge in the water line at the rinse sink; use V332 if the manufacturer's specified pressures are exceeded.

V316

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

There should be a written plan which incorporates the manufacturer's guidance detailing expected preventative maintenance of the reprocessing systems in use. The records of maintenance should be congruent with the plan. If manufacturer's guidance is not available, preventative maintenance of reprocessing systems should be performed on a semiannual basis, at a minimum.

V317

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

There should be documentation to verify that testing of repaired equipment for expected functioning was completed successfully prior to returning the equipment to service.

V318

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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

Substance/material	Limits (PEL)[a]
Acetic acid	10 ppm TWA[b]
Chlorine dioxide (syn: chlorine oxide)	0.1 ppm TWA
Citric acid	None developed
Formaldehyde	0.75 ppm TWA 2 ppm STEL[c](15 min) 0.5 ppm action level
Glutaraldehyde	0.2 ppm ceiling NIOSH/OSHA
Hydrogen peroxide	1 ppm TWA
Peracetic acid	None developed
Phenol	5 ppm TWA

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)

Although the equipment for air testing may not be kept on-site, it should be available for use if staff or patients complain about germicide vapors.

There should be a schedule for routine air-level testing for germicides vapors, along with references describing the safe exposure levels, and if there are any circumstances which would require an unscheduled test.

The reprocessing area must be kept clean and free of clutter. Blood splashes should be immediately cleaned and the affected surfaces disinfected.

V319

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

In the United States, the Occupational Safety and Health Administration requires that Safety Data Sheets (SDS), also known as Material Safety Data Sheets (MSDS) be readily available to all employees for potentially harmful substances handled in the workplace under the Hazard Communication regulation (OSHA, 29 CFR 1910.1200(g)). In 2012, the US adopted the 16 section Safety Data Sheet to replace Material Safety Data Sheets. This became effective on December 1, 2013. For more information on hazard communication standards, see OSHA's Hazard Communication Standard: Safety Data Sheets.

The dialysis facility must have written procedures relating to the safe storage and handling of all chemicals used for reprocessing. The written procedures must be consistent with the SDS (also called MSDS), provided by the chemical manufacturer or distributor.

Policy must address, and personnel must be knowledgeable of, the precautions for safe storage and handling, the appropriate methods for chemical containment and cleanup, and emergency procedures for both minor and major germicide spills.

These written procedures must be readily accessible to all employees in the facility.

V320

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Reprocessing personnel and patient care staff must wear PPE appropriate to the risk of potential exposure to germicide, blood, and other potentially infectious substances for the tasks performed.

Various germicides require different precautions as to PPE, eyewash, respirators, and spill control materials. The germicide manufacturer's guidance or the MSDS provide this specific information.

The supplies for managing a minor germicide spill (containment materials, additional protective equipment, etc.) must be easily accessible from the reuse room.

V321

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

"Clean" and "dirty" dialyzers must be stored separately; the reprocessing cycle status of any dialyzer must be clearly apparent at all times. Stock must be organized to allow rotation and prevent use of out-of-date materials. Reprocessed dialyzers in storage should be protected from unauthorized access to prevent tampering and any potential damage from manipulation by untrained users.

V322

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002/A1:2003
9 Reprocessing supplies
9.1 Specifications and testing

Over the past few years, bleach (sodium hypochlorite) manufacturers have begun selling household bleach in many new formulas. The concentration of sodium hypochlorite has gone from 5.25% to 6.15% in many cases. The CDC has not changed its recommendations for diluting the bleach to take into account these percentage changes.

AAMI Rationale for the Development and Provisions of this Recommended Practice

A.9 Reprocessing supplies
A.9.1 Specifications and testing

Testing of all incoming materials had been proposed. In recognition of the fact that most medical supplies are certified by the vendor and not tested by the user, the AAMI RDD Committee decided to recommend that supplies need not be tested by the facility doing hemodialyzer reprocessing if they are marketed for hemodialyzer reprocessing.

Additional Guidance:
Most materials used in reprocessing will not require testing by the user since they are validated and certified by a vendor. If the facility is using a material not commonly used in reprocessing, it may not be certified by a supplier as meeting necessary specifications . For these materials, there must be documentation of testing done by trained staff members to verify that the product meets the necessary specifications.

V323

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.9.2 Inventory control

The AAMI RDD Committee suggested that supplies should be used on a first-in, first-out basis to avoid deterioration over time in storage.

Additional Guidance:
Expired supplies must be discarded or quarantined for return to the vendor. Note that testing strips (which may be found in multiple locations in the reuse room and treatment floor) may require dating when opening and should be discarded based on the number of days since opening. Note that some reprocessing supplies, such as blood port caps, do not have expiration dates.

V324

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Process control enables users to verify that the equipment is functioning correctly. This can be achieved by testing for the expected parameters (e.g., verifying the accuracy of the TCV measurement) or by adhering to the manufacturer's guidelines for automated equipment.

A "significant change" would include a change from a manual to an automated system, a change from one automated system to another, a change in the germicide, or a major repair of the reprocessing equipment.

V325
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

The reuse manual should document how the concentration of germicide will be tested.

If heat disinfection is the reprocessing method, records of each batch of dialyzers processed must include an indicator, such as an automated time/temperature recording log, that the dialyzers were exposed to the appropriate temperature for the time required.

If a chemical, such as citric acid, is used to enhance heat disinfection, a presence test is also required before clinical use of the dialyzers.

If an incubator or oven is used to raise the dialyzer storage temperatures, a recording thermometer should be in use to ensure sufficient temperature is consistently maintained. Records should document that these devices functioned as expected.

V326

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Each dialysis facility that reprocesses and reuses dialyzers must maintain a record that identifies at a minimum the following information to be considered complete:

1. *Identification of the new dialyzer,*
2. *Date of each reprocessing step,*
3. *Identification of the person performing the procedure,*
4. *Their signature or other identifying mark, and*
5. *Results of tests of device performance and safety.*

This record can be maintained as a reprocessing log, or in the individual patient's medical record. A permanent record (paper or electronic) must be maintained to enable tracking each dialyzer's history and performance testing; information recorded on the dialyzer label must also be recorded either in a log or in the patient record, as the labels are discarded with the dialyzers.

The systems in place must allow patients access to the record of use/reprocessing of their dialyzer while ensuring the privacy of the other patients' records. If the reprocessing record is maintained in a reprocessing log, and a patient is requesting access to their records for the reprocessing and reuse of their dialyzer, records and health information for other patients must be protected.

V327

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Precautions must be in place to ensure that each dialyzer is used only for one patient. Each reprocessed dialyzer must have a permanently affixed label uniquely identifying the patient using that dialyzer. Each patient must always receive treatment on their own dialyzer, and dialyzers must not be mismatched to patients.

V328

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

When a patient is provided a new dialyzer intended for reprocessing, that dialyzer must be labeled with the patient's name before or at the first use. Dialyzers that are used without being labeled with the applicable patient's name must be discarded.

V329

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.10.2 Label composition

The AAMI RDD Committee initially recommended using indelible ink to label the dialyzer but changed the recommendation to any method resistant to normal reprocessing and use procedures; other satisfactory materials exist, and requiring indelible ink might preclude some techniques, such as bar coding.

Additional Guidance:
Facility-applied labels must not obscure the pertinent information on the manufacturer's label and must leave at least a portion of the blood path uncovered to allow visualization of a section of the fibers from header to header.

V330

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.10.3 Information recorded

A proposal to include all the recommended information on the label was rejected because space is limited on the label, and such extensive labeling is deemed unnecessary. Displaying the number of previous uses on the label is recommended so that this information is readily available. Displaying the date of the last reprocessing facilitates verification that sufficient time has elapsed since the introduction of the germicide to achieve sterilization or disinfection.

Additional Guidance:

At a minimum, except for home dialysis patients, each dialyzer must be labeled with the patient's name, the number of previous uses, and the date and time of the last reprocessing.

For patients with similar names, a warning is necessary to alert staff and prevent dialyzer mix-ups. Direct care staff must be knowledgeable of the method used to alert them about dialyzers of patients with the same/similar names. Dialyzers in use must demonstrate the use of warning labels if there are two or more patients with similar names on the census.

Since the labels are discarded with the dialyzer, the information on the label must also be kept in a permanent record, which may be electronic. The record of dialyzer reprocessing is considered part of the patient's medical record.

V331

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice A.11.1 Transportation and handling

During the 2002 revision of this recommended practice, the AAMI RDD Committee recognized that the refrigeration temperature of the dialyzers stored for extended periods of time was not specified. It was decided to recommend that dialyzers not reprocessed within 2 hours should be refrigerated and not allowed to freeze. The AAMI RDD Committee believed that this was sufficient to retard bacterial growth.

Additional Guidance:

Personnel should wear appropriate PPE to handle used dialyzers until reprocessing is complete. The infection control recommendations from the Centers for Disease Control and Prevention for transporting dialyzers include the following: "For dialyzers and blood tubing that will be reprocessed, cap dialyzer ports and clamp tubing. Place all used dialyzers and tubing in leakproof containers for transport from station to reprocessing or disposal area."

This requirement for appropriate transportation and handling procedures for used dialyzers would be considered met if the tubing is disposed of at the patient's chairside directly into a waste receptacle and all the ports on the dialyzer are immediately capped.

All dialyzer ports should be capped when the dialyzer is not in use or not being currently reprocessed, to prevent spills of blood or blood products, leakage of germicide, and entrance of air into the dialyzer. If used dialyzers are transported in a common carrier (e.g., a basket) the potential for cross-contamination must be eliminated (i.e. exteriors must be free of visible blood and all ports capped or each dialyzer contained in a sealed bag).

If used dialyzers are refrigerated prior to reprocessing, the facility's policy must define maximum refrigeration times, temperature ranges, and quality controls in place to ensure the practice is safe.

Practices such as allowing dialyzers to remain at room temperature for prolonged periods during the reprocessing process (e.g., after rinsing and before filling the dialyzer with germicide) must be validated to ensure that patient safety is not compromised.

If dialyzers are sent to an off-site location for reprocessing, the survey process must include a visit to that site to determine compliance with this and all other reprocessing requirements.

V332

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002/A1:2003
11.2.1 Rinsing/cleaning

Many facilities pre-clean dialyzers. This process is typically accomplished with an apparatus developed by users and is intended to remove gross deposits of blood and products before rinsing and cleaning with a reprocessing machine or device.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.2.1 Rinsing/cleaning

Aqueous liquids rather than gases such as air are preferred for rinsing and cleaning.

Additional Guidance:
Maximum pressures allowed during reprocessing will be defined in the dialyzer manufacturer's directions for use (DFU). Use of higher pressures may cause breaks in the dialyzer fibers and potential blood leaks. A pressure gauge must be in place to monitor the pressure of the treated water source used for rinsing the used dialyzers, and the maximum limits of the pressure to be used must be defined and known to the operator.

Use V315 if there is no pressure gauge in the water line at the rinse sink; use this tag (V332) if the manufacturer's specified pressures are exceeded.

V333

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

All water used for rinsing and reprocessing the dialyzer interior must meet the requirements of AAMI RD52:2004 regarding allowable bacterial and endotoxin levels. Refer to § 494.140(a) (V178) for details on microbial counts and endotoxin concentration levels . The interior of the dialyzer should never be exposed to tap water. The facility must monitor the water supply to the reprocessing station(s) for bacteria and endotoxins.

V334

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002
11.4.1.2 Dialyzer header cleaning and disinfection

Over tightening the header caps may cause damage to the cap, and under tightening the cap may cause blood leaks.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.4.1.2 Dialyzer header cleaning and disinfection

The practice of header removal to remove clotted material has increased over the years. Removing the header allows the user to remove the clotted material from the end of the fiber bundle and the O-ring header assembly. The method of removing the clotted material has been a concern. Some facilities use running water (AAMI quality) to remove the clotted material, whereas others use 4x4s or instruments to scrape away the clotted material. The main concerns of using 4x4s or instruments to scrape away the clotted material are (1) infection, (2) plugging of fibers, and (3) damage to the end of the fiber bundle.

In the past, removing the headers was associated with reported incidents of bacterial and pyrogenic reactions in patients. The patient reactions ceased to occur when the headers were disinfected by dipping the O-ring, header, and end of the dialyzer into the appropriate disinfectant. The research on this problem pointed to a double-fault failure system: 1) the bacteria seemed to be coming from a contaminated water source, and 2) the bacteria were not killed by the normal disinfection process. Dipping the dialyzer corrected that situation.

Several concerns are raised when the headers are not removed and the user attempts to clear the header space of clots. These concerns include infection and damage to the end of the fiber bundle. A multitude of items are used to clean the header space, including water sprays, paper clips, tie wraps, and the like. With water sprays, the possibility of contaminated water always exists. Other items that are inserted can damage the end of the fiber bundle. If the item inserted into the dialyzer is not disinfected between uses, it can cause bacterial transmission; however, the dialyzer is usually disinfected after the header space is cleaned. Automated header cleaning devices are commercially available.

Additional Guidance:
According to the Centers for Disease Control and Prevention (CDC), if the ends of the dialyzer (header caps) are removed for cleaning, only a stream of AAMI quality water may be used to clean blood clots, etc. from the exposed ends and the header caps of dialyzers.

If the header caps are removed during reprocessing, facility staff must ensure that the caps, O-rings, and the ends of the dialyzer are immersed or saturated with germicide prior to reassembly, and that the components are reassembled wet with germicide. Cleaning of header caps and dialyzer ends must be closely audited for any breaks in technique which could put the patient at risk.

V335

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002/A1:2003
11.2 Rinsing/cleaning
11.2.4

A cleaning agent, such as sodium hypochlorite, shall be rinsed from the dialyzer before adding formaldehyde, in order to avoid noxious fumes and degradation of disinfectant. Combining sodium hypochlorite and peracetic acid may produce hydrochloric acid vapors, which are harmful if inhaled.

Additional Guidance:

While one chemical may be used as a cleaning agent and a second chemical used as a germicide, the first chemical must be rinsed from the dialyzer before the next chemical is added, unless it has been demonstrated that mixing of the two chemicals is safe and effective. Allowing chemicals to mix may risk unexpected reactions that could lead to staff injury or damage to the structural integrity and performance of the dialyzer. If bleach is used as a cleaning agent, a procedure must be in effect to limit the time the dialyzer may be exposed to bleach, as prolonged exposure may damage the dialyzer membrane.

V336

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002/A1:2003
11.3 Performance measurements

The performance characteristics of dialyzers may change following reprocessing. The ultrafiltration coefficient may increase or decrease. Clearances of small or large molecular weight solutes may also increase or decrease depending on the chemicals, methods, and dialyzer membrane used. The dialyzer labeling and medical literature should be consulted for information related to changes in in vitro and in vivo performance.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.3 Performance measurements

The essential function of the hemodialyzer is mass transfer adequate to provide the prescribed care to the patient. A change in TCV has been documented in the medical literature as an indirect measurement with a close relationship to the retained mass transfer of small molecules by the hemodialyzer, and may be used for routine testing of residual dialyzer performance.

A.11.3.1 Performance test after each use

Clearance, a measure of the solute transport of the hemodialyzer, should be maintained within acceptable limits to ensure that dialysis is adequate to prevent uremic complications. Although direct clearance measurements could be used to demonstrate compliance with the ± 10% change in urea clearance, determining the urea clearance for each dialyzer reprocessed is impractical. There are also indirect tests that reflect the mass transfer characteristics of a dialyzer, which may be used in lieu of clearance measurements. A change in the residual TCV of hollow-fiber hemodialyzers is the most widely used indirect test for changes in small molecule clearance. This method has been shown to be a good index to monitor the solute transport capacity of the reprocessed hollow-fiber hemodialyzer. The volume of a hollow-fiber hemodialyzer (TCV) is readily measured in the clinical setting. When methods of reprocessing are used that do not cause a significant change in the permeability or geometry of the membrane, a loss of TCV of 20% corresponds to a loss of urea clearance of less than 10%. Volume change is recommended as a QC test only for hollow-fiber hemodialyzers because other hemodialyzer geometries do not have the relatively noncompliant blood compartment necessary for the validity of this measurement in predicting solute transport.
The AAMI RDD Committee recognized that other factors can influence the effective clearance of toxins during the dialysis session or can influence interpretation of the results. These factors include the following:

- *Fistula recirculation;*
- *Accurate blood and dialysate flow rates;*

- *Accurate time of dialysis;*
- *Compliance with dietary limitations;*
- *Selection of appropriate hemodialyzer type and blood and dialysate flow rates;*
- *Membrane surface coating that may affect higher molecular weight toxins;*
- *Variations in the original clearance of the hemodialyzer;*
- *Variations in the clearance of the hemodialyzer caused by reuse.*

Users should be aware that the HEMO Study in 1999 identified both reductions and increases in the clearance of ß2 microglobulin with the use of certain combinations of dialyzers, cleaning agents, and reuse germicides.

Of particular concern to the AAMI RDD Committee were any variations in hemodialyzer functions related to reuse procedures. Although cases have been documented, they are rare, especially when compared to the frequency of other factors listed above. For this reason, the AAMI RDD Committee strongly felt that the monitoring requirements of AAMI section 13 are of great importance to use in conjunction with the individual hemodialyzer measurements recommended in AAMI 11.3.

Additional Guidance:

Every dialyzer expected to be reprocessed must have its original total cell volume (TCV) measured prior to the first use. "Dry pack" dialyzers, i.e., dialyzers used without preprocessing, must be discarded after the first use and not reprocessed.

All staff who reprocess or reuse dialyzers must demonstrate understanding that a drop in TCV to less than 80% of the dialyzer's original volume requires the discard of that dialyzer, to prevent that patient from receiving a less than adequate treatment. Staff must also be aware of other criteria dialyzers must meet for continued reuse (e.g., limit on the number of times a dialyzer may be reused, reasons for discard).

If a manual reprocessing system is in use, the graduated cylinder used for measuring TCV must be emptied completely between uses and placed on a level surface to ensure accurate readings. The reading should be made at eye level, and the operator should have charts available to use in determining whether the remaining volume is sufficient (at least 80% of the original volume) to continue using that dialyzer.

For automated systems, a system must be in use to validate that the volume measurements are accurate.

V337

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice A.11.3.3 Blood path integrity test

The 1986 edition of the AAMI recommended practice did not include a blood path integrity test. Following recommendations from the Centers for Disease Control and Prevention (CDC), the AAMI RDD Committee agreed to add this test to the second edition of the recommended practice. This test is based on the observation that only a small amount of air leaks through wetted membranes, resulting in a pressure drop of less than 10% of the test pressure. A maximum allowable pressure drop is not given because of variations among test systems and dialyzers.

Additional Guidance:
Recognize that manual reprocessing systems may require each dialyzer be tested separately. Automated systems must include the pressure leak test in the method and apparatus used for testing the integrity a dialyzer prior to its reuse.

V338

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice A.11.4 Germicide

In the early 1990s, the FDA began actively regulating all liquid chemical germicides with health care indications. To avoid the potential problem of regulating the same product under multiple classes, the FDA decided to regulate liquid chemical germicides as a separate type of medical device; therefore, it determined that they were unclassified devices. In an effort to ease the burden of this dual regulation, a memorandum of understanding (MOU) was signed between the FDA and the EPA that gave the FDA primary responsibility for premarket efficacy data review of liquid chemical sterilant and high-level disinfectants and gave the EPA primary responsibility for premarket efficacy data review of general purpose disinfectants.

Additionally, the FDA adapted the basic terminology and classification scheme described by Spaulding (1971) to categorize medical devices, and the four levels of processing as proposed by the CDC: sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection. Also, the FDA regulatory authority over a particular instrument or medical device dictates that the manufacturer is obligated to provide the user with adequate instructions for the "safe and effective" use of that instrument or device. Those instructions must include methods to clean and disinfect or sterilize the item if it is marketed as a reusable medical device.

Additional Guidance:
The germicide in use must be approved for the dialyzers used at the facility, and the concentration of germicide in the reprocessed dialyzers must be sufficient to achieve the different levels of disinfection needed for the respective parts, i.e. high-level disinfection for treating the blood and dialysate compartments of the dialyzer and low-level disinfection for treating the exterior of the device.

V339

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002/A1:2003

11.4.1 Interior (blood/dialysate compartment)
11.4.1.1 Germicidal process

If formaldehyde is used as the sole germicidal agent, the CDC recommends that a concentration of 4% (W/V) be used in both the blood and dialysate compartments with a minimum contact time of 24 hours at a temperature of at least 20° C; lower concentrations or shorter contact times are appropriate if equivalent results can be demonstrated under other conditions. Formaldehyde used for reprocessing dialyzers shall not be cloudy. Concentrated formaldehyde stored under adverse conditions can polymerize to form paraformaldehyde, a white precipitate. Formaldehyde should be of United States Pharmacopoeia (USP) standards or better quality. When other germicides are used, the manufacturer's instructions should be followed. If maximum storage temperature limitations exist, records should be maintained to document this criterion.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.4.1.1 Germicidal process

Unfortunately, no realistic procedure exists whereby a dialysis center can monitor the effectiveness of the disinfection procedure. Such sophisticated microbiological tests cannot be performed in dialysis centers because they require the use of specialized equipment and highly trained microbiologists. Due to these constraints, a center should adhere strictly to established protocols for QC and QA. Tests for total bacteria and endotoxin in the water used to make up the germicide should be conducted at least monthly. If there are problems in maintaining water quality at the level established by ANSI/AAMI RD62:2001, Water treatment equipment for hemodialysis applications (referenced in RD52:2004), the testing may need to be performed more frequently.

Testing the germicide's final-use concentration should be a part of the center's QC program as well as verifying that each dialyzer was filled with germicide.

Potency testing of each batch of germicide is specifically recommended for batches of manually-prepared germicides, regardless of whether they are used with a manual or an automated system. Germicide solutions diluted online by automated machines should be checked for concentration at least monthly.

CMS requires (at 42 CFR § 494.50) that dialyzers not be subjected to multiple germicide solutions because of possible combined actions of the germicides on the hemodialyzer membrane. This requirement does not apply to the original sterilization process or chemical cleaning agents to which the hemodialyzer may be exposed for short periods during the cleaning process for reuse.

Additional Guidance:
The reuse staff must be knowledgeable about the germicide used and the risks this germicide presents to him/her and to the patients, such as injuries that may be caused by mixing reactive materials such as sodium hypochlorite and formaldehyde.

Containers of germicide should be dated to indicate dilution and discard dates.

V340
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

If a manual reprocessing system is in use, the blood and dialysate compartments must be filled with a volume of germicide equal to three times the total volume of the blood and dialysate compartments of the dialyzer (to equal three compartment volumes) in order to reach at least 90% of the prescribed germicide concentration. Reuse logs must include documentation of verification of the desired (prescribed) concentration of germicide.

Used and new port caps must be disinfected prior to use. The reuse technician should be knowledgeable about the minimum contact time required for germicide disinfection of port caps.

V341
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

ANSI/AAMI RD47:2002/A1:2003 Requirements as Adopted by Reference 42 CFR § 494.50(b)(1)

11.4.1.6 Chemical germicide concentration

[For] **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 *[shall]* be thoroughly mixed *[before use].*

Interpretive Guidance 494.50(b)(1)

The system in use must include verification of germicide concentration in the dialyzers after reprocessing.

If the germicide is diluted by the user (batch), the germicide manufacturer's instructions for dilution must be followed, and the solution must be thoroughly mixed before use. If each dialyzer is tested for germicide concentration prior to rinsing, it is not necessary to test the germicide concentration before use of the batch.

If the germicide is diluted on-line, the concentration in a dialyzer from each reprocessing system must be checked immediately after reprocessing at least monthly.

V342

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice

A.11.4.2 Exterior

Sodium hypochlorite at a concentration of 0.05% is usually suitable [for external cleaning]. Certain commercial low-level disinfectants may cause some plastics used for dialyzers to crack after repeated or prolonged exposure.

Low-level germicides satisfactorily clean the exterior of the device to a degree comparable with what a new dialyzer receives. For example, 1:100 dilution of household bleach will achieve the concentration of sodium hypochlorite specified [here].

Additional Guidance:
The exterior of each dialyzer must be cleaned after reprocessing steps are complete. Spraying the dialyzer with germicide is generally unsatisfactory, unless all the surfaces of the dialyzer are covered with the spray. Dialyzers may be dipped or allowed to soak in a germicide solution, or wiped with a disposable cloth saturated with a germicide solution.

V343

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.5 Inspection

The [AAMI RDD] Committee considered a recommendation not to accept hemodialyzers with visible clots because venous filters are not used for all hemodialyzer circuits, leading to the risk of embolization to the patient if a clot were to break loose. The [AAMI RDD] Committee decided to reject this proposal because the allowable clots are required to be small and in stagnant areas that are present during the first use of the hemodialyzer and because there is no evidence of embolization from reprocessed hemodialyzers that meet this criterion.

A proposal that the number of dark, clotted fibers evident upon external inspection be limited to five was not accepted because a considerably larger number may be clotted without significant adverse effect on performance and because some authorities do not agree that this criterion is essential to an aesthetically pleasing appearance. A recommendation that hemodialyzers with a pink or brownish tint not be acceptable was also deleted because this condition is difficult to define and because glutaraldehyde disinfection results in a slight tan color of the membranes that has not been shown to impair the safety or performance of the hemodialyzer.

V344

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

The status of all dialyzers being reprocessed must be clear. If facility policy allows dialyzers which initially fail criteria to be repeatedly reprocessed, or if dialyzers which

have failed are not immediately discarded, the status of those "failed" dialyzers must be clearly indicated.

V345

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)
Additional Guidance:

The AAMI RDD Committee were, unaware of any adverse effects of storage for up to 1 month. Dialysis facilities that store its multiple use dialyzers for more than one month should have documented evidence that such a time period does not pose a risk to patient safety..

There might be occasions when reprocessed dialyzers are stored for extended periods of time, such as when patients are absent (e.g. hospitalized, vacation). There must be a system for ensuring dialyzers are not stored longer (without reprocessing) than the maximum time limit specified by the germicide manufacturer and facility policy.

V346

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

AAMI Rationale for the Development and Provisions of this Recommended Practice A.12 Preparation for dialysis and testing for chemical germicides and potentially toxic residues

When the [AAMI RDD] Committee revised RD47 in 2002, it decided that sufficient information was available to indicate that the residual level of formaldehyde should be reduced to less than 3 ppm. The testing technology for residual formaldehyde had also improved, and it was feasible to easily test to less than 3 ppm.

The [AAMI RDD] Committee considered establishing maximum residual levels for germicides other than formaldehyde. Because these newer germicides are all cleared by the FDA and could have different allowable levels of residuals even for the same generic type of germicide, [they] determined that it is best to recommend that the manufacturer's instructions for use be followed. The [AAMI RDD] Committee noted that toxicology studies are favorable for some of these agents, and the FDA reviews labeling information for them, which includes the maximum residual level.

When checking for the presence or concentration of the germicide in the hemodialyzer, [do not place anything] into the blood or dialysate ports of the device (e.g., test strip or syringe) to withdraw the sample. Doing so may damage the fibers of the dialyzer and lead to blood leaks during dialysis. . , If a germicide test strip or kit is being used, the instructions provided by the manufacturer should be followed.

Additional Guidance:
The reagents used for the germicide tests must be sensitive to the levels specified by the germicide manufacturer (i.e. high level for presence test, low level for residual test).

V347

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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:

- **The reprocessed dialyzer shall be legibly labeled with the information recommended in [AAMI] 10.3.**
- **There should be no indication of structural damage or tampering with the dialyzer.**
- **The ports of the dialyzer should be properly capped.**
- **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.**
- **The duration and conditions of storage should be appropriate for the agent or method used to sterilize or disinfect the dialyzer; and**
- **The cosmetic appearance of the dialyzer should be aesthetically acceptable to the staff and the patient.**

Interpretive Guidance § 494.50(b)(1)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.5 Inspection

The [AAMI RDD] Committee recognized that the patient should be included in the aesthetic evaluation of the hemodialyzer.

V348

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 people 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 people 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)

Standard of practice requires the final check be done when the patient is present for that treatment. If possible, patients should be encouraged to check their dialyzers for their names. Patients who sign the treatment record for this item should understand what their

signature means. If patients are unable to identify their dialyzers, two staff should do so and record the verification prior to initiating the dialysis. Note that some facility policies require two staff to verify patient/dialyzer identification for all reused dialyzers.

V349

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 procedures (e.g., heat) 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)

Staff must be able to determine the date and time of each dialyzer's last reprocessing. Responsible staff (e.g., reuse technician, direct care staff) must ensure the dialyzers have been exposed to the germicide for the required contact time before set up and use.

For systems using heat disinfection, staff must verify the dialyzer was exposed to the appropriate temperature for the required time period to ensure disinfection.

V350

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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

The presence of germicide may be ensured by directly testing each dialyzer for the presence of germicide. Certain germicide manufacturers require this testing before the germicide is rinsed from the hemodialyzer, and these instructions should be followed.

Interpretive Guidance § 494.50(b)(1)

Manufacturers of peracetic acid and glutaraldehyde require every dialyzer be tested for presence of a sufficient concentration of germicide after storage and before use.

The test for germicide presence (at the potency recommended by the germicide manufacturer) should be done before rinsing and priming.

V351

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 *before the rinsing step*], the presence of germicide may be ensured by *a direct presence test of each hemodialyzer or the use of process control and sampling of the dialyzer for germicide. Sections 12.3.2.1 and 12.3.2.2 provide examples of what can be used to comply with this requirement.*.

12.3.2.1 Process control

- **Use hemodialyzer germicide filling equipment with on-line automatic monitors during the germicide dilution and hemodialyzer filling process; or**
- **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

- **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 a positive test result does not necessarily demonstrate the presence of an adequate concentration of formaldehyde. Samples should be taken immediately after the dialyzers have been reprocessed.**
- **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.**
- **Sampling and testing are to be accomplished before patients use any hemodialyzers processed on this shift.**

Interpretive Guidance § 494.50(b)(1)

ANSI/AAMI RD47:2 002/A1:2003
12.3.2.1 Process control

Note that use of dye may be inappropriate with certain germicides such as peracetic acid.

12.3.2.2 Sampling for process validation

NOTE— The requirements of this section are fulfilled if every dialyzer is subjected to post-storage/pre-priming direct presence testing.

Additional Guidance:

This tag refers to procedures that may be used to validate that dialyzers, reprocessed with germicides that don't require the presence testing of each dialyzer, are adequately disinfected and safe for use. If each dialyzer is not tested for germicide presence, procedures for both process control and testing a sample of dialyzers for germicide concentration are required.

For certain germicides, the facility may use a blue dye (as process control) to indicate the presence of germicide in the dialyzers. The absence of blue coloring should not be used as the sole indicator of the absence of germicide. Any process control procedure should be used in conjunction with a procedure for testing a sample of dialyzers, as described in this tag.

V352

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

The dialyzer rinsing/priming and preparation for use procedures followed must be in accordance with the dialyzer manufacturer's requirements for the germicide in use.

V353

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 reinstituted after [any] delay sufficient to bring concentrations of germicide above the recommended level (rebound) [by elution from these compartments]. 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)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.12.4.1 Testing for residual germicide

Because certain germicides have been demonstrated to disperse into the solid components or less rapidly exchangeable compartments of the of the hemodialyzer, the priming, removal, and residual testing process should be reinstituted after any delay that provides sufficient time for concentrations of germicide to rebound above the recommended level by elution from these compartments.

A number of procedural steps have been identified that, if not followed, may cause residual germicide to remain in the hemodialyzer following rinsing. The following list of instructions, though not all inclusive, should be carefully considered when developing a facility's rinsing procedure:

- *Air bubbles in the fibers can cause individual fibers to become blocked. Be sure that the arterial line is fully primed before [it is connected] to the*

hemodialyzer. If using peracetic acid-type germicide, [the blood side should be flushed] before beginning dialysate flow.

- *Air trapped in the dialysate side of the hemodialyzer may cause germicide to also remain trapped in portions of the hemodialyzer. [The dialyzer should be rotated] during the rinsing process. This action normally releases the trapped air and allows the germicide to be fully rinsed.*
- *Germicide may back up into the heparin or monitor lines. [The heparin line must be] clamped [so] that fluid is not forced into the monitor lines.*
- *Germicide may back up into the saline bag during the rinsing procedure. [Procedures for initiation of treatment must account] for all situations that may force fluid from the dialysis circuit back into the saline bag.*
- *Take care to avoid a false-negative residual disinfection test, which can happen if you sample too quickly after a quantity of saline has been infused.*
- *Discard the prime solution when beginning blood flow to the hemodialyzer.*

Additional Guidance:

If the extracorporeal circuit is prepared ahead of time, staff should repeat the residual germicide test just prior to treatment initiation to allow detection of any "rebound" of germicide. This is particularly a concern if fluid circulation through the circuit and dialyzer is stopped, as may happen when a patient is late coming to treatment.

If facility practice is to discard the priming solution by "bleeding patients on," policy and practice should reflect a requirement that a staff member constantly attend that patient while the venous line is open as blood fills the extracorporeal circuit, to prevent accidental blood loss.

Generally, manufacturers of dialyzers labeled for reuse address the need to discard the prime solution by advising users to replace the saline bag used for priming and refresh all fluid in the extracorporeal circuit with saline from the new bag prior to beginning patient treatment.

V354

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. Home dialysis patients and their assistants should be instructed in the appropriate observation, recording requirements, and reporting procedures.

Interpretive Guidance § 494.50(b)(1)

Adequacy, fluid removal, anemia management and patterns of infection may be related to poor reprocessing practices. If reuse is being done for home patients, which is rare, those patients or their dialysis caregivers must be instructed in and fully cognizant of their responsibilities for reuse.

V355

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 attributable 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 tests for residual germicide (see [AAMI] 12.4.1).

Interpretive Guidance § 494.50(b)(1)

AAMI Rationale for the Development and Provisions of this Recommended Practice A.13.2 Symptoms

Evaluation by a physician is required to determine whether symptoms might constitute an adverse reaction to the reprocessed dialyzer because symptoms during dialysis are

commonly the result of other factors, such as infections not attributable to dialysis, and to hypovolemia. First-use syndrome is a symptom complex characterized by nervousness, chest pain, back pain, palpitations, pruritus, and other usually mild symptoms, occurring minutes following the initiation of dialysis with a new dialyzer. [The syndrome is defined by some authorities] to include the anaphylactoid reaction [occurring usually] immediately after the initiation of dialysis in some patients using dialyzers sterilized with ethylene oxide. In addition to first-use syndrome, serious reactions have been reported in patients taking ACE (angiotensin-converting enzyme) inhibitors and dialyzed on certain synthetic membranes. This reaction is now known to involve increased bradykinin release accompanied by suppression of bradykinin degradation.

Additional Guidance:

Physicians or non-physician practitioners (i.e., advanced practice registered nurses or physician assistants) functioning in lieu of physicians are responsible for evaluating the symptoms discussed in this regulation. Patient temperatures must be checked pre- and post-treatment, and signs of infection must be evaluated for any potential relationship to reprocessing/reuse.

One of the symptoms of germicide infusion is severe pain and burning in the patient's vascular access. Patients may interpret pain in the vascular access site at the onset of dialysis as being related to needle insertion pain.

V356

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 the 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 report 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)

In dialyzer reprocessing, the term "complaint" refers to deviations from expected outcomes (e.g. dialyzer failures, patient reactions, blood leaks), as well as to patient complaints related to reused dialyzers.

The facility must maintain a record of dialyzer complaints. Each complaint should be investigated, and any reuse incidents reported in the QAPI records with corrective actions as indicated.

Responsible staff (e.g., the chief technician, area technical manager, nurse administrator, medical director) should consider if there have been any trends in complaints, and take indicated action. This information should be incorporated into the facility's QAPI program. Refer to V635.

Facility staff must comply with the FDA's Medical Device User Reporting requirements. Refer to V383.

V357

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 methods should be evaluated (see [AAMI] 11.3.1) and appropriate adjustments made in the reprocessing procedure.

Interpretive Guidance § 494.50(b)(1)

The complaint investigation records should include reports of any blood leaks.

V358

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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, dose of erythropoietin stimulating agent) [requires] an investigation of all practices, including reuse. Reports of investigations should be filed in the complaint log.

Interpretive Guidance § 494.50(b)(1)

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.13.4 Clinical results

Critical assessment of chemistries and the delivered dose of dialysis (Kt/V or urea reduction ratio), as is done monthly, provides a clear trend line to assess treatment. This scrutiny of the patient's treatment and course is the primary confirmation that hemodialyzer performance anticipated from TCV or other indirect estimation is accurate and adequate. The overall effectiveness of the entire treatment, not only the clearance of the dialyzers, is measured. No other measure of the effectiveness of new or reused dialyzers is as clear or relevant. Trend lines developed from this data characterize the quality of therapy. . . If the practitioner has concerns for "middle molecules" or other clinical parameters, these factors should also be part of the assessment of the delivered therapy.

There are many reasons for an apparent reduction in the mass transfer of urea, other than decreased hemodialyzer clearance as a result of inadequate reprocessing (such as recirculation, decreased dialysis time or blood flow rate, or an inappropriate dialysis prescription). To document adequate mass transfer, parallel measurements of pre- and post-creatinine levels are helpful. When problems develop with any patient or group of patients, monitoring intensity should be increased, and other methods should be used to analyze the problem and define corrective action.

V359

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 patient's 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)

ANSI/AAMI RD47:2002/A1:2003
11.3.2 Ultrafiltration

In vitro ultrafiltration coefficients should not be used to predict in vivo results.

AAMI Rationale for the Development and Provisions of this Recommended Practice
A.11.3.2 Ultrafiltration

Ultrafiltration rate (UFR) is the flow rate of fluid that passes through the membrane under a given pressure gradient at a given temperature. It is the product of the ultrafiltration coefficient of the hemodialyzer (KUF) and the transmembrane pressure. The KUF, and thus the UFR at a given transmembrane pressure, may be affected by changes in the intrinsic permeability of the membrane, the surface area of the membrane, and the presence of hydraulically resistive deposits on the membrane. Cleaning agents, such as sodium hypochlorite, may affect the intrinsic water permeability of many types of dialysis membranes.

In vitro KUF is not recommended to predict in vivo ultrafiltration performance because the former overestimates the latter in hollow-fiber hemodialyzers. This difference occurs in part because of the additional hydraulic resistance of the formed elements and proteins in blood.

Additional Guidance:
Assessment for compliance with this requirement should find patients are weighed before and after each treatment. Missed weights should be rare and include an explanation for the weight not being obtained. Repeated entries of "unable to stand" should result in a change in the plan of care to allow determination of pre- and post-treatment weights.

V360

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

A.14 Quality assurance

The FDA's 1987 compliance policy guide (7124.16) advises reuse practitioners to establish the following: (a) adequate device cleaning and sterilization; (b) the lack of adverse effects on device quality or physical characteristics; and (c) certainty that the device remains safe, reliable, and effective for its intended use. The [AAMI RDD] Committee believes that compliance with those recommendations necessitates use of regularly examined reprocessing procedures that are based on methods of demonstrated effectiveness and are carried out under conditions safe to the patient and the personnel.

Table 2—Quality assurance audit schedule

	Monthly	Quarterly	Semi-Annually	Annually
Patient information policy (14.3)				X
Equipment manuals and procedures (14.4)				X
Equipment maintenance and repair policies (14.4)				X
Environmental safety (8.1)				X
Environmental safety (8.2)		X		
Environmental safety (8.4)		X		
Reprocessing supplies (9)			X	
Water treatment* (11.4.1.5)	X			
Hemodialyzer labeling (10)		X		
Reprocessing procedures** (14.8)	X		X	
Procedures for preparation for dialysis (14.9)		X		

** More frequent monitoring may be required initially as described in 11.4.1.5.*
***These functions may allow for a less frequent review period, as indicated in their respective sections, according to the specified circumstances. ***
Note: Numbers in parentheses refer to AAMI sections.

Additional Guidance:

The QAPI Condition at § 494.100 (Tag V625) requires the facility's quality improvement program to reflect the complexity of the dialysis facility's organization and the services it provides. In other words, if a dialysis facility's services include reuse, reuse audits must be performed on the required schedule and reported in the QAPI activities. For many of the audits, there is a two-tier system of review required: the review of the process by the person assigned (i.e., reprocessing by the reuse technician), and oversight of that review by another person qualified to do so (i.e., the technical supervisor observing the reuse technician performing reprocessing).

If the facility participates in a centralized reprocessing program, the QA audits done in the reprocessing facility must be provided to the patient treatment facility and reviewed as part of the QAPI of that facility. Any complaints related to the reprocessing of dialyzers would need to be reported to the patient treatment facility sending the applicable dialyzers.

V361

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

ANSI/AAMI RD47:2002/A1:2003
14.2 Schedule of quality assurance activities
High-volume tasks that are recognized as hazardous should have frequent (weekly or daily) oversight. Practices with little potential for harm may need critical scrutiny on only a quarterly or annual basis.

V362

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

Centralized reprocessing requires that relevant procedures and manuals be audited at both the reprocessing site and the user facility.

V364

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 for compliance with the provisions of [AAMI] 8.1, [Reprocessing area and ventilation], at least annually. Compliance with the provisions of [AAMI] 8.2, [Storage area], and [AAMI] 8.4, [Personnel protection] should be audited quarterly.

Interpretive Guidance § 494.50(b)(1)

There must be documentation to support that designated staff conducted an annual review of the implementation of germicide air testing procedures, and the physical condition of the reprocessing area.

Quarterly evaluations of the area where dialyzers and supplies are stored are required, as well as quarterly evaluations of the implementation of policies for use of PPE and Standard Precautions when direct care and reprocessing staff are working with reprocessed dialyzers.

Centralized reprocessing requires that this audit be done at the reprocessing site as well as at the user facility.

V365

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 for compliance with the provisions of [AAMI] section 9 [Reprocessing supplies: Specifications and testing, and inventory control] at least semiannually.

V366

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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 for compliance with the provisions of [AAMI] section 10 at least quarterly.

Interpretive Guidance § 494.50(b)(1)

AAMI Section 10 includes the following: Hemodialyzer labeling, Time of labeling, Label composition, and Information recorded. These audits should be recorded quarterly.

Centralized reprocessing requires that this audit be done at the reprocessing site as well as at the user facility.

V367

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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)

For a new reuse program, monthly audits of reprocessing steps must be done at a minimum. For an established program, audits of the practice of reprocessing should be done semiannually, unless problems are identified, which would require more frequent audits until a pattern of compliance is established.

Centralized reprocessing requires that the reprocessing site perform these audits and report the results to all user facilities.

V368

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

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.

Interpretive Guidance § 494.50(b)(1)

This regulation requires at least quarterly audits (observations) of the set-up for dialysis, including testing for presence of germicide, testing for residual germicide, and verification of the patient identity with the reprocessed dialyzer.

Responsible staff (e.g., nurse manager, administrator, medical director) must be able to describe these audits, provide documentation the audits were accomplished, and provide evidence that any concerns identified were addressed.

Facilities that participate in centralized reprocessing are responsible for performing the audits of the steps in the reuse process which occur during preparation for dialysis when reprocessed dialyzers are being prepared for reuse.

V378

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.50(b)(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)

Each manufacturer of dialyzers for multiple use is required by FDA to provide at least one acceptable reprocessing method with at least one germicide. The facility may use that method/germicide or choose an alternate method. If the facility has chosen an alternate method, there must be documentation that the chosen method has been validated as safe and effective.

V379

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.50(b)(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

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.50(c) - 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, section 13, at tags V354 and V355.

V381

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

The facility must have a standardized procedure to ensure blood and dialysate cultures and dialysate endotoxin testing are obtained in the event of a patient reaction possibly related to dialyzer reprocessing and/or reuse.

V382

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

In this context, "cluster" refers to a group of hemodialysis patients suspected of having adverse reactions that could be clinically related to dialyzer reprocessing and/or reuse practices.

Responsible staff (e.g., chief technician, area technical manager, medical director) must be able to describe actions to be taken if a group of patients experiences adverse reactions potentially related to reprocessing/reuse. If a cluster of adverse patient reactions associated with reprocessing/reuse was identified, dialyzer reprocessing/reuse should be suspended, pending investigation.

V383

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

The dialyzer manufacturer may or may not be responsible for reporting adverse outcomes related to reprocessing/reuse, depending on their legal liabilities. This regulation, however, requires the facility to be responsible for reporting any adverse

outcomes potentially related to reprocessing/reuse, as required by law. Facility policy should address adverse occurrence reporting.

V400

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.60 Condition: Physical environment

Interpretive Guidance §494.60

This Condition addresses the requirements related to the building and equipment of the dialysis facility and incorporates by reference the ambulatory health care occupancy provisions of the 2012 edition of the Life Safety Code of the National Fire Protection Association and the Tentative Interim Amendments (TIA 12-1 through TIA 12-6).

The primary survey task used to assess compliance with this Condition is the observation of the environment and equipment maintenance. A survey of the requirements found at V400-V407 of this Condition will be conducted by the health and safety surveyors who conduct the usual ESRD surveys. A survey of the requirements related to Life Safety Code (LSC), found at V417-V418, will be done by specific surveyors trained as fire specialists and may be conducted at a separate time.

Noncompliance at the Condition level should be considered if identified deficient practices are pervasive, serious in nature, and/or a potential risk to health and safety. For example, serious deficient practices in the construction or maintenance of the physical environment and/or equipment that have or are likely to have an impact on the health and safety of patients, staff or the public should be considered as noncompliance at the Condition level. Such triggering situations may occur simultaneously, and their degree of noncompliance should be considered based on the nature of the events.

V401

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§494.60 - 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:

Safe environment means that there are no obstacles that would present risks for trips and falls, such as loose floor tiles; no areas that would pose infection control risks, such as broken work surfaces; and no outside doors that remain propped open, allowing entry of unauthorized individuals, insects, or animals, or creating a hazard in the event of fire.

Functional environment means that all systems in the building, such as lighting, heating, and air conditioning, are operational.

A comfortable environment includes providing sufficient space for patient privacy and access to necessary equipment, while also maintaining a reasonable noise level. For example, this may involve requiring the use of earphones when televisions or other entertainment devices are in use, as they can disturb others. Monitoring a comfortable temperature is addressed at V405.

V402

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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)

The dialysis facility building must be constructed in accordance with applicable State and local building codes. The plumbing, electrical, and heating, ventilation, and air conditioning (HVAC) systems must be appropriately constructed and effectively maintained.

All buildings and building systems must be maintained free from defects and/or hazards to ensure safety and functionality. Integrity of all surfaces (e.g., countertops, floors, walls) must be intact, clean, and free from damage. Intact surface integrity enables effective cleaning and limits the potential for microbial growth on porous surfaces.

Systems to ensure patient safety should be in place, such as a method for patients to call for help from the restrooms and exam rooms. Access to patient treatment areas, reprocessing areas, water treatment systems, supply storage, and dialysis equipment should be restricted to authorized personnel only. Access limitation does not preclude visits or tours by individual(s) authorized and supervised by facility personnel.

V403

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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)

All equipment used at the dialysis facility and dialysis equipment used by home dialysis patients must be maintained in a safe and functional working condition. The facility's program for preventive maintenance and repair of all equipment must be in accordance with the equipment manufacturer's instructions.

Staff must operate and maintain the equipment in accordance with manufacturer's instructions. Malfunctioning machines awaiting repair must be removed from service and should be labeled or tagged to prevent use. The facility should have a plan for the operation and routine maintenance of at least the following equipment and equipment systems:

Hemodialysis delivery system:

- *High flux dialyzers may only be used with machines specified by the manufacturer as capable of accurately monitoring and controlling fluid removal.*
- *If heparin pumps are incorporated into the delivery system, the pumps must be maintained as clean and functional.*
- *As required by manufacturers, testing of safety features, e.g., alarms, pressure holding tests, and independent verification of dialysate pH and conductivity should be conducted prior to each dialysis treatment.*

"Dummy" drip chambers:

- *"Dummy" drip chambers are fluid-filled chambers that are used to bypass the dialysis machine's air detectors.*
- *The practice of using a "dummy" drip chamber to prepare a dialysis machine for patient use is hazardous to patient safety and risks the undetected infusion of air into a patient if the "dummy" drip chamber is not removed at the initiation of dialysis.*
- *The presence and availability of "dummy" drip chambers in the hemodialysis patient treatment area is considered an immediate and serious threat to patient health and safety. Unintentional failure to remove the "dummy drip chamber" from the air detector places the patient at risk for potential life-threatening events including air embolism and other possible adverse effects as use of a dummy drip chamber during a patient's dialysis treatment would be inconsistent with the manufacturer's DFU.*
- *Use of a dummy drip chamber on the treatment floor departs from the standards of care for dialysis. The use of dummy drip chambers in dialysis facilities is referenced in several clinical studies, and warnings against using dummy drip chambers in the treatment area are included in nearly all manufacturers' instructions. The use of "dummy" drip chambers in the dialysis facility is typically reserved for machine maintenance purposes and is only used outside of the patient treatment area.*

Water treatment system:

Requirements for monitoring and maintenance of the water treatment system are incorporated into the Condition for water and dialysate quality at § 494.40 and should be cited there.

***Dialyzer reprocessing system**:*

Requirements for monitoring and maintenance of dialyzer reprocessing systems are incorporated into the Conditions for Reuse of Hemodialyzers and Bloodlines at § 494.50 and should be cited there.

Ancillary equipment:

- *Ancillary equipment may include, but is not limited to: functional and clean patient scales, centrifuge, refrigerators, incubators for in-house performance of water/dialysate cultures, emergency generators, blood pressure monitoring equipment, infusion pumps, patient thermometers, eye wash stations, conductivity and pH meters, Hoyer lifts, and equipment required to provide in-house laboratory testing (e.g. blood glucose meters, heat blocks, equipment for activated clotting times (ACT), supplies for testing for occult blood and hematocrit levels).*
- *Maintenance of refrigerators should include the monitoring of temperatures to ensure these are appropriate for the items stored.*
- *If a generator is present, documentation should be available regarding testing and maintenance per the manufacturer's instructions.*
- *Records should be available regarding the daily cleaning, testing, and periodic calibration of pH and conductivity meters as recommended by the manufacturer.*
- *Documentation of periodic calibration of patient scales, blood pressure devices, blood volume monitors, and laboratory equipment, as applicable, should be available.*

Emergency equipment:

Emergency equipment as referenced at E-0028 of Appendix Z should be clean, functional, and accessible. Use E-0028 for the lack of required emergency equipment; use this tag for failure to maintain the emergency equipment.

Furniture:

- *Patient treatment chairs, facility wheelchairs, and waiting area chairs must be maintained to allow effective cleaning/disinfection.*
- *Torn upholstery must be repaired or replaced; broken mechanisms (e.g. footrests, reclining levers) must be repaired or the equipment removed from use.*

The facility equipment maintenance program should include documentation regarding all equipment or devices used for home patients, whether maintained by the facility or by durable medical equipment suppliers (DME). Refer to the Condition for Care at home at

V597 if problems with the maintenance and/or exchange of home dialysis equipment are identified.

V404

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

There are no specific square-footage requirements for dialysis treatment areas unless specified by state or local regulations.

"Sufficient space" to provide needed care would allow space for:

- *All dialysis equipment, supplies and items for each patient;*
- *Caregivers to provide emergency care including cardiopulmonary resuscitation (CPR), the use of emergency equipment including access to needed supplies, stretcher and emergency personnel; and,*
- *The provision of personal privacy when needed, i.e., sufficient space to allow for use of some type of privacy screens.*

Note that privacy requirements are addressed in V406 of this section, and under the Condition for patients' rights at V454.

"Sufficient space" to prevent cross-contamination would allow space to:

- *Prevent blood or body fluid spatters from one patient or station to another;*
- *Prevent contact between machines, chairs and other equipment;*
- *Reasonably accommodate patient belongings;*
- *Provide privacy and aseptic care of catheters including dressing changes;*
- *Safely dispose of bodily wastes/fluids and hazardous waste; and,*
- *Readily access hazardous waste receptacles.*

The space around the hemodialysis stations should be sufficient for all of the above. The space allowance should take into consideration the space taken up by patients' dialysis chairs when reclined with foot rests up.

V405

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

The facility must make reasonable efforts to provide a comfortable environment for patients and staff, in spite of conflicting perceptions of "comfortable."

It is not uncommon for patients to feel cold during their dialysis treatments, and there are many reasons that some patients experience feeling uncomfortable in the facility. Some reasons for feeling cold include:

- *Anemia: many patients with chronic kidney disease do not produce enough red blood cells which circulate and carry oxygen throughout the body. This leads to patients feeling cold and tired;*
- *Skin exposure, if the patient has a graft or fistula;*
- *Remaining seated for 3-4 hours during treatment with limited ability to move around; and*
- *Blood temperature: during dialysis, blood is circulated outside of the body, sent through the dialyzer to filter wastes and toxins and then returned back to the patient which may lead to some patients feeling uncomfortable and cold.*

Dialysis facility staff tend to experience more warmth than patients due to the PPE that is worn and staying active for extended periods of time to perform their duties, which may affect their perception of what constitutes a comfortable temperature. Dialysis facility staff should take measures to ensure temperatures within the facility are maintained at a comfortable level. Unlike operating rooms, which are required to maintain cooler air temperatures, dialysis facilities may use the standard temperature range of 70°F–75°F (21°C–24°C) to achieve a greater degree of patient and staff comfort (CDC guidance for Environmental Infection Control in Health-Care Facilities).

The dialysis facility must make attempts to address any causal factors that lead to a patient feeling uncomfortable with the room temperature set by the dialysis unit. For example, "reasonable accommodations" would include offering hats, blankets, or other warming devices. Patients that are seated near vents or windows may also experience feeling cold or uncomfortable and may need to be moved to another area of the room. When cold, some patients find it helpful to use a glove for the hand on their access arm, others find wearing a cap helpful.

§ 494.60(c)(4) requires the patient to be in view of staff during hemodialysis treatments to ensure patient safety. This includes direct visualization of their vascular access site to assess for patency and appropriate connections, e.g. central venous catheter site or an AV fistula/graft. If patients choose to use a blanket or other covering, their vascular access site, bloodline connections, and face must be visible throughout the treatment. A

head covering on a patient is acceptable, as are gloves. If there are concerns for patient or vascular access site visualization during hemodialysis treatments, refer to V407.

V406

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

Privacy must be provided for the use of a bedpan or commode during dialysis, initiating and discontinuing treatment when the vascular access is placed in an intimate area, for physical exams, and for sensitive communications.

There should be sufficient numbers of privacy screens or other methods of visual separation available and used to afford patients full visual privacy when indicated. Exam rooms should have a door or other method to ensure privacy can be provided. Arrangements for private conversations may need to be outside of the patient treatment area in a private location.

V407

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

Each patient, including their face, vascular access site, and bloodline connections, must be visible to a staff member throughout the dialysis treatment. Allowing patients to cover access sites and line connections provides an opportunity for accidental needle dislodgement or a line disconnection to go undetected. This dislodgement or disconnection could result in exsanguination and death in minutes.

V417

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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 2012 edition of the Life Safety Code of the National Fire Protection Association (NFPA 101 and tentative interim amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4) applicable to Ambulatory Health Care Occupancies [which is

incorporated by reference in paragraph (f) of this section], regardless of the number of patients served.

Interpretive Guidance § 494.60(d)(1)

ESRD facilities that do not provide one or more exits to the outside at grade level from the patient treatment area must comply with the requirements contained in the 2012 edition of the Life Safety Code (NFPA 101) and the Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3 and TIA 12-4 applicable to the Ambulatory Health Care Occupancies, regardless of the number of patients served.

Dialysis facilities that provide one or more exits to the outside at grade level would be exempt from meeting the requirements in the 2012 edition of the Life Safety Code (NFPA 101) and the applicable tentative interim amendments. Exempt facilities must continue to comply with state and local fire codes.

"Exit to the outside at grade level from the patient treatment area level" is to mean that ESRD facilities are on the ground or grade level of a building where patients do not have to traverse up or down stairways to evacuate to the outside. Accessibility ramps in the exit area that provide an ease of access between the patient treatment level and the outside ground level are not considered stairways.

A dialysis facility required to comply with the LSC must operate in accordance with the code chapters (Chapters 20 or 21) applicable to ambulatory health care occupancies. However, a dialysis facility may be located in a mixed occupancy building. If a dialysis facility is ***located in a building with other tenants and occupancies****, it must be separated by a one-hour fire-resistance-rated wall in accordance with the LSC. For purposes of this regulation, when a portion of the dialysis facility is used intermittently by another entity (e.g., an exam room is used for the nephrologist's office practice) it is not intended that the portion used intermittently would be separated from the dialysis facility by a one-hour fire wall.*

*If the dialysis facility is l****ocated within a hospital, but not separated from the hospital by two-hour fire wall*** *construction, the dialysis facility must meet the hospital LSC requirements. If a hospital-based chronic outpatient facility provides acute services for hospitalized patients in the same space and within the hospital walls, the outpatient dialysis facility must meet the more-stringent hospital chapters of the LSC.*

Survey instructions found in State Operations Manual (SOM), Appendix I, are used as applicable, along with the Fire Safety Survey Report Form, 2786U to survey for fire safety. The fire safety standard will be surveyed by a fire specialist from the State Agency or a CMS-approved Accrediting Organization, if accredited; generally, the LSC inspections will be done separately from the rest of the ESRD facility survey.

V418

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

The 2012 LSC requires buildings with unprotected structural elements to have sprinkler systems. Specifically, the 2012 LSC requires that buildings with the construction type of Type II (000), Type III (200), and Type V (000) buildings and two or more stories to be protected throughout by an approved, supervised automatic sprinkler system (2012 LSC section 21.1.6.1).

Regulation exempts existing dialysis facilities that have been certified since October 14, 2008 from needing to install sprinkler systems if the facility is located in a building that was constructed on or before January 1, 2008, and if State law permits (i.e., the facility has a valid certificate of occupancy).

For the purposes of this part, "constructed" refers to facilities that had obtained approval for all required building permits or had completed all of the plan reviews in jurisdictions that do not require building permits.

Dialysis facilities that are newly constructed, or have undergone rehabilitation after January 1, 2008, must comply with the LSC provisions for sprinklered buildings.

If the dialysis facility is required to be sprinklered and is in a multiple occupancy building, the entire building must be sprinklered throughout, as required under the LSC.

V419

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

A State may apply to CMS for review to determine if a State's fire and LSC requirements adequately protect a dialysis facility's patients from fire hazards. The CMS review process will determine if a State is allowed to substitute the state rules in this area for the requirements of the LSC, NFPA 101. If CMS approves the State Code, the LSC, NFPA 101 shall not apply.

V420

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§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)

CMS may waive specific provisions of the Life Safety Code (LSC). This waiver may be granted if the facility is unable to comply with a specific requirement of the LSC, and if complying with that requirement would cause an unreasonable hardship for the dialysis facility. The waiver will only be granted if it is determined that the health and safety of the dialysis facility's patients are not adversely affected by the waiver. In some cases, the waiver may be limited to a specific time period.

Guidance on the LSC waiver process is found in Appendix I of the State Operations Manual (SOM).

V421

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

''Adjacent to'' can mean sharing a wall, ceiling or floor, with a facility.

V422

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

Staff, as well as patients receiving services in the dialysis facility, are generally capable of self-evacuating from the patient treatment area in the event of an emergency when there is an exit to the outside at the same level as the patient treatment area. If the

dialysis facility does not provide for one or more exits to the outside at grade level from the patient treatment area, it must meet all applicable provisions of the Health Care Facilities Code, regardless of the number of patients served at any given time.

Health Care Facilities Code, Chapters 7, 8, 12, and 13 are not applicable to dialysis facilities.

No tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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.

V424

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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: 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, 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

§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 Guidelines §494.62

The ESRD facility must comply with all Emergency Preparedness requirements under this condition. This condition consists of multiple standards. Please refer to State Operations Manual Appendix Z – Emergency Preparedness Requirements for All Providers and Suppliers for guidance regarding these requirements.

No Tag

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

Refer to all applicable E-Tags

§ 494.62 Condition of participation: Emergency preparedness.

Interpretive Guidance § 494.62

For all applicable requirements under Emergency Preparedness, please refer to Appendix Z of the State Operations Manual. ESRD Facilities must also comply with the requirements outlined in Appendix Z.

Subpart C – Patient Care

V450

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70 Condition: Patients' rights.

Interpretive Guidance §494.70

This Condition requires the facility to provide respect, privacy, information, and appropriate services for their patients, as well as an internal grievance mechanism and information about external grievance mechanisms.

The survey of this Condition is primarily accomplished through interviews with patients and observations of care delivery and staff-patient interactions. Review of medical records and applicable policies for these requirements are indicated if any issues are identified by the observations or interviews.

Condition level noncompliance should be considered if there are serious and/or pervasive deficient practices identified that seriously threaten one or more of these rights. Examples of Condition level noncompliance include, but are not limited to, a pattern of:

- *Failure to treat patients with respect and dignity, to provide an opportunity for private communication, or to prevent exposure of private body areas during dialysis causing patients emotional discomfort; and,*
- *Cognizant patients/designees not being aware of their options for treatment modalities or grievance mechanisms.*

V451

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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

When they being their treatment at the facility, patients (or their representatives) must be notified of the rights that protect them, as well as the responsibilities that are expected of them. To promote patient safety and strengthen the relationship between a patient (and/or their representative) and their care team, patients should be provided with this information when they begin their treatments. Information that is provided should be understood and reciprocated. The patient's readiness and ability to fully comprehend this information may be impacted by reasons such as stress and anxiety that some new patients may experience when starting dialysis. For these situations, the facility should

determine an appropriate point in time at the beginning of their treatment to inform them of their rights and responsibilities. Typically, information should be provided to the patient and/or their family or caregiver(s) within the first (6) dialysis treatments. By this time, patients have generally overcome any initial stress and anxieties related to dialysis initiation.

Informing patients could include providing verbal explanations, audiovisual presentations, and/or written materials. Documentation should confirm that the required information is provided to patients.

*Patient representative: The HIPAA Privacy Rule establishes a foundation of Federally-protected rights which permit individuals to control certain uses and disclosures of their protected health information. Along with these rights, the Privacy Rule provides individuals with the ability to access and amend this information, and the right to an accounting of certain disclosures. There may be times when individuals are legally or otherwise incapable of exercising their rights, or simply choose to designate another to act on their behalf with respect to these rights. Under the Privacy Rule, a person authorized (under State or other applicable law, e.g., tribal or military law) to act on behalf of the individual in making health care related decisions is the individual's "personal representative." Subject to certain exceptions, the Privacy Rule at 45 CFR 164.502(g) requires covered entities to treat an individual's personal representative as the individual with respect to uses and disclosures of the individual's protected health information, as well as the individual's rights under the Rule. *

All states define an age of majority. Most states have set their age of majority in statute. It varies between 21 and 18 years of age; in most states in the United States, the age of majority is 18 years old. Persons younger than this age of majority are considered minors, and are under the care of a parent or guardian unless they are emancipated. For the pediatric dialysis population, the parent or guardian of a minor is considered to be a "designee" for that child. However, older youths with decision-making capacity may be included in decision-making with the parent's consent.

For more information on personal representatives and who must be recognized as the individual's personal representative, please see OCR guidance for "Personal Representatives".

V452

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

In all verbal and nonverbal communications, patients must be treated with respect, dignity, and sensitivity. Interactions among patients, staff, and others must demonstrate observance of patients' rights and consideration of a patient's physical condition, emotional state, and cultural background. Patients should be able to question procedures or staff performance (e.g., whether or not a staff member washed their hands prior to initiating the patient's treatment) without fear of reprisal.

It is not uncommon for dialysis facilities to serve patients with challenging behavioral and psychological needs. These patients often have feelings of anxiety, resentment, or anger and may exhibit difficult or disruptive behavior such as nonadherence (skipping or shortening treatment), using profane language or arguing with staff or other patients, and yelling out. Facility policies should have guidance and policies in place for strategies for treating disruptive behavior in a respectful and dignified manner. Rude, abrupt or demeaning behavior, physical or mental harassment, or punishment are not acceptable and should not be imposed for purposes of discipline or staff convenience. Rude or demeaning behavior would include name calling. The use of physical restraints should be limited to situations that jeopardize the immediate physical safety of the patient, staff, or other patients in the facility.

A restraint does not include a personal escort or orthopedic device, surgical dressing or bandage, a protective helmet, or other method to hold a patient while conducting routine aspects of the dialysis treatment.

V453

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(2) - Standard: Patients' rights. The patient has the right to— Receive all information in a way that he or she can understand;

Interpretive Guidance §494.70(a)(2)

Patients and/or designees need to receive information in a way that the patient can understand. Staff should consider patients' literacy levels, whether they have communication disorders (low vision/blindness, hearing loss, or speech impairment), and whether a language other than English is their primary language. Methods to validate that provided information was understood should be employed; examples would include "teach back," asking the patient to reflect back to the staff member what they understood, or return demonstration of a skill.

The interdisciplinary team's (IDT) comprehensive assessment should assess for any information needed by the patient to sufficiently manage their needs and identify any barriers to receipt of that information that would need to be addressed and incorporated into their plan of care. Communication options for those with vision loss include verbal communications, large print, and Braille. Communication options for those with hearing loss include lip reading, sign language, pictograms, tele-communication devices for the

deaf, and written communications. Options to communicate with those who cannot speak include providing written documents, audio formats, and using sign language.

There should be a reasonable facility language access plan for communicating information in various non-English languages if there is a need. Since there may be a variety of languages spoken at any facility, it would be unreasonable to expect that all written patient materials will be translated into every language. However, the facility must comply with legal requirements for communicating with those with limited English proficiency (LEP) under Title VI of the Civil Rights Act of 1964 and Section 1557 of the Affordable Care Act which require covered entities, including recipients of federal funds to take reasonable steps to provide meaningful access to their programs, services, and activities accessible for individuals with LEP. Reasonable steps may include oral interpretation services in non-English languages by a qualified interpreter (either in-person or with remote communication technology), as well as written translations of documents such as patients' rights policies, consents for treatment, forms that require a legal signature, etc. Staff should document in the patient's medical record how forms requiring a signature were explained to patients/designees who have vision, speech, or hearing barriers, and for individuals with LEP.

V454

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(3) - Standard: Patients' rights. The patient has the right to— Privacy and confidentiality in all aspects of treatment;

Interpretive Guidance §494.70(a)(3)

Patients have the right to privacy and confidentiality in both the verbal and physical aspects of their treatment.

Patients have the right to privately discuss their condition and treatment. Staff should allow the patient to direct where discussions of sensitive topics should occur and ask the patient if they want to schedule a time to discuss a sensitive issue away from the treatment area. Any staff-patient interactions that require privacy should be conducted in private. To allow for private conversations between patients and staff members, there should be ready access to a room in the facility where patient and/or family meetings can be held in private. Plan of care conferences may be conducted chairside rather than in a private location if a patient grants permission.

Patients have the right to privacy during activities that expose private body parts while in the dialysis facility. This includes activities related to use of vascular access sites located in the groin or chest and physical examinations. Options for ways to comply with this requirement include the use of privacy screens, curtains, or blankets. Staff must be able to observe the patient's vascular access, bloodline connections, and face at all times during hemodialysis treatment. Refer to V407 under the Condition for physical environment.

V455
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(4) - Standard: Patients' rights. The patient has the right to— Privacy and confidentiality in personal medical records;
Interpretive Guidance §494.70(a)(4)

Patients should be able to expect the facility to maintain confidentiality of their medical record information. Patients' health records must be protected from casual access. Hard copy medical records should be stored in a secure location when not in use.

Computer screens containing patient information should not be left open and unattended with patient specific information on display and computerized systems should require passwords and permissions to access medical records.

The facility must inform patients of their privacy rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule through a notice of privacy practices.

A signed release is not required by the HIPAA Privacy Rule to share protected health information for continuity of care, such as but not limited to providing emergency care or contacting other dialysis facilities as a part of the protocol for involuntary discharge or termination of treatment or when asking the police to help locate a patient so they can receive dialysis.

Patients have the right to read their own medical record, have corrections made to that record, and to have a copy of their record for which a nominal fee may be charged. The facility must actively seek to honor patients' requests to have a copy of their medical record as quickly as its recordkeeping system permits.

Certain circumstances under the HIPAA Privacy Rule may not permit a patient or their designee to have the right to review their medical record. Any established HIPAA violation should be referred to the Office of Civil Rights and/or cited under 42 C.F.R. § 494.20 for non-compliance with Federal, State, and local laws and regulations. Under the HIPAA Privacy Rule, reasons why a patient or their designee would not have the right to review their record include:

- *The records are psychotherapy notes or compiled in reasonable anticipation of, or for use in , a civil, criminal, or administrative action or proceeding, or access is prohibited by law pursuant to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a, to which the health care provider is subject or the health care provider is exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR 493.3(a)(2).*
- *The patient is an inmate of a correctional facility and access could jeopardize the health, safety, security, custody or rehabilitation of the patient, other inmates, or*

the safety of any officer, employee or other correctional system employee, including the transporter;

- *The patient is participating in a research project that includes treatment and is ongoing and the patient agreed to the denial of access and has been informed that access rights will be reinstated upon completion of the research;*
- *The records are subject to the Privacy Act, 5 U.S.C. 552a, and the denial of access under the Privacy Act would meet the requirements of that law.*
- *Access to the medical record would reveal a confidential source under a promise of confidentiality that is not a health care provider;*
- *A licensed health care professional has determined, in the exercise of professional judgment, that the access to the medical record is reasonably likely to endanger the life or physical safety of the individual or another person;*
- *The medical record makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person.*
- *The individual's personal representative makes the request for access and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.*

Confidential treatment and release of patient medical record information is also addressed in the Condition for medical records at V727 and V728.

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V456

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(5) - Standard: Patients' rights. The patient has the right to— 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)

Patients have the right to know about and participate in all aspects of their care and treatment to the extent they desire. Self-cannulation may be performed by the patient in any facility upon receiving appropriate training and demonstrating competence, should they so choose. The facility must encourage patient participation in care planning. Examples of ways to promote this participation include, but are not limited to, offering the patient the option to participate in IDT care planning or to attend a planning meeting in-person or by teleconference from home. "Chair-side" review of the plan of care is also acceptable, if sufficient privacy can be provided. Patients also have the right to accept or decline to participate in their care.

Patients must be notified of changes to their dialysis prescription and the reason for those changes. Patients should be encouraged to disclose any concerns they have with the proposed changes.

Patients have the right to refuse the change without fear of discharge. Patients have the right to refuse any aspect of treatment, to refuse to participate in experimental research, and to discontinue their dialysis treatments completely.

V457

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(6) - Standard: Patients' rights. The patient has the right to— 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)

This standard requires the facility to inform patients about advance directives, including the right to formulate advance directives. The standard does not require that all patients have an advance directive.

Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions. Advance directives include written documents such as living wills and durable powers of attorney for health care decisions (also called a health care proxy or medical power of attorney) as recognized by State law.

Many states have enacted laws requiring patients' advance directives and "do not resuscitate" (DNR) preferences to be honored. Facilities are required to know and comply with such state laws. If state law does not address this facet of health care, and the facility's policy does not allow the honoring of a patient's advance directive, there must be a protocol in place for facilitating the patient's transfer to a facility that will honor the advance directive, if the patient so chooses.

The inclusion of patients' advance directives in their medical records is addressed at V730.

V458

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(7) - Standard: Patients' rights. The patient has the right to— 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)

Documentation in patient records must demonstrate that facility staff provide unbiased education to patients/designees about transplantation and all dialysis treatment options (modalities and settings) offered for kidney failure, whether or not those options are offered at the current dialysis facility. This includes alternate scheduling options for in-center hemodialysis patients who attend school or are working. Patients who work or attend school should be encouraged to continue doing so and facilities should recommend the most appropriate modality and setting for their dialysis. Examples of how facilities may meet this requirement include developing a resource information packet for patients or providing patients an existing resource list of facilities that offer alternate schedules or home dialysis treatment options found at Medicare's Dialysis Facility Compare, and Home Dialysis Central.

The requirements for assessment of patients for home dialysis and transplantation are addressed at V512 and V513 and at V553 and V554, respectively, under the Condition for Patient plan of care.

V459

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(8) - Standard: Patients' rights. The patient has the right to— Be informed of facility policies regarding patient care, including, but not limited to, isolation of patients;

Interpretive Guidance §494.70(a)(8)

Facility staff must inform patients regarding facility policies related to patient care, including the isolation of patients with infectious diseases. For example, patients should be informed if changes in their treatment location and/or schedule can be expected if they are diagnosed with an infectious disease requiring isolation (i.e., Hepatitis B). Refer to V128 under the Condition for Infection Control for requirements regarding isolation of patients.

V460

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(9) - Standard: Patients' rights. The patient has the right to— Be informed of facility policies regarding the reuse of dialysis supplies, including hemodialyzers;

Interpretive Guidance §494.70(a)(9)

This requirement only applies to facilities that practice reprocessing and reuse of dialyzers or dialysis supplies.

The patient must be informed if the facility practices reuse of dialyzers and/or dialysis supplies and of options available if they opt not to participate in the reuse program. Some State laws require facilities to allow patients to opt not to reuse their dialyzers and/or require the patient's written consent for dialyzer reuse.

The requirements for informed consent for dialyzer reuse are addressed at V312 under the Condition for Reuse.

V461

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(10) - Standard: Patients' rights. The patient has the right to— 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)

Medical records should show that a patient's medical status was discussed with a patient/designee by a physician or a non-physician practitioner (i.e., advanced practice registered nurse or physician assistant). There should be few, if any, cases when a patient/designee cannot be informed about the patient's medical status.

V462

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(11) - Standard: Patients' rights. The patient has the right to— Be informed of services available in the facility and charges for services not covered under Medicare;

Interpretive Guidance §494.70 (a)(11)

Patients must be informed of charges for any services that may not be covered by Medicare. If a facility plans to bill a patient for items and/or services which are usually covered by Medicare but may not be considered reasonable and necessary in a particular situation (according to § 1862 of the Social Security Act), the patient must be informed and be offered an Advanced Beneficiary Notice of Noncoverage (ABN) to sign pursuant to § 1879 of the Social Security Act.

V463

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(12) - Standard: Patients' rights. The patient has the right to— Receive the necessary services outlined in the patient plan of care described in § 494.90;

Interpretive Guidance §494.70 (a)(12)

Patients have the right to receive individualized care for the necessary services outlined in the patient plan of care, as determined by the facility IDT, and to be included on that team. The care specified in the plan of care should be delivered to the patient or the plan of care should be revisited.

V464

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

Facility staff should inform patients about what is expected of them (the patient), while receiving services at the facility. Some examples of facility expectations for patient conduct and responsibilities include, but are not limited to: treating others (staff, patients, visitors) with mutual respect; following the plan of care (e.g., taking ordered medications, following fluid and diet restrictions); keeping appointments and/or notifying the facility if they will be late or miss a scheduled appointment; notifying the facility of changes in residence and contact information; and, providing information on payers and changes in insurance.

V465

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(14) - Standard: Patients' rights. The patient has the right to— Be informed of the facility's internal grievance process;

Interpretive Guidance §494.70 (a)(14)

Each facility must develop and implement an internal grievance process, as required in the Condition for Governance at V765.

Facility staff must inform patients about the internal grievance process and the steps to follow for filing an internal grievance. Refer to V765 for the components of the internal grievance process. Use those tags for failure to implement the process. Use this tag for failure to inform patients about the process.

V466

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a)(15) - Standard: Patients' rights. The patient has the right to— 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)

The facility must establish a procedure for informing patients about how they can seek external help to resolve grievances that cannot be resolved internally, or if patients are not comfortable using the internal process. The facility staff must inform each patient/designee how to contact the appropriate external entity to file a grievance, including the ESRD Network and the State survey agency.

Refer to V470 for the requirement of posting contact information for the ESRD Network and State survey agency.

V467

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(a) - Standard: Patients' rights. The patient has the right to—
(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)

Every patient must be free to file a complaint or grievance within the facility or externally with the ESRD Network or State survey agency. Facility staff should inform patients that they can file a grievance anonymously or through a representative without being afraid that they will be treated differently or denied services.

"Reprisal" would include retaliation or revenge and could include perceived punishment, isolation, the intentional infliction of physical pain or emotional distress, or, involuntary discharge from the facility.

V468

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 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)

Patients must be given information about the facility policies for routine and involuntary discharges.

Refer to the Condition for Governance at V766-V767 for involuntary discharge or transfer requirements and guidance, including acceptable reasons for involuntary discharge. Use those tags for failure to follow the involuntary discharge procedures. Use this tag for failure to inform patients about the transfer and discharge policies.

V469

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(b) - Standard: Right to be informed regarding the facility's discharge and transfer policies. The patient has the right to –
(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)

The involuntary discharge procedures described at V767 identify the steps that a facility must follow prior to the involuntary discharge of a disruptive and abusive patient. After following the required procedures at § 494.180(f)(4), a facility must give at least 30-days prior written notice to any patient whom they opt to discharge involuntarily, except in the case of a patient who makes severe and immediate threats to the health and safety of others.

An "immediate threat to the health and safety of others" is considered to be a threat of physical harm. For example, if a patient has a gun or a knife or is making credible threats of physical harm, this can be considered an immediate threat. Verbal abuse is not considered to be an immediate threat. In instances of an immediate threat, facility staff may utilize abbreviated involuntary discharge or transfer procedures. These abbreviated procedures may include taking immediate protective actions, such as calling "911" and asking for police assistance. In this scenario, advance notice may not be possible or required and there may not be time or opportunity for reassessment, intervention, or contact with another facility for possible transfer, as outlined at V767.

V470

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.70(d) 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(d)

The facility must post all of the patient rights listed in V452-V469 in a common area of the facility which is routinely available to in-center and home dialysis patients. This posting is meant to augment, not substitute, communicating these rights to each individual patient in a way the patient can understand.

Information that must be posted includes the list of patient rights, and, the mailing addresses and contact information (including complaint telephone numbers) for the applicable ESRD Network and State survey agency.

V500

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80 Condition: Patient assessment.

Interpretive Guidance § 494.80

This Condition addresses the requirements for an IDT assessment of patient needs; the requirements related to meeting those needs are contained in the Condition for Patient plan of care at §494.90.

Compliance with this Condition is determined by: observation of practices; interviews of patients, personnel and medical staff; and, review of medical records.

Condition level noncompliance should be considered if there are serious and/or pervasive deficient practices identified in the provision of individualized interdisciplinary comprehensive assessments of patients and their care needs. Examples of Condition level noncompliance include gross non-conformance with any related standards within a Condition, which may include but is not limited to:

- *Assessments not being completed for multiple patients within the timelines required;*
- *A pattern of one or more professional members of the IDT not participating in their relative area of patient assessment;*
- *A pattern of general standardized assessment "findings" without evidence that individual patient needs are assessed.*

The Bipartisan Budget Act of 2018, effective January 1, 2019, amended Section 1881(b)(3) of the Social Security Act to say that any individual determined to have ESRD receiving home dialysis may choose to receive monthly ESRD-related clinical assessments via telehealth (H.R. 1892, Section 50302). This applies to an individual only if they received a monthly face-to-face clinical assessment (without the use of telehealth) in their first three months of treatment. Home dialysis patients who opt for remote clinical assessments must continue to receive face-to-face assessments at least once every three consecutive months. Telehealth services may be used for dialysis-related

consultation, office visits, and, medication management. The medical record must indicate that at least one of the visits every 3 consecutive months was furnished face-to-face by a physician, clinical nurse specialist, nurse practitioner, or physician assistant. Telehealth communication must be interactive, meaning audio and visual communication must occur in real-time.

V501

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80 - 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

While multidisciplinary team members work sequentially and use the medical record as the chief means of communication, IDTs work collaboratively with regular meetings to discuss patient status and the evolving plan of care. Working as a team allows for working toward common goals, pooling of expertise, and a forum for problem solving.

The IDT is composed of the members designated in the regulations, including the patient or a patient designee if the patient so chooses. Patients must be given the option and encouraged to participate in their assessment and care planning process. The professional members of the IDT participating in the patient's comprehensive assessment must meet the qualifications outlined in the Conditions for Personnel Qualifications at § 494.140.

"Individualized" means each assessment is unique to a particular patient and addresses that patient's needs. "Comprehensive" means the assessment covers and addresses all issues that are actionable by the dialysis facility; this could include referrals to specialists for assessments that are beyond the capacity of a dialysis facility.

The comprehensive patient assessment must demonstrate a congruent integration of the evaluations completed by each team member, identifying the patient's individual needs and allowing for planning for necessary care and services. Team members may choose to conduct one-on-one interviews with the patient or may opt to set up team meetings which would include the patient in order to collect the appropriate assessment information.

This assessment may be incorporated into one document or composed of sections developed by each team member, but it must address the specific criteria as outlined in V502-V515. Electronic or paper formats are acceptable.

Required frequencies of patient assessments are addressed at V516- V520.

V502

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(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)

ESRD patients may have many co-morbid conditions that impact their individual care needs. The IDT evaluation of the patient's current medical and co-morbid conditions includes information from the patient's medical history, physical exams, and, nursing histories.

Non-physician practitioners, i.e., advanced practice registered nurses or physician assistants, functioning in lieu of physicians, may conduct medical portions of this evaluation, in accordance with State law and facility policy.

The nursing assessment must be conducted by a registered nurse and include evidence of assessing the patient's clinical needs.

Documentation of the etiology of the patient's kidney disease and a listing of any co-morbid conditions should be in the medical record. While copies of histories and physicals (H&P) from hospital admissions may be included, the assessment should address the patient's current presentation and health status, including the patient's medical condition related to their kidney disease.

V503

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: (2) Evaluation of the appropriateness of the dialysis prescription,…

Interpretive Guidance §494.80(a)(2)

A hemodialysis (HD) prescription includes the number of treatments per week, length of treatment time, the dialyzer, specific parameters of the dialysis delivery system (e.g., electrolyte composition of the dialysate, blood flow rate, dialysate flow rate), anticoagulation, and the patient's target weight. An appropriate HD prescription is tailored to meet the individual patient's dialysis needs. For example, if the patient experiences intradialytic muscular cramping or a fall in blood pressure, a reevaluation of the related components of the dialysis prescription (e.g., target weight, ultrafiltration rate (UFR), dialysate sodium level) would be indicated; if a patient's laboratory values

show an elevated or low potassium, a change in the dialysate potassium may be indicated.

A peritoneal dialysis (PD) prescription must take into consideration the peritoneal transport rate (determined by peritoneal equilibration testing [PET]), residual renal function, total body surface area, certain medical conditions, and, personal preference. The PD prescription includes the number of exchanges or cycles to be done each day, the volume of fluid to be used with each exchange, whether fluid is always present in the peritoneal cavity (except for brief periods between draining and reinfusion of dialysate), and, the concentration of glucose or other osmotic agent to be used for fluid removal (which may vary according to a prescribed sliding scale). Use of automated, manual, or a combination of automated/manual techniques should also be addressed. An appropriate PD prescription meets the patient's dialysis needs. As examples: if the patient has difficulty accomplishing 5 exchanges during the day, the IDT should consider other options, such as overnight treatments using a cycler.

The patient record should demonstrate that the patient's individual dialysis needs have been assessed and that the current dialysis prescription has been evaluated to determine whether it is meeting those needs.

V504
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: evaluation of the appropriateness of the…**blood pressure, and fluid management needs.**

Interpretive Guidance §494.80(a)(2)

Note: this guidance is a continuation of the requirement at §494.80(a)(2)

Because of the adverse effects of ESRD, many patients experience spontaneous changes of blood pressure and fluid management needs, the management of which may require reassessment of medication needs, adjustments in target weight, and changes to the plan of care.

The comprehensive assessment should include evaluation of the patient's pre/intra/post and interdialytic blood pressures, interdialytic weight gains, target weight, and related intradialytic symptoms (e.g., hypertension, hypotension, muscular cramping) along with an analysis for potential root causes.

For pediatric patients weighing less than 35 kg., blood volume monitoring during hemodialysis should be available in order to evaluate body weight changes for gains in muscle weight vs. fluid overload.

Citation should not be based solely on the patient's clinical results for blood pressure and fluid management. Any deficiency in this area must be supported by the facility's lack of identification and assessment of the patient's hemodynamic status and/or failure to develop or implement an appropriate plan to help meet the patient's needs.

V505

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(3) Laboratory profile …**

Interpretive Guidance §494.80(a)(3)

Laboratory work-up should include, but not be limited to, comprehensive metabolic testing, dialysis adequacy, complete blood count, iron studies and screening for HBV.

The IDT evaluation should reflect recognition of values/results that would need to be addressed in the patient plan of care.

As laboratory results may fluctuate, the IDT must evaluate the values as they become available and take indicated actions

V506

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: (3) …**immunization history, and medication history.**

Interpretive Guidance §494.80(a)(3)

Note: this guidance is a continuation of the requirement at §494.80(a)(3) "Immunization history" should include documentation of (1) standard immunizations received, such as pneumococcal, Hepatitis, and influenza, (2) vaccinations that result from emerging infectious diseases such as COVID-19 vaccination, and (3) screenings for infectious diseases such as tuberculosis. The immunization record is expected to include at least the patient's immunization history as of the effective date of this regulation.

The Centers for Disease Control and Prevention (CDC) recommends that all dialysis patients:

- *Be screened for TB on or before the first dialysis treatment and be rescreened if TB exposure is detected. The frequency of TB screening should be based on a facility's risk assessment, including the community's TB profile. If the facility is*

located in an area with a high incidence of TB, screening may be indicated more frequently.

The CDC recommends that the two-step Mantoux skin test be used for baseline testing to reduce the likelihood of mistaking a booster reaction for a new infection. The interferon gamma release assay (IGRA) is a fairly new method for TB surveillance and can be used as an alternative testing method, with each facility evaluating the benefits and indications for its use. The advantages of IGRA include the availability of results within 24 hours and the elimination of the probability of a boosted reaction on subsequent testing.

Chest X-rays are acceptable to rule out active TB disease but may not properly identify exposure to TB or latent TB infections. See additional information regarding CDC recommendations for TB testing on the CDC website at: https://www.cdc.gov/tb/topic/testing/default.htm.

- *Be offered influenza and pneumococcal vaccine and have immunization histories for these vaccines be tracked. Both are universally recommended for this population and relate directly to infection control issues.*
- *The CDC expectations for Hepatitis vaccinations are detailed at V126 and V127.*

"Medication history" should include a review of the patient's allergies and of all medications that the patient is taking, including over-the-counter medications and supplements. The assessment should demonstrate that all current medications were reviewed for possible adverse effects/interactions and continued need.

V507

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(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)

Each patient's hematologic status must be evaluated for determination of their individual anemia management needs.

Evaluation should address the patient's anemia, including an assessment of the need for erythropoiesis-stimulating agents (ESA) and/or iron therapy. Evaluation should also address the patient's volume status, potential for bleeding, infection and other causes of hypo-response.

Citation should not be based solely on the patient's clinical laboratory results for anemia. Any deficiency for anemia management must be supported by the facility's lack

of identification and assessment of the patient's hematologic status and/or failure to develop or implement an appropriate plan to help meet the patient's hematologic needs.

Requirements for the plan of care for anemia management are at V547.

V508

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(5) Evaluation of factors associated with renal bone disease.**

Interpretive Guidance §494.80(a)(5)

Disturbances in mineral and bone metabolism are common in patients with ESRD, often resulting in hyperparathyroidism and Chronic Kidney Disease (CKD) mineral and bone disorder if not managed effectively.

Evaluation should include the patient's laboratory values for calcium, phosphorous, and parathyroid hormone (PTH), along with a review of the patient's current CKD mineral and bone disorder medications (e.g. phosphate binders, vitamin D analogs, calcimimetic agents), over-the-counter medications, dietary factors, and medical conditions that may impact this issue.

Pediatric patients present significant special needs in the areas of growth and development and CKD mineral and bone disorder. A facility treating pediatric patients should follow current professionally-accepted clinical practice standards for evaluating and monitoring the pediatric patient population in this area.

Citation should not be based solely on the patient's clinical laboratory results for disturbances in mineral and bone metabolism, e.g. phosphorus and calcium levels. Any deficiency for mineral and bone metabolism management must be supported by the facility's lack of identification and assessment of the patient's metabolic status and/or failure to develop or implement an appropriate plan to help meet the patient's needs.

Requirements for the plan of care for CKD mineral and bone disorder management are at V546.

V509

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(6) Evaluation of nutritional status by a dietitian.**

Interpretive Guidance §494.80(a)(6):

The evaluation of each patient's nutritional status must be conducted by a qualified dietitian as defined in these regulations at V689 and V690. Examples of nutritional parameters to be addressed include, but are not limited to:

- *Nutritional status;*
- *Hydration status;*
- *Metabolic parameters such as glycemic control (if diabetic) and cardiovascular health;*
- *Anthropometric data such as height, weight, weight history, weight changes, volume status, amputations;*
- *Appetite and intake;*
- *Ability to chew and swallow;*
- *Gastrointestinal issues;*
- *Use of prescribed and over-the-counter nutritional, dietary, or herbal supplements;*
- *Previous diets and/or nutrition education;*
- *Route of nutrition;*
- *Self-management skills;*
- *Attitude to nutrition, health, and well-being; and,*
- *Motivation to make changes to meet nutrition and other health goals.*

The assessment may include information from the person that cooks and provides meals for the patient, whether this is the patient, family, caregiver, or a nursing home/long-term care (LTC) facility. Before interviewing family members or caregivers, the dietitian should obtain the patient's permission to conduct the interview with the relevant individual(s). If the patient is a resident of a LTC facility, the dietitian should contact the staff of the LTC facility as part of the assessment and to provide continuity of care.

Other members of the IDT may contribute to portions of the comprehensive assessment which correlate with the nutritional evaluation (e.g., medical history/co-morbid conditions at V502, fluid management at V504, laboratory profile at V505, medication history at V506, CKD mineral and bone disorder at V508, psychosocial factors at V510, and adequacy of the patient's dialysis prescription at V518).

Recognition and evaluation of nutritional needs is critically important in pediatric patients. A facility treating pediatric patients should adhere to current, professionally accepted clinical practice standards for evaluating and monitoring the pediatric patient population. The dietitian must consider the special nutritional needs of this patient population.

Citation should not be based solely on the patient's clinical laboratory results for nutrition management (for example, serum albumin levels). Any deficiency in nutritional management must be supported by the facility's failure to identify and assess the patient's nutritional status and/or its inability to develop or implement an appropriate plan to meet the patient's needs.

Requirements for the plan of care related to nutritional status are outlined at V545.

V510

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(7) Evaluation of psychosocial needs by a social worker.**

Interpretive Guidance §494.80(a)(7):

The evaluation of psychosocial needs must be conducted by a qualified social worker as defined by these regulations at § 494.140 (d)(1)(2) (V691). Examples of psychosocial parameters to be addressed by the qualified social worker include, but are not limited to:

- *Cognitive status and capacity to understand;*
- *Ability to meet basic needs;*
- *Ability to follow the treatment prescription;*
- *Mental health history, capacities, and needs for counseling;*
- *Substance abuse history, if any;*
- *Current ability to cope with and adjust to dialysis;*
- *Expectations for the future, and living with kidney failure and treatment;*
- *Educational and employment status, concerns, and goals;*
- *Home environment, including current living situation;*
- *Legal issues (e.g., court-appointed guardian, advance directive status, and health care proxy);*
- *Need for advocacy with traditional (nursing home) and non-traditional housing (e.g., homeless shelters, group homes);*
- *Financial capabilities and resources;*
- *Access to available community resources; and,*
- *Eligibility for Federal, State, or local resources.*

Other members of the IDT may contribute to portions of the comprehensive assessment that correlate with the psychosocial evaluation (e.g., patient preferences for modality and self-care at V512, evaluation for transplant referral at V513, family/support systems at V514, and evaluation for referral to rehabilitation services at V515).

Requirements for the plan of care related to psychosocial status are listed at V552.

V511

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(8) Evaluation of dialysis access type**

and maintenance (for example, arteriovenous fistulas, arteriovenous grafts and peritoneal catheters).

Interpretive Guidance §494.80(a)(8)

The efficacy of the HD patient's vascular access and the PD patient's peritoneal catheter correlates with the quality (adequacy) of their dialysis treatments and is of vital importance to their overall health status.

Each HD patient should undergo an evaluation to determine the most appropriate type and location of vascular access, as well as the capacity of the vascular access to facilitate adequate dialysis treatments.

Completion of this evaluation may include referrals to other facilities, such as a radiologist or interventionist for vessel mapping or a vascular surgeon for access placement. Such referrals may occur as part of an assessment or as part of a plan of care if the referral is intended to address inadequate vascular access.

Evaluation of a PD patient's peritoneal catheter would include assessment of the exit site and tunnel for signs of infection, and of the catheter for patency and proper function.

The requirements for vascular access plan of care are at V550 and V551.

V512

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(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)

Evaluation of abilities, interests, preferences, and goals may be demonstrated by at least one member of the team documenting an assessment of the patient's current interests in life and ability to pursue those interests, preferences for treatment, and goals, including what they expect from dialysis treatment. Patients should be encouraged to participate in their care, within the limits of their capacity and desire.

If patients express a desire for enhanced participation in their own care (e.g., weighing themselves, monitoring blood pressure, holding needle sites, self-cannulation), the facility staff should evaluate and plan for applicable self-care training.

Refer to the Condition for Care at Home at V585.

Evaluation of the preferred modality means that all options of modalities (hemodialysis, peritoneal dialysis) and settings (in-center, home) were presented to each patient, and their goals, preferences, and expectations were given priority in decision-making.

If a patient is determined not suitable for or declines home dialysis therapy, the reason must be documented in their plan of care, as required at V553

V513

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(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)

The IDT comprehensive assessment must demonstrate that each patient is evaluated for suitability for transplantation referral, using selection/exclusion criteria provided by the transplant program.

The regulations for transplant programs require the development and provision of written selection criteria upon request to patients and dialysis facilities. Selection criteria vary among transplant programs. If a dialysis facility refers patients to multiple transplant programs, the facility should have the selection criteria for each program on file and available to patients. Additionally, patients are free to select a transplant program other than the ones normally utilized by the dialysis facility for referrals.

If the assessment finds a patient is not suitable for transplantation, the reason for the non-referral should be documented as part of the comprehensive assessment.

The requirements for the plan of care for transplant status are at V554.

V514

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following: **(11) Evaluation of family and other support systems.**

Interpretive Guidance §494.80(a)(11)

This evaluation should start with an interview of the patient. If one or more members of the IDT need to seek additional protected health information about the patient from family or other supporting individuals, a health care provider may discuss the patient's health information if the patient agrees or, when given the opportunity, does not object. Generally, the HIPAA Privacy Rule allows staff to ask family members involved in the individual's care or other caregivers for information they may know about a patient to help the IDT provide care for the patient. HIPAA does not prohibit a staff member from educating a family member or other support person involved in the individual's care about how to assist the patient with diet, medications, and coping with kidney failure. Educating the patient with family or other caregiver(s) (when possible) ensures that everyone receives the same information. For more information about when a health care provider is allowed to share a patient's health information with the patient's family members, friends, or others identified by the patient, see HIPAA's guide for Communicating with a Patient's Family, Friends, or Others Involved in the Patient's Care.

Areas to be evaluated include family composition and history, the patient's willingness to seek help, and spiritual or religious support systems. Some or all portions of this evaluation may overlap with the requirements for the psychosocial assessment described at V510.

Pediatric patients present special situations. Facilities that treat pediatric patients must have policies that address the need to evaluate the family and other support systems of the pediatric patients.

V515

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(a) Standard: Assessment criteria. The patient's comprehensive assessment must include, but is not limited to, the following:

(12) Evaluation of current patient physical activity level.
(13) Evaluation for referral to vocational and physical rehabilitation services.

Interpretive Guidance §494.80(a)(12) and (13)

These requirements are not intended to indicate that the facility is responsible for fully assessing each patient's activity level/physical capabilities. It is expected that the IDT would be able to evaluate each patient's activity level to the extent necessary to determine whether the patient is a candidate for referral to the appropriate professional(s) for further evaluation and possible rehabilitation services.

A member of the IDT should interview the patient/designee about the patient's current level of physical activity, ability to perform activities of daily living, and/or barriers to independence. The assessment should include observation of the patient's ability to

ambulate, transfer, and perform other physical activities pertinent to the dialysis environment (e.g., holding needle sites, etc.).
Pediatric patients may also warrant rehabilitation services. Pediatric patients should be encouraged to attend school full-time, if possible. If school attendance is not possible, other options should be offered for school-age children to obtain an education.

Vocational rehabilitation referrals may be appropriate for older youth and adult patients who wish to return to work and/or enhance their independent living skills.

Patients who may warrant physical rehabilitation referrals include those with physical limitations and/or difficulty in performing activities of daily living independently.

The requirements for the plan of care for rehabilitation status (including making referrals) are at V555.

V516

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.80*(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 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.

Interpretive Guidance §494.80(b)(1)

Each new dialysis patient must undergo a comprehensive assessment within 30 days or 13 treatments following admission. This requirement applies to all new dialysis patients, regardless of the treatment modality. Patients returning to dialysis from a failed transplant or changing modalities are also considered "new" patients. If the comprehensive patient assessment and plan of care for an experienced dialysis patient transferring from one dialysis facility to another is received with the patient in transfer, the receiving facility's IDT must conduct a reassessment within three months of the patient's admission to the new facility. This same provision (i.e., completion of a reassessment within 3 months of admission) would also apply to transient patients received with an assessment and plan of care. Refer to V408 for disaster situations and requirements.

Prior to the first dialysis treatment, an "initial assessment" must be completed.

Recognize that the transfer of a large number of patients at once (e.g., with the opening of a new facility, or in the event of an adverse occurrence or disaster impacting the functionality of the transferring facility) may affect the staff's ability to complete this requirement within the mandated timeline. If this is the case, the facility should develop a

plan to ensure the prompt completion of assessments for transferred patients and a method to triage patients' needs for assessment.

V517

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80**(b) Standard: Frequency of assessment for patients admitted to the dialysis facility. (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)

Patients new to dialysis and/or in a new dialysis setting frequently need time to adjust and adapt to the dialysis treatment. The 3-month comprehensive reassessment enables the IDT to re-evaluate:

- *how well patients follow their treatment plan,*
- *their educational, psychosocial, rehabilitation, and nutritional needs,*
- *their current adjustment to the dialysis regimen,*
- *how well the patient is coping with kidney disease, and,*
- *the accuracy and appropriateness of patients' plans of care.*

The medical director's responsibilities include ensuring that all policies for patient admissions and care are adhered to, which includes policies for patient assessment and reassessment. In order for the medical director to make this determination, the policies must include a system in place to ensure completion of the 3-month comprehensive patient reassessments.

V518

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80**(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) and (2)

Monthly assessment of dialysis adequacy for all HD patients, and at least every 4 months for PD patients, must be demonstrated.

The facility must have a method or procedure in place for obtaining the blood samples used for the Kt/V or an equivalent measure. The facility must ensure that the method/procedure used will result in an accurate outcome. At the time of the publication of these regulations (April 15, 2008, 73FR20369), the recommended method stipulated for drawing blood samples to measure Kt/V included the following:

- *Pre- and post-samples are drawn at the same treatment;*
- *Pre-sample is drawn just prior to the start of treatment;*
- *Slow flow or stop pump technique is used for the post sample; staff should slow the blood pump speed to 50-100 mL/min for 15 seconds before drawing blood; in the event the equipment in use does not allow for "slow flow," then "stop flow" may be substituted.*
- *After 15 seconds, staff should draw the post-dialysis BUN sample from the arterial port closest to the patients.*

All facility staff members must follow the same prescribed procedure for obtaining blood samples used for assessing the adequacy of the patient's prescription.

Home hemodialysis patients should be instructed to draw their samples in this same way.

Recognize that obtaining the sample to measure adequacy for PD patients depends on their cooperation with bringing samples of dialysate effluent and urine. If a scheduled sample is not obtained, staff should document the missed test, reschedule the test (including obtaining a blood sample on the same date as the fluid samples are collected), and consider providing reminders and re-educating the patient.

V519

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.80*(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)(1)

A complete and comprehensive reassessment of each patient must be conducted at least annually for stable patients. The first annual reassessment would be due 12 months after the 3-month reassessment, or 15 months after the patient's admission to the facility. Any reassessment must be accompanied by a revision of the plan of care to reflect findings of the assessment, i.e., at least annually for stable patients.

Annual reassessments for stable patients are the required minimum; more frequent reassessments may be performed if required by facility policy or clinical concerns.

If patients who have been identified by staff as "stable" demonstrate one of the issues listed as criteria for being considered "unstable," this finding would be cited at V520.

V520

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.80(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— **(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), and (iv)

The criteria listed in this section are the minimum criteria for classifying patients as "unstable." The IDT members have the flexibility to use their professional judgment to develop more stringent policies and add other assessment criteria to the definition of "unstable," based on their unique patient population and patient characteristics.

Hospitalization and readmission rates will vary based on the characteristics of the patient population. For the Medicare dialysis population, facilities and survey agencies may use the most recently published Dialysis Facility Report to identify the national average for length of stay (extended hospitalization) and readmission rates (frequent hospitalization).

Clinical and psychosocial deterioration is a key indicator in patient mortality and quality of life. "Marked deterioration in health status" should be specifically identified and documented by the IDT. The following conditions are examples consistent with deteriorations exemplified in the renal disease patient:

- *Change in ambulation severe enough to interfere with the patient's ability to follow aspects of the treatment plan;*
- *Hypotension, restlessness, pruritus, or other symptoms severe enough to prevent completion of the majority of dialysis treatments;*
- *Sudden onset of recurrent cardiac arrhythmias;*
- *Recurrent infections (not recurring hospitalization);*
- *Chronic congestive heart failure with chronic hypotension;*
- *Advanced or metastatic cancer or other organ system disease that interferes with the patient's ability to follow aspects of the treatment plan;*
- *Chronic or recurrent peritonitis*

"Significant change in psychosocial needs" would include any physical or mental health event that interferes with the patient's ability to follow aspects of the treatment plan. Such events may include instability in one's own or an immediate family member's

employment, physical or emotional abuse, deterioration in mental or functional status, amputation, housing instability, death or major illness in the family, consideration of terminating treatment, and loss of emotional support. In addition, any patient considered at risk for involuntary discharge or transfer must be considered "unstable" and as such, must be reassessed monthly. Note that V767 requires patients at risk for involuntary discharge to be reassessed prior to actual discharge or transfer from the facility.

"Poor nutritional status" would include failure-to-thrive symptoms, such as loss of body weight and low serum albumin levels.

"Unmanaged anemia" would include continued lab findings of hemoglobin/hematocrit values that are outside the range defined by community-accepted standards or the Centers for Medicare and Medicaid Services (CMS) Clinical Performance Measures (CPMs). Refer to the Measures Assessment Tool (MAT), which lists the current professionally accepted clinical standards and current CMS CPMs.

"Inadequate dialysis" would include a trend of results for Kt/V or URR that do not meet the minimum for a three-month period. Inadequate dialysis would also include symptoms related to fluid management, such as volume overload or depletion; intradialytic symptoms, such as syncope or congestive heart failure; hypertension; or the need for extra treatment(s) for fluid removal.

Facilities must have a method for classifying patients as "unstable." Documentation should be available of a monthly reassessment and plan of care revision that addresses the issues related to the classification of the patient as "unstable" until the issues have been resolved or the IDT (including the patient if possible) determines that the condition is chronic and the active care plan adequately addresses the issues.

Some changes leading to the patient classification of "unstable" are clearly within the purview of a specific member of the IDT. For example, while housing instability falls within the realm of the social worker, expect to see documentation of communication regarding a change in housing between the social worker and other members of the IDT who can determine the specific impact of that change on their specialty. The participation of some team members in some changes that do not impact their specialty may be limited.

V540

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90 Condition: Patient plan of care.

Interpretive Guidance § 494.90

The Condition is directly related to the Condition for patient assessment, as the plan of care is built upon the patient assessment. The individual plan of care is revised after each patient assessment, and portions of the plan must be updated if the target goals for each area are not achieved or sustained.

The Condition for patient plan of care reviews individual patient outcome data and addresses the goals and plans set for individual patients, while the Condition for quality assessment and performance improvement (QAPI) reviews aggregate data for trends and commonalities and addresses facility-wide goals and improvement plans.

Survey tasks, including observation, patient and staff interviews, and medical record review, are used to evaluate compliance with this Condition. Identification of issues such as lack of blood pressure monitoring at the frequencies required by facility policy or as indicated by the patient's condition, or the failure to respond to hypertension or hypotension, may indicate a failure to develop or implement a portion of the plan of care. Each patient should be treated individually. When a specified target is not met, the plan of care should either be adjusted to achieve the target or an explanation provided by the IDT in areas where the target cannot be met.

Examples of condition-level noncompliance would include, but not be limited to:

- *Serious and/or pervasive deficient practices identified in the development or implementation of individualized plans of care;*
- *A pattern of failure to revise the applicable portion of the plans of care when the current plan did not result in achieving or sustaining the intended outcome; or,*
- *A pattern of failure in updating the plans of care when indicated by the patient's condition.*

V541

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90 – 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

The IDT consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician who is treating the patient for ESRD, a social worker, and a dietitian (see § 494.80). Each team member must meet the qualifications outlined in the Condition for Personnel qualifications at § 494.140.

The facility must recognize the patient or their designee as a member of the IDT and encourage the patient's participation in developing and updating the plan of care. The patient's needs, wishes, and goals must be considered in making decisions about the plan

of care. If a patient chooses to use a designee, written authorization from the patient must be obtained for the sharing of protected health information with the designee.

A registered nurse must serve as a member of the team and should have knowledge of the patient. The registered nurse participating in the plan of care for home dialysis patients should work in the home dialysis program and have knowledge of the specific needs of home dialysis patients.

The written patient plan of care must be individualized for the patient, built on the comprehensive assessment as outlined at V502-515 under the Condition for patient assessment, and include at a minimum: problem(s) identified at assessment/reassessment, measurable goals/outcomes, planned interventions for achieving the goals, timetables, and reassessment date(s). A review of the plan of care, treatment records, progress notes, laboratory reports, and other relevant documents should demonstrate the implementation of the plan of care.

The patient plan of care encompasses all the care, services, and treatment interventions that the IDT determines to implement to meet the patient's specific needs. The written patient plan of care may be a single document or composed of separate sections, but it must be congruent and reflect the integration of comprehensive assessments contributed by all members of the IDT. Electronic or paper formats are acceptable.

Timelines for meeting the specified targets should be based on setting reasonable targets for the individual patient, considering the severity of the problem and the extent of the planned interventions (e.g., acute issues should have shorter timelines).

The measurable outcomes specified in each patient's plan of care must be current, evidence-based, and professionally accepted. Goals and outcomes for some patients may need to be initially different from these targets, then incrementally changed to the standard target value as the patient's outcome improves. For example, to maintain fluid balance and adequate blood pressure control, a target treatment time for an individual patient may be identified as 3 hours; however, longer hemodialysis times may be necessary when the patient experiences large intradialytic weight gains or uncontrolled blood pressure.

V542

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.90*(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)

An interdisciplinary plan of care must be developed for each patient. Facilities must have a system for developing patients' plans of care. The IDT members are expected to

interact and share information from the comprehensive assessment to facilitate the development of the plan of care.

To ensure the development of a congruent and integrated patient plan of care, the facility may conduct IDT conferences or utilize another mechanism that ensures the development of an integrated plan. A substitute mechanism for a team conference needs to facilitate discussion among team members about the information gathered from the comprehensive patient assessment and provide opportunities for team coordination and development of an effective, individualized plan of care for the patient, ensuring the desired outcomes are achieved. To facilitate full team participation in conferences, any member, including patients, may participate via telecommunication.

V543

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …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)

Volume status is measured in terms of the dialysis patient's "target weight," or estimated dry weight (EDW): what the patient would weigh if they were "dry." A patient in the EDW should be asymptomatic and normotensive on minimal blood pressure medications, while preserving organ perfusion and maintaining existing residual renal function. A patient at their EDW attains normotension for most of the interdialytic period, while avoiding orthostatic hypotension or postural symptoms either during or after dialysis. Excess fluid accumulation may have adverse effects (e.g., hypertension, left ventricular hypertrophy, cardiovascular complications, hospitalizations). Removal of excessive fluid or removing it too quickly during a single dialysis treatment, or reducing the patient's weight below their target, may cause hypotension, muscle cramping, and clotting of the vascular access. Each patient should be weighed before and after each treatment. The ultrafiltration component of the hemodialysis prescription should be optimized to achieve a goal of rendering the patient euvolemic and normotensive. With successful fluid management, the number of medications a patient needs for blood pressure control may be reduced. There should be a target weight identified for each patient, and evidence that failure to achieve the target weight through the dialysis treatment is addressed.

Evidence of implementing the plan of care for this aspect would include treatment records reflecting attainment of the target weight at the end of each treatment, or documentation acknowledging that the target weight was not attained, along with an assessment of the reason for not achieving it and a plan to correct this issue. The plan should include frequent assessments of the target weight with adjustments as indicated, scheduling additional treatments as necessary, educating staff on machine settings and

monitoring, counseling the patient on fluid intake, and implementing other interventions as needed for the specific patient and circumstances.

Patients' blood pressures must be monitored before, during, and after treatment, and abnormally high or low values must be addressed. Excessively high or low blood pressure measurements during treatment, without evidence of assessment and action to address those values, would indicate that the plan of care for this parameter was either not developed or not implemented.

V544

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(1) Dose of dialysis.… 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(a)(1)

Note: this guidance is a continuation of the regulatory requirement at § 494.90(a)(1).

The patient plan of care should use dialysis adequacy goals in accordance with current professionally accepted clinical practice standards/CMS CPMs.

The patients' dialysis prescriptions (dialyzer, blood flow rate, dialysate flow rate, length of treatment time) and the efficacy of the vascular access affect the dose of dialysis delivered. If alarms stop the dialysis ultrafiltration "clock," the "remaining treatment time," or planned treatment time may need to be extended to fulfill the patient's dialysis prescription.

To meet this requirement, the IDT should review the Kt/V results to determine if the patient's adequacy values achieve the goal. If not, the IDT should compare treatment orders and dialysis treatment records to ensure the prescribed dose of dialysis is being delivered. If the patient is not receiving adequate treatment, the IDT should develop a plan to address the problem. For example, if a conventional 3 times a week HD patient's Kt/V is below 1.2 for several consecutive testing periods, a causal analysis should be done and the plan of care revised to address the identified problems.

Patients should have a clear understanding of dialysis adequacy and the consequences of skipping or shortening dialysis treatments. If the patient shortens treatments, misses treatments, or gains excessive fluid between treatments, the prescribed dose of dialysis may not be able to be delivered. If a patient routinely shortens or skips treatments, the plan of care for adequate treatment should investigate the root cause(s) (e.g., fear of intradialytic morbidity, prolonged recovery time, schedule conflicts with life responsibilities, transportation issues) and work with the patient to reduce or correct the

cause(s). Ultimately, the patient can choose to continue behaviors that result in lessened treatment results. With documentation of educational efforts, the patient's choice can serve as an explanation for a plan of care that does not achieve standard treatment results.

The requirements for patient assessment of dialysis dose are outlined at V518.

V545

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(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)

The facility must have established target goals for patients' albumin levels and monitor each patient's body weight trends. Other nutritional markers, including but not limited to sodium, calcium, phosphorus, and potassium, should also be routinely monitored. Facilities may use additional nutritional markers and assessments as determined by the IDT. At the time of publishing these regulations (April 15, 2008, 73 FR 20369), two methods of measuring albumin were in use, each with a different range.

If the patient record indicates a trend of problems in the patient's nutritional status, the IDT must develop and implement an outcome-oriented plan of care to address these issues. For example, if the patient's albumin levels are consistently below target levels, an individualized plan of care should be developed to address the possible causes (e.g., inadequate dialysis, poor understanding of diet, limited access to nutritious food, fluid volume overload). To meet the requirement to "achieve and sustain an effective nutritional status," the medical records of patients with outcomes lower than the expected standard should demonstrate continuing efforts tailored, implemented, assessed for success, and revised to address the individual patient challenges in this area. In the event the patient has a wasting disease, cachexia, or chronic inflammation contributing to a poor nutritional state, the plan of care should acknowledge these as limiting factors in achieving and sustaining the goal for nutritional status.

While it is not expected or required for facilities to provide nutritional supplements, the dietitian is expected to assist patients in achieving their nutritional goals by providing education, counseling, and encouragement.

The requirements for patient assessment of nutritional status are at V509.

V546

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(3) Mineral metabolism. Provide the necessary care to manage mineral metabolism and prevent or treat renal bone disease.**

Interpretive Guidance § 494.90(a)(3)

Disturbances in mineral and bone metabolism are common in patients with ESRD, often resulting in hyperparathyroidism and Chronic Kidney Disease (CKD) mineral and bone disorder, if not managed effectively. The lab markers of calcium, phosphorus, and parathyroid hormone (PTH) are generally used to monitor mineral metabolism.

Expect the facility to have established target goals for patients' calcium, phosphorus, and PTH levels, which reflect professionally accepted clinical practice standards. Refer to the Measures Assessment Tool (MAT), which lists the targets for CKD mineral and bone disorder.

Interventions for prevention and management of CKD mineral and bone disorder may include nutritional counseling and the administration of medications (e.g., phosphate binders, vitamin D analogs, calcimimetic agents). If the facility is using a medication algorithm/protocol for managing CKD mineral and bone disorder, the care for each patient must be individualized. The physician or non-physician practitioner (i.e., advanced practice registered nurse or physician assistant) is responsible for ordering medications and laboratory tests and may or may not prescribe standing orders or utilize a standard algorithm.

Pediatric patients have special growth and development needs that require management in this area. Facilities treating pediatric patients should have specialized methods for monitoring and management of CKD mineral and bone disorder.

The methods used for managing CKD mineral and bone disorder should be evident in the review of records, including laboratory reports, orders for CKD mineral and bone disorder management medications (e.g., vitamin D analogs), and medication administration records. Each patient's laboratory values must be monitored, values outside the target levels addressed, doses adjusted, and medications administered as ordered. If the patient's mineral metabolism goals are not being attained to "manage and prevent or treat" CKD mineral and bone disorder, the team should identify potential causes and address the barriers that may be preventing the patient from reaching the target values (e.g., failure to take medications or follow prescribed diet, lack of understanding or resources to obtain medications). Patients should be educated to understand their role in managing the prescribed diet, medications, and managing bone health. Enlistment of patients to be involved in their care is critical to success and attainment of these goals.

The requirements for patient assessment of CKD mineral and bone disorder are at V508.

V547

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(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)

The facility must establish targets in anemia management that reflect professionally accepted clinical practice standards.

The IDT should have a plan for managing patients' anemia. The laboratory reports, orders for erythropoiesis-stimulating agents (ESAs), and medication administration records should be considered as a part of the anemia management program. Facilities that use medication algorithms or protocols for managing anemia must ensure that the care for each patient is individualized. The physician or a non-physician practitioner (i.e., advanced practice registered nurse, or physician assistant) is responsible for ordering medications and laboratory tests and may or may not use standing orders or a standard algorithm.

Each patient's laboratory values must be monitored, and those outside the target levels must be addressed by adjusting doses and administering ESAs as ordered. Hemoglobin/hematocrit values must be measured at least monthly; many facilities measure these more frequently, especially if the values are outside the recommended target range or the patient has co-morbid conditions (such as cardiovascular disease), which may warrant more frequent monitoring. The IDT team must assess each patient to identify their unique needs for anemia management.

If there is a trend of problems in managing an individual patient's anemia, the IDT must develop an outcome-oriented plan based on their assessment of the problem and identification of possible barriers to attaining the goals. Due to various co-morbid conditions (e.g., sickle cell disease, persistent iron deficiency, frequent hospitalizations, chronic blood loss, cancer, infection, fluid volume overload), some patients may not respond to ESA therapy as expected. In the event of hyporesponse, there must be evidence that the patient was evaluated for the possible underlying cause(s) of resistance to anemia management therapy, and the plan of care revised accordingly. ESA therapies have been found to be detrimental to some patients when administered at high doses or when the hemoglobin level is driven above 13. The IDT must consider all information regarding ESA therapies when managing the anemia of individual patients.

The requirements for patient assessment of anemia are at V507.

V548

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: (4) Anemia… **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(a)(4)

Note: this guidance is a continuation of the regulatory requirement at § 494.90(a)(4).

An evaluation of the home dialysis patient's knowledge and competency in safely and effectively administering ESAs should be conducted by a qualified team member who is authorized to train and administer the medication. The dialysis industry typically conducts evaluations through a home dialysis nurse. Use this tag if issues specifically related to the safe use and storage of ESAs are identified. Refer to the Condition for care at home at V585.

V549

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(4) Anemia. …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(a)(4)

Note: this guidance is a continuation of the regulatory requirement at § 494.90(a)(4).

The facility must monitor patients' blood pressure levels and take action upon significant abnormalities for each patient. Hypertension may have many causes; failure to develop and implement a plan to control high blood pressure should be cited at V543.

Measurements of patients' iron stores include serum ferritin and transferrin saturation. The facility must establish targets for iron management that reflect professionally accepted clinical practice standards.

If the IDT chooses to use medication algorithms or protocols for anemia/iron management, the care for each patient must be individualized. The physician or a non-physician practitioner (i.e., an advanced practice registered nurse or a physician

assistant) is responsible for ordering medications and laboratory tests and may or may not use standing orders or an algorithm.

The IDT must develop a program for anemia and iron management, and monitor laboratory results, orders for intravenous iron preparations, and medication administration records to address values outside the target levels. Laboratory values outside the target levels must be addressed; doses adjusted as necessary; and medications administered as ordered.

If there is a trend of problems in iron management for an individual patient, the IDT must develop an outcome-oriented plan based on their assessment of the problem and identification of possible barriers to attaining the goals.

The requirements for patient assessment of anemia/iron are at V507 and for blood pressure/fluid management at V504.

V550

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(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)

Based on the comprehensive assessment, the facility IDT must develop and implement a plan of care to facilitate each hemodialysis patient receiving and maintaining the most appropriate and optimal vascular access identified for that patient.

A well-functioning vascular access enables the hemodialysis patient to receive efficient/adequate dialysis treatments, enhancing their quality of life. The determination of which type of vascular access is the most appropriate for the individual patient requires the integration and coordination between the facility IDT, including the patient/designee, and may include referrals for vessel mapping, surgical consult, Doppler studies, etc., enlisting the participation of other facilities, such as primary care physicians, surgeons, interventional radiology, and surgical or vascular access centers for access placement and maintenance.

To meet this requirement to "achieve and sustain" vascular access, the patient's medical record must include evidence of the evaluation and the basis for the decision for placement of the current vascular access. If the records from the surgeon are not available, the patient's physician, advanced practice registered nurse, or physician

assistant is expected to provide this information from communication with the surgeon. If the patient's vascular access is not an arteriovenous fistula, the record should indicate why the patient was determined not to be a candidate for a fistula. If a patient has been dialyzed with a central venous catheter for more than 90 days, there should be an active plan in place for the placement of a more permanent vascular access, or information in the record should demonstrate that a catheter is the most appropriate vascular access for that patient. Some patients may not be candidates for a fistula or graft; each patient has the right to make an informed choice. Patients must be informed and educated about the benefits, risks, and hazards of each type of vascular access (V456). Repeated education may be needed. The IDT must involve the patient/designee in the plan for vascular access. The facility social worker should be involved and determine whether psychosocial considerations, such as body image, needle fear, or anxiety, need to be addressed.

Vascular access monitoring is addressed in V551. Requirements for vascular access assessment are at V511.

V551

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(5) Vascular access…. 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(a)(5)

Note: this guidance is a continuation of the regulatory requirement at § 494.90(a)(5).

The facility must have an ongoing program for vascular access monitoring and surveillance to detect failure early and facilitate timely referral of patients for intervention when indications of significant stenosis are present. Patient education should address self-monitoring of the vascular access.

Monitoring strategies may include physical examination of the vascular access, observation of changes in adequacy or pressures measured during dialysis, difficulties with cannulation, or challenges in achieving hemostasis. Precipitating events should also be noted, such as hypotension or hypovolemia. Surveillance strategies include device-based methods, such as access flow measurements, direct or derived static venous pressure ratios, and duplex ultrasound.

For patients with grafts and fistulas, the medical record should show evidence of periodic monitoring and surveillance of the vascular access for stenosis and signs of impending failure. The documentation of this may be on the dialysis treatment record, progress notes, or on a separate log. A member of the facility staff must review the vascular access monitoring/surveillance documentation to identify adverse trends and act if indicated.

Refer to the Conditions for Infection Control at V147 and V148, as well as the Condition for QAPI at V633, which also cover the monitoring and surveillance of vascular accesses.

V552

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(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):

To address the patient's psychosocial needs and to achieve and sustain an appropriate psychosocial status, each patient's plan of care must reflect the information obtained from the applicable components of the IDT comprehensive assessment under the Condition for patient assessment at V502-V515, including the psychosocial assessment at V510. The plan of care must include interventions individualized to meet that patient's psychosocial needs and aimed at optimizing the patient's adjustment to kidney failure and its treatment. The social worker is expected to help patients achieve their psychosocial goals. Counseling services for patients and their families should focus on helping them cope with kidney failure and dialysis, follow the treatment plan, and achieve the patient's rehabilitation goals.

This regulation does not require facilities to use any specific assessment tool; rather, it requires the social worker to choose a "standardized mental and physical assessment tool" that is used as a monitoring aid to assist in determining the patient's psychosocial status. There is flexibility in the assessment tool used to evaluate a patient's mental and psychosocial status; however, the tool must be age-appropriate, i.e., adult and pediatric patients should be assessed using an assessment tool tailored to their respective age groups. The tool must be administered and the results measured at regular intervals, as well as on an as-needed basis.

The "regular intervals for which an assessment tool must be used may be specified by the form or survey of choice. The social worker should adhere to the instructions and guidelines set for the tool being used when measuring a patient's mental and psychosocial status. If no such specification exists, the dialysis facility should establish a regular interval for administering the assessment tool. For example, the Kidney Disease Quality of Life 36 survey (KDQOL-36) is one of the most widely used measures of Health-Related Quality of Life (HRQOL) for patients with ESRD. The KDQOL-36

assessment survey is administered at the time of the first reassessment (i.e., within 4 months of initiating treatment) and repeated at least annually thereafter. Examples of use on an "as-needed basis" include repeating the survey with patients who have experienced a significant life-changing event (e.g., loss of spouse or caregiver, loss of job, recent move to a nursing home) or a change in their health status.

The social worker must have a system for routine use of the assessment survey, evaluation of the results, and incorporation of the survey results into the development and updating of the psychosocial portion of the plan of care.

Referrals for social services may include those to providers of community mental health services, transportation providers, in-home support services, food banks, or other available community resources. Patients will vary in their needs for interaction with the social worker and may require referrals to other social services. Enhanced and more frequent social services interventions are expected for patients who present with or develop greater psychological, social, and/or financial issues.

The requirements for assessing patients' psychosocial needs are outlined at V510.

V553

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(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):

The patient plan of care must reflect the information from the IDT evaluation of the patient's suitability for and level of interest in home dialysis modalities required under the Condition for patient assessment at V512.

Patient records must demonstrate that each patient was informed about all available dialysis modalities and locations for home dialysis training if that service is not available at this facility (V458). If the patient expressed interest in home dialysis and was determined to be a suitable candidate, the plan of care should list use of this modality as a goal and identify ways to achieve it (e.g., timeline for training in home dialysis at the current facility, referral to a facility certified for home training and support). If the patient declines or is deemed unsuitable for home dialysis, the IDT must document the rationale for this decision.

V554

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(7) Modality. (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)

The patient's plan of care must reflect the information from the IDT's evaluation of the patient's suitability for transplantation referral, as required under Condition V513 for patient assessment.

In accordance with the requirements at § 494.70(a)(7): Patients' rights, the dialysis facility must inform each dialysis patient about all treatment modalities and settings when they begin their treatment. This includes discussions about transplantation. The patient record must show evidence that the patient was informed about transplantation as an option. Discussions about organ transplantation should include information on living and deceased kidney donation, Medicare-approved transplant program(s) in the geographical area, and each transplant facility's selection criteria. Each patient's record must reflect the IDT's determination regarding the patient's suitability and whether the patient accepted or declined referral for transplantation, along with the reason for non-referral.

If a patient is determined to be suitable for transplantation referral, the IDT must document the referral and provide applicable information to the transplant program as appropriate or when requested.

Documentation in patient records should agree with the patient's understanding of their status as a transplant candidate. Patients may contact a transplant program directly to schedule an appointment for more information and evaluation. If this is the case, the IDT should be aware of the self-referral. A patient's insurance coverage and a transplant program's selection criteria may dictate which transplant program(s) the patient can access.

V555

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(a) Standard: Development of patient plan of care. …The plan of care must address, but not be limited to, the following: **(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):

The patient plan of care must reflect the information from the interdisciplinary patient evaluation/assessment for rehabilitation status required at V515. The goals for the plan of care in this area must be individualized for the patient (e.g., returning to a former occupation, obtaining an educational certificate or diploma, resuming normal household activities, etc.) and reflect the patient's preferences.

Pediatric patient services should address normal growth and development needs, educational needs, and age-appropriate activities, especially if dialysis treatments occur during hours when the child would normally be in school. The social worker should be aware of the availability of community referral options for physical and vocational rehabilitation services for all patients, as well as educational resources for pediatric patients, if applicable for this facility. The IDT should have a plan and procedure for making referrals for rehabilitation.

The IDT must provide and document assistance (e.g., education, encouragement) and referrals, if indicated, which were aimed at enabling patients to maintain or return to their desired level of functioning at work, school, home and in their community.

V556

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(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) and (ii)

The IDT consists of, at a minimum, the patient/designee, a registered nurse, the qualified social worker, the qualified dietitian, and the patient's physician. Refer to the Condition for patient assessment at V501. The patient's level of participation should be controlled by the patient's (not the staff's) motivation; however, staff encouragement can improve patient motivation. Each patient's plan of care must show evidence of the participation/contribution from all of the professional members of the IDT.

Each team member is expected to sign the plan of care, including the patient. The patient's signature is to acknowledge the information in the plan. If the patient chooses not to sign their plan of care, the reason for refusal must be documented.

V557

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(b) Standard: Implementation of the patient plan of care. **(2) Implementation of the initial plan of care must begin within the [later][sic] 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)

The timeline for both the completion of the initial comprehensive assessment and the beginning of implementation of the initial patient plan of care is the later of 30 days from the date of admission or 13 hemodialysis treatments at the facility. Refer to V516. For patients who have more than 3 treatments a week, e.g., those on peritoneal dialysis or daily/nocturnal hemodialysis, the plan of care is expected to be completed within 30 days from the date of admission, excluding any days the patient is hospitalized during that period.

The plan of care should be dated to indicate when the plan was initiated. Although the plan of care must be initiated within the required timeline, the schedule for full implementation of the plan will vary depending upon the complexity of the plan.

In order for dialysis treatment to be initiated, each patient must have an initial dialysis prescription, orders for care, and baseline physical and nursing assessments before treatment is begun at the facility. See V715 under the Condition for medical director for this requirement.

V558

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(b) Standard: Implementation of the patient plan of care. **(2) … 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(b)(2):

Note: this guidance is a continuation of the regulatory requirement at § 494.90(b)(2).

As specified in the Condition for patient assessment at V519 and V520, when there is an interdisciplinary comprehensive reassessment of the patient, the plan of care must be updated accordingly and implementation initiated within this timeline.

Monthly updates of the plan of care are required for unstable patients, while annual updates are acceptable for stable patients. Refer to V520 for the minimum criteria for stable vs. unstable status.

The implementation of updates to the patient plan of care must be completed within 15 days of the reassessment.

V559

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(b) Standard: Implementation of the patient plan of care. **(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) and (iii)

If the current plan of care has not been successful in achieving the goals identified by and for the patient within the identified timetables, there must be evidence that barriers to achievement of the goals were identified and that the plan was reviewed and revised, as indicated. For example, if the patient's Kt/V is below the expected goal for more than one month, the physician or the non-physician practitioner might adjust the dialysis prescription by extending the treatment time or changing the dialyzer. If the patient's Kt/V remained below target the following month, the team should collaboratively identify the potential reasons the patient is not reaching the minimum goal for hemodialysis adequacy and implement changes in the plan of care to address and resolve the identified barriers. This example would not require a reassessment and completely new plan of care; if this is the only area where the goal was not met, the patient could be considered "stable," and only the plan of care for adequacy would require adjustment.
This requirement is not met if the patient's plan of care is not adjusted to reflect the patient's current condition and there is no evidence that the IDT is working to address ongoing problems (e.g., uncontrolled hypertension, hyperkalemia, missed treatments, inaccurate or unattainable target weight) which may result in adverse outcomes for the patient. This requirement is not satisfied if the only reason documented for failure to achieve goal(s) is "patient noncompliance" or "non-adherence." If the team believes the cause of the failure to reach the goal is non-adherence, the IDT efforts should focus on identifying potential causes of the non-adherence and addressing those causes. The IDT must recognize each patient has the right to choose less than optimal care when the patient determines optimal care would negatively impact their quality of life.

These regulations require the IDT to demonstrate its members are actively attempting to meet each patient's plan of care goals. This Condition does not "require" a patient to meet every goal. Any member of the IDT, including the patient, may document why goals are not met or cannot be met.

V560

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(b) Standard: Implementation of the patient plan of care. **(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):

This requirement ensures that patients see a medical practitioner (i.e., physician, advanced practice registered nurse or physician assistant) at least monthly. The patient may see the practitioner in the dialysis facility (before, during or after treatment), or in the physician's office. If the patient is seen in the physician's office, the record of care for that visit must be available in the patient's dialysis medical record.

"Periodically while the hemodialysis patient is receiving in-facility dialysis" refers to in-center patients and should generally result in at least quarterly practitioner visits at the dialysis center during dialysis treatment. By periodically visiting the patient in the dialysis facility, the physician has an opportunity to assess the patient's response to treatment and observe the team's care.

At a minimum, monthly medical progress notes should document that a physician or a non-physician practitioner (i.e., advanced practice registered nurse or physician assistant) has seen each patient, addressed their status, and reviewed their plan for renal and active comorbid problems.

A monthly visit is required for each home patient by either a physician, an advanced practice registered nurse, or a physician assistant. This visit may be conducted in the dialysis facility, at the physician's office, or in the patient's home (either in person or through telehealth).

Section 50302 of the Balanced Budget Act of 2018 amended sections 1881(b)(3) and 1834(m) of the Social Security Act to allow home dialysis patients the option to receive certain ESRD-related clinical assessments via telehealth. Effective January 1, 2019, home dialysis patients may choose to receive ESRD-related clinical assessments via telehealth. In order to receive clinical assessments via telehealth, the amendment requires the home dialysis patient to receive a face-to face clinical assessment (without the use of telehealth), i.e. "in person" visits, at least once a month during the initial 3

months of home dialysis; and then at least once every 3 consecutive months thereafter (83 FR 59452, 59495 (Nov. 23, 2018).

V561

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90(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) and (3)

Average waiting times for receiving a kidney transplant may be 3-5 years for most transplant programs, and even longer in some geographical regions of the country. The ability to receive a transplant will vary based on health, compatibility, and availability of organs. Requiring the facility to track patients' transplant referrals and their status on the transplant wait list is intended to enhance the communication and coordination between the transplant center and the dialysis facility so that patients do not get "lost" along the way in the transplant referral, evaluation, and waiting period.

Tracking completion of the tests and evaluations required for a transplant work up and waiting list active status is primarily the responsibility of the patient in partnership with the transplant center. However, by communicating and coordinating activities with the transplant center, the dialysis facility IDT may be able to adjust their plan of care to facilitate the patient's transplantation goal. This communication should be systematic and documented.

A "change in status" refers to a medical or psychosocial event that could either temporarily or permanently change a transplant patient's ability to receive a transplant. The "change" could either enhance or limit a dialysis patient's opportunities to receive a transplant. Examples of status change events include cardiac events, weight loss, cessation of smoking, patient death or identification of a new potential living organ donor. The transplant center should be notified at the time of any change in status.

The facility's patient transplant referral/waiting list status tracking may be centralized, but must also be documented in each referred patient's medical record.

V562

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.90**(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)

Patient education and training must be provided in a manner that both meets the patient's needs and addresses their preference for dialysis care and management. Each dialysis patient and/or their family member or caregiver must be offered the availability of information for each of the subjects within this requirement. While some subjects will apply to all dialysis patients, i.e. education on aspects of dialysis, including the dialysis experience, dialysis management, and infection prevention and personal care, others will apply to individuals on a case-by-case basis and determined by their needs and desires.

Based on their assessment and expressed interests, patients should be informed of their options for managing their renal disease, which may include education for in-center dialysis, home dialysis or self-care, physical rehabilitation services, palliative care, and/or transplantation. The scope of these discussions will be determined by the needs of the patient.

The IDT should have the skills and expertise needed to educate dialysis patients in these subjects, and to provide this education in a manner understood by the patient and family/caregiver.

Patients/designees must receive education regarding the types, risks, benefits and care of their vascular access, personal hygiene related to dialysis access, infection prevention, dietary and fluid management, etc. The patient's medical record must demonstrate the provision of patient education and training in the listed subject areas, as applicable. There may be a single form or section of the medical record for information on patient education or it may be located in various parts of the record, such as the progress notes of the members of the IDT.

V580

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100 Condition: Care at home.

Interpretive Guidance § 494.100:

This Condition applies to dialysis facilities that are certified to provide home dialysis services.. This Condition focuses on items that are unique to the home dialysis modality. All applicable ESRD Conditions must be met regardless of whether the setting is in-center or at home.

Condition-level noncompliance should be considered in, but not limited to, the following circumstances:

- *Serious or pervasive problems with the oversight of care or provision of services for home dialysis patient which has or could impact their health and safety;*
- *Patient and/or caregiver inadequately trained yet verified as competent in performing home dialysis procedures, resulting in poor clinical outcomes or adverse events;*
- *A pattern of failure to review clinical or technical lab reports and records; and,*
- *Insufficient monitoring of the water treatment system for home hemodialysis.*

V581

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100 – 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:

Home dialysis patients are considered part of the census of the ESRD facility and are entitled to the same rights, services, and efforts to achieve expected patient outcomes as the in-center dialysis patients of the facility. The requirements of 42 CFR part 494, including those listed at the Conditions for patients' rights, patient assessment, patient plan of care, and QAPI, apply equally to home dialysis patients and in-center dialysis patients.

Home dialysis patients include those receiving peritoneal dialysis (PD) and hemodialysis (HD) therapies at home. At the time of publishing these regulations (April 15, 2008, 73FR20369), there were:

1. *Two methods of PD routinely available to home patients: continuous ambulatory peritoneal dialysis (CAPD), and continuous cycling peritoneal dialysis (CCPD), also known as automated PD (APD); and,*
2. *Three methods of HD routinely available to home patients: conventional home HD (treatments generally 3 to 4 hours, 3 days a week), short daily home HD (2-3 hours, 5-6 days/week), and, nocturnal home HD (6-8 hours, 3 to 6 nights/week).*

At the time of publication of these regulations (April 15, 2008, 73 FR 20369), several different technologies for home hemodialysis were available. These included: conventional water treatment components and single-pass (conventional) dialysis machines; integrated systems which used manufacturer packaged, bagged dialysate or which incorporated water treatment and dialysate preparation and delivery into one system; and, sorbent-based systems which utilized columns (cartridges) of chemicals to

regenerate the used dialysate for recirculation through the dialyzer. All of these, and any future home hemodialysis technologies developed, present the home dialysis facility with both common and unique challenges for monitoring to ensure the continued efficacy and safety of the home hemodialysis patients' treatments.

The IDT as defined at V501 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 who meet the requirements as specified under the Condition for Personnel qualifications. Most home dialysis patients are active participants in their care and actively engaged with the IDT in their plan of care.

The medical records of home dialysis patients should contain evidence of the care and management aspects of patient assessment, plan of care development and implementation of that plan of care by the facility IDT as outlined in these regulations.

V582

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100**(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):

As defined at § 494.10, "home dialysis" means dialysis performed at home by an ESRD patient or caregiver (also called a helper) who has completed an appropriate course of training as described in § 494.100(a); "Self-dialysis" means dialysis performed in-center, with little or no professional assistance, by an ESRD patient or their caregiver who has completed an appropriate course of training as specified in § 494.100(a).

A certified dialysis facility approved for outpatient maintenance dialysis services needs no additional certification or approval to provide in-center self-dialysis or to teach an in-center patient to perform all or part of their dialysis treatment (e.g., self-cannulate, monitor blood pressure). If a patient expresses a desire to perform self-dialysis in-center, the facility IDT's response should incorporate an assessment of that patient for self-care training and planning for the goal of self-care, as appropriate. Refer to V512 under patient assessment. Any patient who performs aspects of self-dialysis care must be trained and verified as competent before independently performing any part of their care.

Home dialysis training must be provided, and the patient and/or caregiver must be verified as competent to perform home dialysis before they are allowed to function independently. Although it is expected that most training for home dialysis would take place at the facility, home training may be provided in the patient's home to meet the individual needs of the patient and/or caregiver. Retraining must be provided whenever there is a change in home dialysis caregiver, treatment modality, or home dialysis

equipment. Retraining may also be indicated if problems arise, such as repeated episodes of peritonitis, vascular access infections, or failure to achieve expected outcomes, including goals for dialysis adequacy and anemia management.

The dialysis facility may provide qualified staff members to assist patients in their homes with performing home dialysis treatments. The dialysis staff member functions in the role of the patient's caregiver and monitors the patient throughout the dialysis treatment. The dialysis facility maintains overall responsibility and oversight to ensure appropriate, qualified staff are assigned and trained. If the staff performing home dialysis treatments is a registered nurse or patient care dialysis technician, they must meet the personnel qualification requirements at §494.140.

All staff that assist patients in providing their home dialysis treatments must meet the practice requirements in the State in which he or she is employed. Performing dialysis-related activities in the role of a patient's designated caregiver would not negate the State-specific scope of practice laws and limitations that apply to a professional staff member.

V583

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.100(a) Standard: Training*. ... The training must— (1) Be provided by a dialysis facility that is approved to provide home dialysis services;**

Interpretive Guidance §494.100(a)(1):

For a dialysis facility to provide a home dialysis program, the facility must be approved for home dialysis services including both training and support. The facility may choose to apply for approval of peritoneal dialysis (PD) only, home hemodialysis (HHD) only, or both services. These services may be added to an existing facility. A new facility may apply for home dialysis services in addition to in-center services, or to provide only home dialysis services. The facility application for home dialysis should be directed to the State survey agency.
The CMS-3427 End-Stage Renal Disease Application/Notification, Survey, and Certification Report should be completed to indicate that the facility is approved for PD and/or HHD training and support.

V584

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.100(a) Standard: Training. ... The training must -* (2) Be conducted by a registered nurse who meets the requirements of § 494.140(b)(2); and**

Interpretive Guidance § 494.100(a)(2):

The nurse responsible for home dialysis training must: be a registered nurse who meets the practice requirements of the State in which he or she is employed; have at least 12 months experience in providing nursing care; and, have an additional 3 months of experience working as a nurse in the specific modality (hemodialysis or peritoneal dialysis) for which the nurse will provide patient/caregiver training. Refer to V685.

The self-care and home dialysis training nurse position may be filled by an employee or a contracted nurse who is a registered nurse and meets the clinical experience requirements at
§ 494.140(b)(2). This position is not required to be full-time. However, if the position is part-time, the facility should have qualified personnel assigned for all approved home modalities to answer questions, respond to patients' concerns and to troubleshoot problems when the home training nurse is unavailable.

While the qualified home training RN(s) is expected to be the primary staff member providing training and support whether training occurs in the dialysis facility or in the patient's home, other members of the clinical dialysis staff may assist in providing the home training, within the scope of practice and expertise/competencies of those staff members. For example, another nurse might reinforce earlier training done by the qualified home training RN; the dietitian might educate the patient about food and fluid limits based on the type of home dialysis treatment; the social worker might offer suggestions for keeping one's job or coping with any stress potentially created by home treatment; and, the biomed staff might coach the patient/caregiver in troubleshooting equipment. The qualified home training RN is responsible to ensure that allof the training is in accordance with the requirements listed in this Condition.

Use V685 for the failure to have a qualified nurse; use this tag if the qualified nurse is not primarily responsible for conducting the training.

V585

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(a) Standard: Training. ... The training must - **(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)-(viii):

The training must be individualized to the needs of each home dialysis patient. Patients and/or their caregivers may be trained in small groups or individually, as long as the individual patient needs are identified and addressed. The information provided should be tailored to the individual's level of understanding. Each of the subject areas listed here should be addressed in the training record. Examples for clarification of the subject areas are as follows:

The "full range" of home dialysis techniques would include:

1. *Specific (step-by step) instructions on how to use the patient's prescribed dialysis equipment (e.g. hemodialysis machine and water treatment components, peritoneal dialysis cycler);*
2. *Specific (step-by step) instructions in home dialysis procedures (e.g. self-cannulation, peritoneal dialysis exchange) to facilitate adequate dialysis as prescribed by the physician; and,*
3. *Training in proper storage and administration of ESAs, if applicable. Refer to V548 for anemia management requirements for home patients.*

Peritoneal dialysis patients must be taught to recognize, manage and report dialysis complications, including, but not limited to: catheter, tunnel or exit site infection; peritonitis; catheter dislodgement; hypotension; hypokalemia; failure of sufficient dialysate to drain from the peritoneal space; and, protein malnutrition. Home hemodialysis patients must be taught to recognize, manage and report such potential complications as vascular access problems (e.g., difficulty with cannulation, a change in bruit or thrill, bleeding), infections, hypertension or hypotension, hyperkalemia, etc.

Technical problems to be recognized, managed, and reported would include: power outages; failure of the PD cycler or HD machine; failure of water treatment components (e.g., chlorine/chloramine breakthrough); clotting of the hemodialysis circuit; dialyzer blood leaks; line disconnection; water supply problems or leaks; and, problems with supply delivery.

The facility training program should include instruction aimed at enabling patients/caregivers to detect, prioritize and report problems and to ensure that they are prepared to recognize and promptly act upon those situations which could present hazards to patient safety. Training home dialysis patients/caregivers to handle medical emergencies that may be anticipated (e.g., syncope, significant blood loss, cardiac events) would include immediate responses/actions and methods for contacting emergency medical systems. Refer to V768.

Training for non-medical emergencies may include those related to mechanical/technical equipment failures (as listed above), as well as preparing for natural or man-made disasters that may result in the inability to dialyze at home as scheduled and/or delays in supply delivery. Refer to V412.

Support services such as mentorship, renal community engagements, and ways to get answers, information, and other resources exist for individuals with renal failure. Patients need to understand how to contact and use their support resources, including access to their assigned facility staff coordinator, physician, home training nurse, dietitian, social worker, dialysis equipment suppliers, machine manufacturers, and water treatment personnel. As with in-center patients, facilities must provide home dialysis patients with contact information for the applicable ESRD Network and State survey agency.

Training for home patients to monitor their own health status should include: the use of equipment to monitor heart rate, blood pressure, temperature, and weight; assessment of vascular or peritoneal dialysis access; recognizing adverse signs and symptoms; and, when, how, and whom to contact if they experience problems with their health or treatment. Recording treatment and health status information for home dialysis patients includes documentation of the dialysis process, using hemodialysis or peritoneal dialysis specific treatment records.

Training for infection control precautions should include, at a minimum, indications for the use of gloves, masks, and other personal protective equipment, methods for hand hygiene, vascular access or peritoneal catheter care and dressing changes, cleaning and disinfecting dialysis equipment, and, cleaning and disinfection procedures for spills and splashes of blood or effluent. Patients/caregivers need to understand how to properly dispose of needles, effluents, disposable items, blood tubing, and dialyzers to minimize risks of infection or injury to self and others and to prevent environmental contamination (e.g. using impervious puncture resistant containers for disposal of sharps, placing empty dialysate bags and dialysis tubing and other contaminated items in intact plastic bags before discarding). The training staff must ensure that patients understand local waste management rules.

According to AAMI, as part of their training for home hemodialysis, the patient/helper should be instructed in any water/dialysate sample collection or any water/dialysate quality tests that they will be expected to perform in their homes. AAMI also states that the patient/caregiver shall be trained how to perform the chlorine analysis and shall be trained regarding what action to take if chlorine is detected above the specified limit. Depending upon the chlorine test used, the patient/caregiver should be capable of distinguishing between different shades of pink or a digital meter should be used to indicate the chlorine concentration. Digital meters should be calibrated to zero prior to testing to ensure accurate measurements.

Home dialysis training materials should address the training content listed in this regulation, at a minimum.

V586

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.100*(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):

Medical records should include documentation of the training provided, and evidence that the patient/caregiver demonstrated competence in performing the home dialysis procedures.

V587

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.100(b) Standard: Home dialysis monitoring. The dialysis facility must –* (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) and (3):

The dialysis facility must obtain and maintain records on all home patients including at a minimum, treatment records, flow sheets, medications administered, and, equipment and water treatment system checks, if applicable. The facility is responsible to ensure that records of dialysis treatments in the home setting are retrieved and reviewed by the appropriate personnel at least every 2 months. Such review assists staff in monitoring home patients' status by determining if patients are following their treatment plans and/or having problems with their dialysis at home. When home hemodialysis or peritoneal dialysis machines have the capacity for interactive electronic documentation of the treatment data, the facility may obtain these data electronically, if the security of the electronic submission is in accordance with HIPAA privacy regulations, or from the patient, through a disc/card brought to the facility.

Home dialysis patients' medical records must include dialysis treatment records and evidence of their timely review by home dialysis personnel. If the patient or caregiver has not provided the appropriate records at least every 2 months, reasonable efforts by facility staff to obtain these records must be made and documented. The patient's plan of care should address any problem with adherence to this requirement. The applicable facility staff member (generally either the nurse responsible for home training, the attending physician, or a non-physician practitioner [i.e., advanced practice registered nurse, or physician assistant]) is responsible for review upon receipt of such time sensitive information as hospitalization data and radiology, pathology, and laboratory results that cannot wait 2 months for review.

V588

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.100*(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):

Whether the home dialysis training facility provides the patients' home dialysis equipment and supplies, or the patient contracts with a DME supplier to obtain the equipment and supplies, the dialysis facility must provide all required support services to its home dialysis patients, as listed in the following tags, either directly or by arrangement.

A DME cannot provide home dialysis training or support services; these services must be provided by an ESRD facility certified for home training and support.

The ESRD facility should enter into an agreement with any individual nursing home for which they will provide dialysis services. The agreement should delineate the responsibilities and coordination of care between the ESRD facility and the nursing home regarding the care of the resident before, during, and after dialysis treatments.

V589

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.100*(c) Standard: Support services. (1) …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):

To assess a patient's home dialysis environment, a home visit should be conducted at the initiation of home therapy and whenever a problem is identified with either patient health or equipment that could be related to treatment at home. Periodic routine replacement of equipment would not necessarily require a home visit be scheduled. The IDT may designate the most appropriate staff member(s) to make the home visit(s).

Documentation of home visits should be included in the medical record. The number, timing, and frequency of home visits should be based on individual patient need as indicated in the patient's plan of care. Distance from the facility or concerns about staff safety should not preclude home visits. If a patient refuses a home visit, the IDT must evaluate their refusal and the potential impact it may have on achieving the goals

identified in the patient's plan of care as well as discuss alternative ways to ensure the patient's health and safety at home.

V590

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(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):

The home training and support facility must identify a specific member of the IDT to be responsible for the coordination of each individual home patient's care. "Coordination of the home patient's care" does not mean that the staff member must deliver all of the care, but may be the contact person on the IDT, be responsible for facilitating communication between the IDT and the patient/caregiver, and ensures oversight/and monitoring of the patient's home dialysis in accordance with the patient's plan of care.

All patients should receive coordinated/integrated care no matter which member of the IDT coordinates that care.

V591

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(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):

This tag should only be cited if there is no systematic care planning for home dialysis patients. While the home patient is expected to play a central role in the development and implementation of the plan of care, the development and review of the home patients' plans of care must meet the same standards as for in-center patients, which are addressed under the Condition for patient plan of care. Problems with individual plans of care for home patients should be cited at the applicable tags under that Condition.

V592

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(iv) Patient consultation with members of the interdisciplinary team, as needed.**

Interpretive Guidance § 494.100(c)(1)(iv):

The home dialysis patients must have access to members of the IDT (i.e. registered nurse, dietitian, social worker, physician treating the patient, as defined at V501), who must be available to provide clinical services as needed by the patient. The IDT should include the staff member who is responsible for the coordination of that patient's care. Contact may be in-person, by phone, by mail or by email with confirmation of patient receipt. The required minimum frequency of contacts may be defined by facility policy, but must meet the individual needs of each patient in accordance with their plan of care.

Note the requirements at V510 for initial and periodic evaluation of all patients by a qualified social worker and at V509 for evaluation by a qualified dietitian.

Stable home dialysis patients are not seen frequently at the dialysis facility. . The facility must have a policy regarding how the appropriate IDT member will consult with the home dialysis patient and to ensure that the home patient's dialysis care provided by the IDT is equivalent to in-center patients. Records of patient consultation by the physician must be documented in the patient's medical record at the facility. Because they are not frequently on-site at the facility, home dialysis patients may see their physicians in their offices instead of seeing their physicians at the dialysis facility. If patients see their physicians in the physician's office, there must be a system in place to transfer information related to the care of the home patient from the physician's office to the dialysis facility.

Note: The requirement at § 494.90(b)(4) (V560), which calls for at least monthly evaluation of all dialysis patients by a physician or another licensed practitioner is separate and distinct from any supportive patient consultations provided by an IDT member.

V593

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(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):

At the time of publishing these regulations (April 15, 2008, 73 FR 20369), several different technologies for home hemodialysis were available. These included: conventional water treatment components and single-pass (conventional) dialysis machines; integrated systems which used manufacturer packaged, bagged dialysate or which incorporated water treatment and dialysate preparation and delivery into one system; and, sorbent-based systems which utilized columns (cartridges) of chemicals to regenerate the used dialysate for recirculation through the dialyzer. All of these, and any

future home hemodialysis technologies developed, present the home dialysis facility with both common and unique challenges for monitoring to ensure the continued efficacy and safety of the home hemodialysis patients' treatments. Because of their differences, the Interpretive Guidance for the following tags (V593-V598) at times refers to one or more of the above-mentioned home hemodialysis technologies as related to the specific requirements and/or exclusions from certain requirements.

Hemodialysis in the home requires specific infrastructure and organization of plumbing and water. The facility home training staff must monitor the quality of water and dialysate used by home hemodialysis patients and conduct on-site evaluations of the home hemodialysis patient's water supply prior to selecting a water treatment system for home hemodialysis to ensure sufficient infrastructure is in place to deliver safe and effective dialysis treatments. Sufficient infrastructure should include, but is not limited to: water supply that can meet the temperature and water pressure demands, stable electrical supply to accommodate hemodialysis, and plumbing requirements to ensure appropriate fittings and installations.

There should be evidence the source water to be used meets the minimum requirements specified by the manufacturer of the water treatment components or of the integrated system, if such is in use. If the source water requirements are not met, there needs to be adequate pre-treatment of the source water to meet those requirements.

Each home water treatment system must include either an RO or a DI treatment component or alternate technology that achieves AAMI standards, and a method to remove metals and chemicals such as chlorine/chloramines.

According to AAMI RD52:2004/Annex C: Special considerations for home hemodialysis at C.3.1 Water supply, if the home is served by a small water system (serving less than 3000 persons), or one classified as an economically or socially-disadvantaged system (serving less than 500 persons), the water entering the residence is not regulated by the EPA Safe Drinking Water Act. Additionally, any municipal system may have received a variance, which can be granted by State drinking water programs for chemical contaminants. If the water is supplied from an individual well, the EPA standard may not be met.

Due to these variables affecting the regulation of the water supply to a home for safe drinking water standards, an annual analysis of the product water quality may not be sufficient. This is because the quality of water from the well can change over time, and private wells are not routinely monitored. More frequent analysis may be needed if the well is subject to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. The additional monitoring may not require a full AAMI analysis if only certain contaminants are known to be of concern.

The home patient's record must include review and acknowledgement of any problems with the source water, and a monitoring schedule for the source water. The patient's

physician should demonstrate awareness of any issues with the source water, and the plan of care should address any issues with source water for the home HD patient.

The home evaluation should address the storage of supplies, including dialysate concentrate(s). The storage area should provide a year-round environment that meets the manufacturer's recommendations for storing supplies.

For home water treatment systems, guidance is found under the Condition for Water and dialysate quality at V595, which highlights the recommendations in ANSI/AAMI RD52:2004: Annex C "Special considerations for home hemodialysis."

V594

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(v) …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) and (B):

The home dialysis facility is responsible for monitoring the quality of the water/dialysate used by home hemodialysis patients, as required by the manufacturer's recommendations and AAMI standards for the hemodialysis system. Water treatment systems for home hemodialysis patients must produce water that meets the AAMI standards and the requirements specified in § 494.40(a) of these regulations.

A chemical analysis of the product water must be done at the start of home treatment and at least once a year near the end of the usability of any disposable component, or when any modifications are made to the treatment components (other than the replacement of disposable components), to ensure that AAMI-defined maximum allowable chemical contaminant levels are not exceeded. If chemical analysis is not conducted as described here, refer to V201 for RO systems or to V206 for DI systems. According to AAMI, more frequent analysis than annual may be needed if there are seasonal variations in source water quality or if the source water is supplied from a well, as detailed in V593. When any repairs are made to water treatment equipment, the impact on water quality should be evaluated, and a chemical analysis should be performed if indicated.

Note: the requirements for in-center use of preconfigured systems are detailed at V276.

V595

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(v) …testing of the water and dialysate system in accordance with—(B)…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):

Chlorine/chloramine levels must be tested prior to the start of each treatment (or before use of each new batch of dialysate) in accordance with AAMI guidance and manufacturer's recommendations or instructions. An appropriate volume of water for the testing method in use should be tested for the presence of chlorine/chloramines. For batch systems (integrated systems that prepare enough dialysate for multiple treatments), the chlorine/chloramines testing shall be performed at the worst-case scenario, i.e., after the preparation of each batch of dialysate, but before use of that batch from a testing port that meets specifications of the manufacturer to be in compliance with the requirements of AAMI. If the test results exceed AAMI's maximum allowable level, the user must discard the batch, replace any applicable components, prepare a new batch of dialysate, and retest.

Recognize that systems that use sorbent technology do not produce water: the product of the sorbent cartridge is dialysate, thus the requirements for the chemical, bacteriological and endotoxin testing of water do not apply. With sorbent technology, due to the low volume of exposure of patients to water (i.e. 6 liters per treatment) and the capacity of the single-use sorbent cartridge to remove chlorine and chloramines, testing for chlorines and chloramines is not required. Sorbent system users are expected to perform bacteriological and endotoxin testing on dialysate.

The medical director must review the results of all water and dialysate cultures and endotoxin levels, and analysis of source and product water for chemical contaminants of each home hemodialysis patient. The facility must maintain documentation of the medical director's review, which should be incorporated as a part of the QAPI program review.

The results of water and dialysate testing for home hemodialysis patients may be included in the patients' medical records or in separate logs. According to AAMI, a log sheet should be provided by the dialysis facility and used to record all measures of water treatment system performance as required by the equipment manufacturer or the dialysis facility.

The ANSI/AAMI RD52:2004 "Dialysate for Hemodialysis" has been incorporated by reference into these regulations, as stated in § 494.40 Condition for Water and dialysate quality. CMS interprets this reference as inclusive of the "Amendment 1 to ANSI/AAMI RD52:2004: Annex C Special Considerations for Home Hemodialysis." This document addresses concerns particular to the home hemodialysis setting. Be aware that many of the provisions of RD52:2004, as outlined in the Condition for water and dialysate quality

at § 494.40, pertain to the home hemodialysis setting when conventional water treatment equipment is used for water purification. The review of conventional water treatment equipment should reference the requirements listed in that Condition for the specific components in use in the home setting. Additional pertinent recommendations from ANSI/AAMI RD52:2004 Annex C, which clarify specific home hemodialysis issues, are as follows:

C.3 Utilities
It is recommended that the utility companies providing water and power to the patient's home be notified that home dialysis is being performed at that location and that restoring service after any interruption should be a priority.

C.3.2 Drain
If the home has a septic tank, the septic tank should be able to process the volume of water from a drain [that is one inch or larger in diameter]. It may not be possible to perform nocturnal hemodialysis in a home with a septic tank since this tank may not be able to support the volume of water delivered to it over an extended period (8 hours). Another possible limitation is that the septic system will be exposed to disinfectant chemicals (bleach, peracetic acid, hydrogen peroxide, etc.) which may kill the bacteria needed for the septic tank to function.

C.5.2 Softener
Attention must be paid to setting the time for softener regeneration, particularly when daily nocturnal hemodialysis is being performed.

C.5.3 Carbon adsorption media
At least one carbon adsorption bed or filter should be installed even if the water supply is from a well and no chlorine is present. In addition to chlorine, carbon can remove organic contaminants from ground water, including solvents, pesticides, industrial wastes, and substances leaking from underground storage tanks. When water is obtained from a municipal water supply, two carbon adsorption devices connected in series and providing the equivalent of an empty bed contact time of 10 minutes, or some other process incorporating safety redundancy for chloramine removal, is recommended. A means should be provided to sample the water between the two carbon adsorption devices. If chlorine is not present in the water, the carbon should be changed on a routine schedule.

C.5.4 Reverse osmosis
Since the product flow rate will decrease with decreasing water temperature, a reverse osmosis system installed without a tempering valve to ensure constant feed water temperature may need to be oversized so that it will deliver the quantity of water required by the dialysis machine with the coldest anticipated water temperature.

C.5.5 Deionization
Deionization systems for home hemodialysis are not required to have a mechanism to prevent product water from reaching the point of use if the conductivity of the water is

one microsiemen/cm or more (specific resistivity of one megohm-cm or less). However, this feature is strongly recommended, particularly in situations where the water treatment system is not located in the room where dialysis treatments are performed or when nocturnal hemodialysis is being performed. If a diversion system is not installed, the patient must be trained to stop dialysis immediately if the conductivity/resistivity monitoring system alarms.

C.5.6 Treated water distribution

Because systems used for home hemodialysis operate intermittently, the distribution system should be designed and maintained to minimize bacterial proliferation. The reverse osmosis system should be disinfected at least monthly according to the manufacturer's instructions. The dialysis machine should be disinfected following each treatment according to the manufacturer's instructions.

C.6.2 Acid concentrate

The patient/caregivers should be trained to know that different hemodialysis machines use different proportioning ratios for concentrate and water and that they should ensure use of the correct acid concentrate for their hemodialysis machine. The acid concentrate used should be documented as part of the treatment record.

C.7 Monitoring

C.7.1 Water and dialysate quality

Sampling for microbiological testing should be performed before disinfecting the water treatment system and dialysis machine. To avoid disconnecting hoses, and opening the system to possible contamination, the system should be designed with the necessary sampling valves.

C.7.2 Equipment

C.7.2.1 General

A log sheet should be provided by the dialysis facility and used to record all measures of water treatment system performance as required by the equipment manufacturer or the dialysis facility. Measurements should be made at least 15 minutes after the water treatment system has been set in operation and before dialysis is initiated. Any alarm associated with a component of the water treatment system should be audible and visible in the patient treatment area. If any measure of water treatment system performance is found to be outside its acceptable range, the dialysis center should be notified.

C.7.2.2 Softener

When a softener is used, the water hardness should be monitored prior to each treatment using a sample obtained through a labeled sample port located between the softener and the reverse osmosis membranes. For hardness tests requiring color differentiation, the person performing the analysis should be able to distinguish between the colors of blue, purple, and red. If the person cannot differentiate these colors, an automated meter should be used.

C.7.2.3 Carbon adsorption media

The chloramine concentration shall be checked prior to each treatment. It may be more convenient to monitor total chlorine instead of chloramine. In that case, the acceptable level for total chlorine shall be 0.1 mg/L, or less. The patient/caregiver shall be trained how to perform the chlorine analysis, and shall be trained regarding what action to take if chlorine is detected above the specified limit. Depending on the chlorine test used, the patient/caregiver should be capable of distinguishing between different shades of pink or a digital meter should be used to indicate the chlorine concentration. Digital meters should be calibrated to zero prior to testing to ensure accurate measurements.

C.7.2.4 Reverse osmosis
Prior to each treatment, the performance of the reverse osmosis system should be monitored by checking the product water conductivity and percent rejection.

End AAMI recommendations.

The facility home hemodialysis staff should be familiar with the recommendations in ANSI/AAMI RD52 Annex C, and the facility policies, procedures and practice must reflect those applicable to the home hemodialysis systems in use.

The microbiological quality of the dialysate should be analyzed quarterly using cultures and endotoxin measurements, or more frequently, if indicated.

If integrated systems are in use, the dialysate should be tested for bacteria and endotoxins near the end of the usability of any disposable water treatment or dialysate components. If the patient uses manufacturer-provided bagged dialysate, cultures of those fluids are not required.

Refer to the Condition for water and dialysate quality at V178 and V180 for action and maximum allowable culture and endotoxin levels in water and dialysate. Results that are out of range require patient evaluation, notification of the patient's physician/medical director, and action taken per facility policy. Documentation should include culture/endotoxin results, physician and medical director notification of any abnormal levels, and a corrective action plan if results are out of range.

Records of results of chemical and microbial testing of home hemodialysis water and dialysate should be available in the home setting and at the dialysis facility providing support; the log of these results may be included the patient's medical record or in a separate record.

V596
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(v) …testing of the water and dialysate system in accordance with—**

(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) and (2):

If analysis of the water and/or dialysate quality indicates contamination (i.e. microbial action levels or maximum level(s) of chemical contaminants are exceeded), the facility should evaluate for possible sample contamination and at minimum, when the threat is low, re-test. If the threat is higher or the re-test remains positive, the facility must correct the water treatment and/or dialysate delivery (machine) system to ensure product water and dialysate meet AAMI standards for chemical levels and microbial counts.

When unable to make such corrections in time to allow home hemodialysis to resume within an acceptable time frame, the dialysis facility must arrange for back-up dialysis until the home system is corrected. If an integrated system is involved and all applicable disposable components are replaced, treatment may continue, with testing to continue per schedule.

If the patient exhibits clinical symptoms associated with water and dialysate contamination that cannot be readily attributed to other causes, the facility must arrange for back-up dialysis until the problem is investigated and resolved. Clinical symptoms for water/dialysate contamination may include, but are not limited to, chills, shaking, fever, vomiting, headache, dizziness, muscle weakness, skin flushing, itching, diarrhea, hyper/hypotension, hemolysis, and anemia. If such symptoms are present, the facility must notify the patient's physician/medical director to determine appropriate action (i.e., culture and treatment).

Facility policies must address, and responsible staff members (e.g., home training nurse, chief technician responsible for the home program, etc.) must be aware of what responsive and corrective actions they should take if microbial and/or chemical test results were elevated, or should a patient exhibit such clinical symptoms, including but not limited to referral for immediate patient evaluation and treatment by the patient's physician or a non-physician practitioner (i.e., advanced practice registered nurse, or physician assistant) and, possible arrangement for back-up dialysis, if needed, until the cause of the symptoms is identified and any problems with the home water treatment and dialysate delivery system are resolved.

V597

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(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):

The dialysis facility is responsible for the oversight and overall management of the home dialysis patient, including assuring that the patient is provided with functional prescribed equipment and supplies.

The dialysis facility or a DME supplier may be responsible for purchasing, leasing, renting, delivering, installing, and maintaining home dialysis supplies and equipment. If the dialysis facility or patient contracts with a DME supplier, there must be a written agreement between the DME supplier and the dialysis facility specifying the responsibilities of each. The dialysis facility is always responsible for oversight of the patient and the dialysis process.

Machines and equipment must be repaired and routine preventive maintenance completed in accordance with the manufacturer's recommendations. The facility should maintain records of preventive maintenance and repairs, even if performed by a DME supplier. If the facility staff members are responsible for performing the maintenance and repair on the home dialysis equipment, personnel file review should show evidence of training and competency verification for all of the different systems the facility maintains.

Some manufacturers use a system for exchange of malfunctioning equipment in lieu of maintenance. If so, documentation should detail what was done to refurbish the equipment used in exchange. This documentation might be a form or letter for each piece of equipment, or could be in the form of a policy or manual from the manufacturer detailing the extent of refurbishing done at each exchange. The facility should keep a log of the serial numbers of all equipment in use at patients' homes; these logs should be updated to reflect any exchange of equipment.

The preventative maintenance and repair logs for the equipment in use at patients' homes should verify the manufacturer's directions were adhered to for periodic preventative maintenance.

V598

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c) Standard: Support services. (1) …Services include, but are not limited to, the following: **(vii) Identifying a plan and arranging for emergency back-up dialysis services when needed.**

Interpretive Guidance § 494.100(c)(1)(vii):

The dialysis facility is responsible for identifying a plan and arranging for timely emergency back-up dialysis whenever needed by the home dialysis patient. Examples of

when back-up dialysis may be necessary include (but are not limited to): when the patient's home dialysis equipment is non-functional, the water quality is not within AAMI standards, the patient's medical conditions warrant a change in modalities, or, a PD patient requires peritoneal catheter replacement and temporary HD. Back-up dialysis should also be available in the event of the need for respite of either the patient or the caregiver.

The facility should assist each home dialysis patient in developing a personal disaster plan that identifies actions to take in the event of a natural or other disaster affecting their home treatment.

The dialysis facility must inform each patient/caregiver of the availability and location of back-up dialysis if equipment fails or if dialysis at home is not possible. The back-up dialysis plan should provide dialysis services that are equivalent to a certified facility.

V599

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.100(c)(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)(2):

The facility must maintain a centralized recordkeeping system for home dialysis patients, which includes documentation of patient assessments and plans of care, training and competency verification, patient monitoring, and records of machine and water treatment/dialysate delivery systems, the latter of which may be in a separate log.

Both the dialysis facility and DME supplier must have recordkeeping systems that are HIPAA-compliant and effective in assuring continuity of care. Concerns with patient privacy rules, e.g. facility practice on who can and receive health information, identified during a Federal health and safety survey will be referred to the Office of Civil Rights (OCR) for compliance review. The regulations for DME suppliers at § 414.330(a)(2) require the DME supplier to report all data for each patient regarding services and items furnished to the home patient to the supporting ESRD facility every 45 days; thus, there should be no issue with the DME supplier providing records within the 2 months allowed by these regulations.

Use this tag if deficient practices in the content or maintenance of home dialysis patients' records are identified. For major issues related to the home patient records, refer to V731.

V625

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 Condition: Quality assessment and performance improvement.

Interpretive Guidance § 494.110:

This Condition looks at facility aggregate data and requires facility-based assessment and improvement of care, while the plan of care Condition expects patient-based improvement of care.

Compliance with this Condition is determined by review of clinical outcomes data and the records of the quality assessment performance improvement activities of the facility, and by interviews of responsible staff including the medical director.

Noncompliance at the Condition level may be warranted if a pattern of deficient practices which could impact patient health and safety is identified. Examples include, but are not limited to:
• Absence of an effective QAPI program;
• Failure to recognize and prioritize major problems that threaten the health and safety of patients; or,
• Failure to take action to address identified problems.

V626

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 – 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:

The professional members of the facility's IDT which must participate in the QAPI activities, must, minimally, consist of a physician, registered nurse, social worker, and registered dietitian. This facility-based team is led by the medical director, who may also serve as the physician representative of the IDT. Each team member must meet the qualifications outlined in the Condition for personnel qualifications for their respective disciplines. The IDT must have effective communications and must produce effective quality assessment and performance improvement (QAPI) activities which positively influence their patient's outcomes. There must be an operationalized, written plan describing the QAPI program scope, objectives, organization, responsibilities of all

participants, and procedures for overseeing the effectiveness of monitoring, assessing and problem-solving activities.

The scope of the QAPI program must be facility-wide: all services provided must be included in the review (e.g., in-center, home hemodialysis, home peritoneal dialysis, reuse, central reprocessing, self-care). Data on current professionally accepted clinical practice standards must be used to track health outcomes, and the program must allow for identification, prevention, and reduction of medical errors, mortality, and morbidities.

If a facility has areas of QAPI that do not meet target levels or areas where the facility's performance is below average (as per data reports), the facility is expected to take action to improve those outcomes.

The important aspects of the QAPI program are: appropriately monitoring data/information; prioritizing areas for improvement; determining potential root causes; developing, implementing, evaluating, and, revising plans that result in improvements in care.

Records of QAPI activities including minutes or another method of demonstrating this analysis and action must be available for review.

V627
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 **(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):

An "ongoing" program continuously looks at indicators as they are available, trends outcomes and develops an improvement plan when indicated. Generally, this would require at least monthly review of indicators, since prescribed patient indicators are typically evaluated with laboratory results monthly and this serves as a functional time frame for trending of data within the facility.

"Indicators" or "performance measures" include at least those specified in this Condition, as well as measures of water and dialysate quality and safety, and safe machine maintenance. Performance expectations are based on current professionally-accepted clinical practice standards. Refer to the Measures Assessment Tool (MAT) provided which lists these and the CMS CPMs.

V628

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)**(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):

The facility's QAPI program monitors the assessment and improvement of care in the facility. CMS-generated data reports, including the Dialysis Facility Reports (DFR) are available to facilities to help them focus their QAPI improvement programs. Each facility should be comparing their performance with community-based standards and with other facilities in their State, their Network and the U.S. and working to improve their outcomes where needed. This comparative data is readily available to all facilities, whether they are corporate-owned or independent.

QAPI requires the use of aggregate patient data to evaluate the facility patient outcomes. Hemodialysis patients and peritoneal dialysis patients should be reviewed separately since factors affecting their clinical outcomes may be different; both groups of patients must be reviewed on an ongoing basis.

Data related to patient outcomes, complaints, medical injuries, and medical errors (e.g., clinical variances, occurrences, and adverse events) should be used to identify potential problems and to identify opportunities for improving care. Some common areas for dialysis care and facility operations that should be in the QAPI program for monitoring include, mortality, hospitalization rates, readmission rates, psychosocial assessment completion rates, water and dialysate quality monitoring, dialysis equipment maintenance, and equipment repairs.

Data should be analyzed by the IDT on an ongoing basis. Based upon the data review, the IDT should discuss the areas which need improvement and develop, implement, and evaluate a plan for such improvement. The facility may use broadly accepted, community-developed standards (e.g.,NKF KDOQI, AAMI) as indicators or performance measures associated with improved health outcomes. Where minimum outcome values have been determined, facilities are expected to provide care directed at achievement of at least the minimum outcome value by all patients. The IDT must work with individual patients who do not reach the target; this work must be reflected in the patient's plan of care for that outcome. Refer to the applicable tag under the Condition for plan of care for individual patient issues.

V629

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(i) Adequacy of dialysis.**

Interpretive Guidance § 494.110(a)(2)(i):
The intent of QAPI in addressing adequacy of dialysis is to maximize the number of patients who achieve the goals for adequate dialysis, which include both successful fluid volume management and clearance of toxins.

To identify opportunities for improvement and track progress in adequacy of dialysis for its hemodialysis and peritoneal dialysis population, the IDT should:

- *Review aggregate patient data;*
- *Identify any commonalities among patients who do not reach the minimum expected targets;*
- *Develop a plan to address those causes;*
- *Implement the plan;*
- *Monitor the effectiveness of the plan; and*
- *Adjust portions of the plan that are not successful.*

The IDT must use current professionally-accepted clinical practice standards as target values. Refer to the Measures Assessment Tool (MAT) provided which lists these standards. If a data report shows that the facility's ranking for hemodialysis adequacy is below the expected average, the facility must demonstrate QAPI review of global factors that might affect adequacy, e.g. missed/shortened treatments, less-efficient dialyzers, and failure to achieve the ordered blood flow rates.

V630

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(ii) Nutritional status.**

Interpretive Guidance § 494.110(a)(2)(ii):

The intent of QAPI in addressing nutritional status is to maximize the number of patients who achieve the goals for this area.

Serum albumin is a valid and useful measure of protein-energy nutritional status in maintenance dialysis patients. Serum albumin levels are commonly and extensively used to evaluate the nutritional status of ESRD patients; low albumin levels are highly predictive of mortality risk. Refer to the Measures Assessment Tool (MAT) provided, which lists current professionally-accepted clinical practice standards in this and other areas.

Serum albumin is affected by inflammation and other factors as well as by diet. The IDT may not be able to have a majority of its patients achieve the desired goal for this area, but should be actively intervening on actionable factors.

V631

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(iii) Mineral metabolism and renal bone disease.**

Interpretive Guidance § 494.110(a)(2)(iii):

The intent of QAPI in addressing the management of CKD mineral and bone disorder is to maximize the number of patients who achieve the goals for this area. Refer to the Measures Assessment Tool (MAT), which lists the current professionally-accepted clinical practice standards in this and other areas.

Since this area is heavily influenced by patient diet, it is critical that patient education, encouragement, and support be included in improvement plans for this indicator. The IDT should evaluate the efficacy of any standardized CKD mineral and bone disorder guideline or algorithm in use if facility QAPI goals in this area are not achieved over consecutive evaluation periods and other factors (e.g., transfers, new admissions, hospitalizations, discharges, recent access surgeries, or acutely ill patients) are not responsible.

V632

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(iv) Anemia management.**

Interpretive Guidance § 494.110(a)(2)(iv):

The intent of QAPI in addressing anemia management is to maximize the number of patients who achieve the goals in this area. Refer to the Measures Assessment Tool (MAT) which lists the current professionally-accepted clinical practice standards and CMS CPMs in this and other areas.

For anemia management, factors that should be tracked monthly for the facility's patient population as a whole include laboratory values for hemoglobin and hematocrit. If facility QAPI goals for anemia management are not achieved over consecutive evaluation periods, the facility IDT should conduct a review of: transferrin saturation (TSAT) levels, ferritin levels, and other iron indices; erythropoietin stimulating agent (ESA) doses and response to those doses; and, any evidence of blood loss, such as repeated episodes of insufficient rinseback of red blood cells or prolonged bleeding post treatment.

If the facility uses a standardized anemia management guideline or algorithm, the IDT should evaluate the efficacy of this tool if facility QAPI goals for anemia management are not achieved over consecutive evaluation periods.

Home and in-center patient outcomes may need to be reviewed separately by the facility in this area as the factors to be addressed may be different. For example, a home peritoneal patient may be reluctant to inject himself/herself with an ESA, resulting in lower values for this measure in the home population.

V633

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(v) Vascular access.**

Interpretive Guidance § 494.110(a)(2)(v):

The intent of QAPI in addressing vascular access is first, to improve the rate of use and preservation of fistulas; second, to decrease the inappropriate use of catheters; and finally, to improve the care provided for all types of vascular access.

To identify opportunities for improvement and track progress in management of vascular access for its hemodialysis population, the IDT must use a standard that has achieved broadly accepted use in the ESRD community. Refer to the Measures Assessment Tool (MAT), which lists the current professionally-accepted clinical practice standards and CMS CPMs for this and other areas.

Fistula survival may be affected by:

- *Cannulation technique problems such as frequent infiltrations related to training issues or individual personnel difficulties;*
- *Episodes of hypotension or hypovolemia; and,*
- *Differences in surgical outcomes.*

The QAPI program should include efforts to reduce the use of catheters and to reduce the incidence of infection related to catheter use. Requirements related to the care of catheters can be found under the Condition for infection control, at V146, V147 and V148.

V634

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(vi) Medical injuries and medical errors identification.**

Interpretive Guidance § 494.110(a)(2)(vi):

The intent of QAPI in addressing medical injuries and identification of medical errors is to minimize the number of occurrences and limit the number of patients and staff who are adversely affected by such occurrences. The medical injuries and medical errors that are captured in the facility's QAPI program may or may not be related to dialysis-related provisions of care. It is expected that the facility's QAPI program addresses those events related to dialysis care and dialysis facility operations. To maintain an effective QAPI program that aims to achieve measurable improvement, the facility should have mechanisms in place to identify medical events within the scope of the dialysis care and services provided.

The facility must compile and the QAPI team must review reports and complaints related to any patient or staff injuries, and treatment or medication errors. Part of the QAPI activity involves tracking any injuries or errors to identify the prevalence of occurrences, commonalities, and causes.

An example of medical injury is a patient fall at the end of their dialysis treatment. Information to identify any trends and detail the facility's response in terms of risk assessment and precautions in place to prevent future falls should be available. Similarly, occurrences such as treatment prescription errors, intradialytic morbidities, and staff needle sticks should be identified, reviewed and trended.

"Intradialytic morbidities" are any adverse symptoms that occur during the dialysis treatment, including but not be limited to seizures, chest pain, hypotension and cardiac arrest. Other events which should be tracked include hospitalizations, deaths, acute allergic-type reactions, blood loss >100 ml, and patient transfers by ambulance from the dialysis facility to a hospital emergency room.

The facility should collect and aggregate data regarding adverse occurrences, and there should be a mechanism to ensure all adverse events are recorded as soon as possible after they occur. The QAPI committee should analyze both isolated and repeated events in their review.

The following guidance can be used as guiding definitions for "error", "medication error", and "adverse drug event". These guidelines are intended for general guidance and should not be considered binding definitions.

"Error" is defined as the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning). An error may be an act of commission or an act of omission (Institute of Medicine, 2004).

"Medication error" is defined as any error occurring in the medication-use process (Bates et al., 1995). Examples include prescribing the wrong dosage, administering the wrong dosage of a prescribed medication, failing to administer (by the provider) or take

(by the patient) a medication, or administering a drug to which the patient is known to be allergic.

"Adverse drug event" is defined as any injury due to medication (Bates et al., 1995). Examples include a wrong dosage leading to injury (e.g., rash, confusion, or loss of function) or an allergic reaction occurring in a patient not known to be allergic to a given medication.

V635

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.**

Interpretive Guidance § 494.110 (a)(2)(vii):

If a facility has a dialyzer reuse program, it must comply with the quality assurance requirements specific to reuse, located at V360-368. These requirements outline periodic reuse processes and practice audits, which must be conducted and documented to ensure the reuse program remains safe and effective. Refer to the Measures Assessment Tool (MAT) for quality indicators related to the reuse of hemodialyzers.

The QAPI meeting minutes should demonstrate oversight of the reprocessing/reuse program and include at least summaries of the required reuse audits.

This tag is used to cite major problems related to quality assessment and performance improvement for the Condition for reuse. Use individual tags in the Condition for reuse of hemodialyzers for citations of specific or isolated issues in the required audits for quality assurance (V360-V368).

V636

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(viii) Patient satisfaction and grievances.**

Interpretive Guidance § 494.110(a)(2)(viii):

The intent of QAPI in this area is to use patient satisfaction surveys and patient grievance investigations as tools to identify opportunities to improve care. The survey should be non-threatening and be conducted in a manner to protect the patient's identity. QAPI discussion of patient satisfaction survey results and patient grievance information should focus on the use of data to inform the care delivery system. If needed changes are identified, there should be evidence of action taken to implement those changes.

Facilities must monitor and track patient grievance reports and outcomes as required at V765; use that tag for issues related to responding to individual grievances.

The In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) survey instrument, a standardized tool for assessing the care experience of in-center hemodialysis patients, is now available for use. In 2007, the National Quality Forum (NQF), an organization established to standardize health care quality measurement and reporting, formally endorsed measures from the ICH CAHPS. More information about the ICH-CAHPS survey can be found here: https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/ICHCAHPS

V637

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110 (a)(2) – The program must include, but not be limited to, the following: **(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) and (C):

The intent of QAPI in addressing infection control is to minimize the number of patients and staff who are exposed to or acquire infectious diseases at the facility.

The facility must record and follow up on all patient infections and serious adverse events. The occurrence of these events should be recorded in a centralized logbook or other tracking mechanism and regularly reviewed, with documentation of the actions taken. Surveillance information available for review should include, but not be limited to: patients' vaccination status (Hepatitis B, pneumococcal pneumonia, and influenza vaccines); viral Hepatitis serologies and seroconversions for HBV (and HCV and ALT, if known); bacteremia episodes; pyrogenic reactions; vascular access infections; and vascular access loss due to infection.

Surveillance information generally includes at a minimum, the date of infection onset, site of infection, full identification of infecting organism(s), and antimicrobial susceptibility results.

Responsible staff should review the results of all routine and diagnostic testing (including culture and serology) upon receipt and ensure that the medical director periodically reviews recorded episodes of bacteremia, vascular access infections, soft tissue infections, and other communicable diseases to aid in tracking, trending, and prompt identification of potential environmental/staff practices issues or infection outbreaks

among patients. It is important to identify the method of transmission whenever possible as well as the immune status of affected and at risk patients. Appropriate State or local public health officials should be notified of viral Hepatitis seroconversions and other infectious diseases, and clusters of adverse events that occur among patients in the facility.

The analysis of patient infection incidence during the periodic QAPI meetings may not be sufficiently timely for identification of an outbreak of infections. Tracking of infections and serious adverse events must be done on an ongoing basis to ensure the safety of the patients.

Actions taken by the facility must be appropriate to the degree of risk to patients and staff. Actions could include: in-service training in infection control; implementation of different protocols for cleaning equipment between uses; and audits of practice regarding infection control precautions for dialysis settings.

Information in this area may be recorded separately or incorporated into the QAPI documents; either method is acceptable, as long as review and analysis of the information collected is apparent.

As infection control indicators are developed, refer to the Measures Assessment Tool (MAT) for a list of the current standards of practice.

V638

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.110(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):

To "continuously monitor" a facility's performance requires that outcome data, achievement of treatment goals, adverse events, infections, falls, errors, etc. be monitored as this data is available or these events occur. Tracking and trending, analysis of root causes, development of improvement plans, implementation of those plans, evaluation of the success of the plan, and revision of the plan should occur as indicated.

Once improvement is made, the facility must have a mechanism to ensure that improvement is sustained. This could include practice audits, review of records, or repeat patient satisfaction surveys, etc.

The medical director should continuously communicate with the governing body about the status of QAPI activities, particularly when resources are required to address program improvements. See V756. If the medical director is a part of the governing body,

there should be some evidence they provide information to members who do not participate in the QAPI meetings. The minutes of the governing body or the minutes of the QAPI committee should demonstrate communication between the governing body and the medical director.

Refer to V756 for the requirements related to the responsibilities of the governing body for QAPI.

V639

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.110(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):

Each fiscal year, CMS generates a Dialysis Facility Report (DFR) for each Medicare-certified dialysis facility. The DFR serves as a resource for characterizing selected aspects of clinical experience at a given facility relative to other caregivers in the state, ESRD Network, and across the United States. Since these data could be useful in quality improvement and assurance activities, the facility could incorporate CMS-generated data reports, along with data reports that the facility produces, to identify all areas needing improvement. Performance improvement areas should be prioritized, ranking those that have potential to affect patient health and safety as more urgent than those that do not have such potential. In setting priorities, the prevalence and severity of the identified problems must be considered.

V640

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.110(c) – Standard: Prioritizing improvement activities*.…The facility must immediately correct any identified problems that threaten the health and safety of patients.**

Interpretive Guidance § 494.110(c):

Examples of conditions which could pose a threat to the health and safety of dialysis patients and require immediate correction include, but are not limited to:

- *Dangerous levels of contaminants in product water;*
- *Unsafe levels of electrolytes in dialysate;*
- *Failure to conduct an accurate pre-assessment;*
- *Setting an inaccurate fluid removal rate;*
- *Failure to provide adequate observation of patient, patient vascular access,*

patient equipment;

- *Defective clinical equipment;*
- *Failure to adequately disinfect reprocessed dialyzers; Failure to reduce residual germicides in reprocessed dialyzers to safe levels;*
- *Lack of qualified staff to perform crucial tests or to meet critical patient needs;*
- *Evidence that staff assigned to perform crucial tests or to meet critical patient needs are not competent;*
- *Potential for cross-contamination between infected and non-infected patients; and,*
- *Failure to use machine-provided safety devices (muting machine alarms, bypassing the air detector, etc.).*

The facility must take immediate, appropriate actions to address any serious threats and ensure patient health and safety.

V660

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.120 Condition: Special purpose renal dialysis facilities.

Interpretive Guidance § 494.120:

This Condition outlines the requirements for dialysis facilities that provide care to patients who need dialysis on a short-term basis because of emergency conditions or because they are staying at remote vacation camps. These "special purpose renal dialysis facilities" (SPRDFs) require a special CMS certification. Due to the limited scope of requirements for SPRDFs, this certification may not exceed 8 months in any 12-month period of time. If rehabilitation efforts are anticipated to take longer than 8 months due to emergency circumstances and the extent of damages, considerations should be given on the impact on patient safety and health prior to issuing any extension to a SPRDF.

If a special purpose renal dialysis facility chooses to be certified as an outpatient dialysis facility, it must go through the initial enrollment and certification process, which includes receiving full initial certification survey to determine compliance with all applicable Conditions for Coverage (CfCs).

This Condition only applies to SPRDFs; it provides information about the availability of this special certification and defines which of the regulatory requirements included in the other CfCs are required to be met by each type of SPRDF. Deficiencies would be cited under each of the applicable Conditions and Standards that are outlined for either the vacation camp or the emergency circumstance facility. This Condition would be cited in the event a facility that applied as an SPRDF did not meet the requirements for that designation. Other Conditions and Standards would also be cited in that situation.

V661

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.120 – 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:

"Vacation camp" SPRDFs are temporary vacation locations that provide (and bill for) outpatient hemodialysis treatments at the camp site. Camps that transport hemodialysis patients to local certified outpatient facilities for dialysis are not considered SPRDFs and do not need to be certified separately to accept the campers as transient patients. Camps that provide only peritoneal dialysis on-site are not required to be certified, as the treatment provided would be considered a "home" treatment.

"Emergency circumstances" for SPRDF applies to a natural or manmade disaster that prevents the use of established dialysis facilities, and applies to a patient or group of patients who cannot otherwise be served in an area. The most common use of certification as an emergency SPRDF is when the usual treatment facility(ies) are incapacitated by weather-related emergencies causing disruption to electrical service, water supplies, or vehicular access. However, a Medicare-approved hospital, long-term care facility, or other provider could request SPRDF certification to provide dialysis to one or more patients that are denied outpatient dialysis by all dialysis facilities within reasonable driving distance because of medical complications (morbidly obese, bedbound, respirator-dependent, tracheotomy requiring frequent suctioning, etc.) or a history of disruptive or threatening behaviors.

In the event a new ESRD facility which has not yet been certified is granted an emergency SPRDF certification, that facility would need to undergo an initial survey for full certification within the 8 month SPRDF certification period in order to continue services and to expand its census beyond those patients who could not otherwise be served in that geographic locality.

V662

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.120(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):

The maximum period of certification is 8 months in any 12-month period. Vacation camps generally operate on a seasonal period, for example a summer camp for children with renal disease. A vacation camp may apply for its special purpose designation one or more times in any given year, so long as the facility is not certified as a SPRDF for more than 8 months in any 12-month period.

Facilities applying for an SPRDF emergency designation in order to accommodate longer term dialysis for patients who are unable to be placed in an outpatient facility must recognize the time-limited nature of this certification and the fact that admissions are limited to those patients who were unable to obtain outpatient dialysis elsewhere in the area. This type SPRDF may also reapply for certification in the following (or any subsequent) year.

V663

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.120*(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):

An SPRDF is to provide care that would not otherwise be available in that geographic area. In the case of vacation camps, the "geographic locality" factor is related to minimizing the time that the patient would be away from camp activities. There may be a dialysis facility within driving distance, but dialysis treatment would take the camper away from the camp activities.

In the case of emergency circumstance facilities, the intent is to temporarily provide service until permanent arrangements are possible (not to exceed the certification limitations under § 494.120(a)).

An SPRDF established to provide care to patients with medical or psychosocial needs which cannot be met in a standard outpatient dialysis setting should define the population it intends to serve in its admission criteria and include in those criteria the lack of outpatient dialysis service for these patients within the geographic area.

No Tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.120*(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):

This is an informational tag. The sections of the regulations listed here outline the survey of a vacation camp SPRDF. If deficient practices are identified, appropriate tags under the referenced regulations should be used to identify deficiencies.

A vacation camp SPRDF must be affiliated with a certified outpatient dialysis facility but will have its own unique CMS certification number (CCN).

Because the SPRDF for a vacation camp will provide service on a temporary basis, it must meet only the specified portions of these regulations.

Note: Due to the limited scope of requirements for SPRDFs for a vacation camp, surveyors should review the regulatory language to verify which requirements would not apply to the special purpose facility.

No Tag

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.120**(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 in any 12 month period.

Note: Due to the limited scope of requirements for SPRDFs for emergency circumstances, surveyors should review the regulatory language to verify which requirements would not apply to the special purpose facility.

V666

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.120*(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):

The facility must contact the patient's physician prior to initiating care in the SPRDF to update that physician on the status of the patient and to coordinate the patient's plan of treatment. In the event of a natural disaster, the facility must make every effort to contact the patient's physician; however, when it is impossible to contact or communicate with that physician, emergency dialysis care must be provided. In this situation, the SPRDF should have standard orders for dialysis, diet/fluids, and medications that the medical director of the SPRDF could prescribe until they communicate with the patient's attending physician.

V667

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.120*(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):

Care in any SPRDF should be documented at the time it is delivered and sent to the patient's permanent facility within 30 days of the last treatment provided by the SPRDF. Additional time may be needed for the transfer of documentation of care in the event of a natural disaster. For example, if a patient's original facility was destroyed and not rebuilt, the documentation transfer may be delayed or even impossible.

Hospitals or skilled nursing facilities that obtain an emergency circumstance SPRDF designation to care for patients with medical or psychosocial needs that cannot be met in a standard outpatient dialysis facility may choose to maintain the original record of care at the SPRDF and forward copies of requested portions of the record to another treatment setting that will be receiving the patient for care. In this case, the records would be expected to be transferred within one working day. Refer to V733.

V675

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.130 Condition: Laboratory services.

Interpretive Guidance § 494.130:

This Condition describes the requirements for clinical laboratory services required to meet the needs of ESRD patients.

Compliance with this Condition is determined by clinical record review and if indicated, staff interviews and review of agreements.

Examples of Condition level noncompliance include, but are not limited to:

1. *The laboratory being used is not CLIA certified; or*
2. *Serious and pervasive problems persist in the methods for collecting and handling the specimens drawn for laboratory analysis.*

V676

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.130 **– 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

Under Clinical Laboratory Improvement Amendments of 1988 (CLIA), laboratory services can only be provided by an appropriately certified laboratory. Arrangements

with these providers must be in writing and signed and should specify: the types of laboratory tests to be performed; methods for collection and handling the specimen(s); and, delivering results, including a timeline for reporting of "alert" (sometimes called "panic") values to a responsible person.

Many facilities have agreements with distant laboratories for routine services; there should also be a provision for service from a local laboratory for time-sensitive testing.

The dialysis facility may provide some testing directly. Generally, this is limited to CLIA-waived tests, such as for blood glucose determinations obtained by blood glucose monitoring devices cleared by FDA specifically for home use, and for stool testing for occult blood.

HLA Laboratories performing Panel Reactive Antibody (PRA) testing for patients on the transplant waitlist must have a "regular" CLIA certificate of compliance or certificate of accreditation which allows the laboratory to perform high-complexity testing.

Laboratory reports should be included in facility records and should include the patient's name and identifier, the date and time the specimen was taken, and the name and address of the laboratory performing the test. Facility policies should address methods for specimen collection, especially pertaining to post-dialysis samples for dialysis adequacy testing to ensure accurate results.

Subpart D- Administration

V680

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140 Condition: Personnel qualifications.

Interpretive Guidance § 494.140:

This Condition defines the qualifications of dialysis facility staff and lists the minimum required content for patient care technician training programs.

Compliance with this Condition is determined primarily by review of medical staff and personnel credential files, educational programs, and policies and procedures for determining "competency" of the various staff members. Facilities must maintain current documentation to demonstrate personnel meet the basic requirements of their assigned roles, including any State specific requirements. When patient or staff interviews or observations of practice raise concerns about competency, the survey process may become more focused to ensure staff members are competent to perform assigned duties and to fulfill their roles in providing safe and effective patient care.

Examples of Condition level noncompliance would include, but not be limited to:

1. *Required IDT member(s) do not meet the qualifications listed,*
2. *Serious or pervasive problems with qualifications and/or competency of the direct care staff, including the patient care technicians.*

V681

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140 **– 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 § 494.140:

All dialysis facility staff, including non-physician practitioners (whether employee, contractor, or credentialed as a member of the medical staff), must meet the applicable qualifications, scope of practice, and board and licensure requirements in effect in the State in which they are employed. All staff members are expected to practice within the licensure and/or certification requirements for their degree, practice setting, and scope of practice as defined by their individual State.

All facility staff must be able to demonstrate competency required to serve the complex needs of dialysis patients and must have the ability to sustain and demonstrate the skills needed to perform the specific duties of their positions. Each facility is expected to determine how each staff member will demonstrate competency. Specific competencies expected to be able to be demonstrated by staff assigned to these tasks include, but are not limited to: skills at testing for chlorine/chloramine levels; operating reuse equipment; following infection control practices designated for dialysis facilities by CDC; identifying and treating intradialytic morbidities, and monitoring patients and equipment alarms during treatment.

V682

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140**(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):

"Board-certification" is a voluntary process by which a physician (or other professional) demonstrates advanced knowledge and skills that go beyond mandatory state licensing

requirements. The process for initial and continuing board certification is specified by the individual board. Board certification is recognized as an accepted industry standard for evidence of proficiency in a specialty. Nephrology is a specialty that requires specialized knowledge and training. Health and safety standards for outpatient dialysis facilities require that each dialysis facility have a medical director who is, among other things, board-certified in internal medicine or pediatrics by a nationally recognized professional board.

The CfC requirements specify that the professional board must be nationally recognized in internal medicine or pediatrics. Currently, there are several recognized professional boards that certify physicians. Medical boards are independent organizations that establish common standards for physicians to achieve and maintain the board's certification. To be considered board-certified, a physician must successfully achieve initial board certification, which is most commonly obtained through a board certification examination. Once an individual is board-certified, they maintain their certification by demonstrating compliance through a Maintenance of Certification (MoC) program, or a comparable pathway for continuous certification.

The medical director must be board-certified in internal medicine or pediatrics by a nationally recognized professional board. The regulatory requirement is not explicit on the particular board from which the certification must be obtained, however, the "board" that is certifying the physician must be a nationally recognized professional board:

1. ***Nationally Recognized**: The professional board by which the medical director is certified is well-known, prominent, and widely recognized by entities across the United States that serve the dialysis population, e.g. The American Board of Pediatrics (ABP).*
2. ***Board-certified**: The medical director's board certification status must be current and active.*
3. ***Professional**: The composition and governance of the individuals who are appointed to serve on the board represent a broad range of experience in patient care, quality improvement, health policy, and education.*
4. ***Verification**: The physician must have a valid, unrestricted license to practice medicine in the state where they are employed. Additionally, health surveyors must verify that the information received for credentialing is accurate. Verification can be performed by interviewing the individual(s) who oversee the facility's credentialing process. Like all dialysis facility staff, medical directors must also meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed.*

Board certification through a particular organization may be evaluated on a case-by-case basis by CMS to determine whether it is a nationally recognized professional board for the noted specialties. This may include a review of whether its standards meet or exceed those of the current nationally recognized boards.

V683

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140(a)**(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):

If the facility is using a physician as medical director who does not meet the requirement at § 494.140(a)(1), there must be documentation available that the Secretary of HHS approved the facility's use of the physician as medical director.

An on-site survey is not required to determine the approval or denial of a medical director waiver request. A desk review may be conducted and CMS should evaluate all materials submitted by the dialysis facility when reviewing and processing a waiver request. Reference State Operations Manual, Ch. 2, Section 2281B for additional information on the review of a medical director waiver request.

V684

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140**(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)-(iii):

"Responsible for nursing services" means the nurse manager provides oversight and direction to all direct care staff that provide dialysis and nursing care in the facility, including but not limited to, input into hiring, evaluating, and terminating these staff.

The nurse manager is the only staff person who must be a direct employee of the facility rather than a contracted employee, e.g. person for whom the facility files a W-2 Tax Form, supervises nursing staff in the dialysis facility, oversees nursing care, makes management and budgetary decisions, etc.

"Full-time" means the nurse manager is available to work in the dialysis facility the number of hours that the facility is open or as facility policy requires for full-time employment. For example, a dialysis facility that is only open for 24 hours a week would need to employ the nurse manager for 24 hours a week to satisfy this requirement. If the facility is open 6 days a week or provides nocturnal dialysis, the nurse manager would

need to be available to work at least 40 hours a week, and provide on-call coverage, in rotation with other qualified staff, all hours that the facility is open, including night and weekend hours.

The nurse manager must be registered and licensed to practice in the applicable State. They must have at least 12 months experience as a registered nurse, and an additional 6 months experience as a registered nurse providing clinical nursing care to patients on maintenance dialysis, in either a chronic or acute setting.

The same registered nurse(s) who meets these requirements may fulfill multiple nursing roles in the dialysis facility as long as the facility has an adequate number of qualified nurses present while patients are dialyzing to meet patients' clinical needs for the level of dialysis care provided. Refer to V758.

V685

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140(b)**(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) and (ii):

The requirement at §494.100(a)(2) requires the home training to be conducted by a registered nurse. "Responsible for …training" means that the registered nurse must be in charge of and provide self-care and home dialysis training for dialysis patients and/or their caregivers. A staff member, other than the registered nurse responsible for home training, may re-educate the patient on certain portions of the training program. In these situations, delegated tasks may not be new material and the delegated task(s) must be consistent with the scope of practice laws and limitations set by the State in which they practice. For example, due to the specialized training that a PCT receives in the operations of a dialysis machine, they may provide the home dialysis patient additional education for cleaning the machine and how to respond to alarms.

Additionally, the registered nurse that is responsible for the home training program must maintain oversight of any delegated portions of the training program to ensure training activities are consistent with facility policies.

For example, the home training nurse
The registered nurse responsible for self-care and the home dialysis training must have at least 12 months experience as a registered nurse, plus 3 months experience as a registered nurse in the specific modality of hemodialysis (HD) and/or peritoneal dialysis

(PD). If one registered nurse is responsible for both the HD and PD programs, that nurse must have 12 months experience as a nurse plus at least three months experience in each respective modality.

V686

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140(b)**(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) and (ii):

There must be one or more designated charge nurses responsible for each shift. If the charge nurse is a registered nurse, they must be registered and licensed to practice in the applicable State where they are employed. If the person functioning as the charge nurse is a licensed practical nurse (LPN) or licensed vocational nurse (LVN), they must be legally authorized to practice as a LPN or LVN in that State.

A charge nurse must have a minimum of 9 months of nursing care experience, and an additional 3 months of specialized experience (to total 12 months) providing clinical nursing care to dialysis patients, in either a chronic or acute setting where maintenance dialysis is administered. The charge nurse position may be filled by a full-time or part-time employee or a contracted nurse who meets these qualifications.

V687

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140(b)(3) Charge nurse. The charge nurse responsible for each shift must**— (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):

A licensed practical/vocational nurse may only assume the role and responsibilities of the charge nurse of a dialysis facility if they have received specific authority from the applicable State board of nursing. CMS did not intend for, and State boards of nursing may prohibit, a licensed practical/vocational nurse supervising a registered nurse.

An LPN/LVN cannot be the only licensed person in a dialysis facility while patients are on dialysis. Refer to V759 which requires a registered nurse to be present whenever in-center patients are being treated.

V688

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140(b)**(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):

Each nurse must have the required State license (refer to V681) and meet any practice requirements for the applicable State.

V689

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140**(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):

The Commission on Dietetic Registration is the credentialing agency for the American Dietetic Association. Dietitians working in dialysis must have evidence of registration with that organization.

V690

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140(c) Standard: Dietitian. The facility must have a dietitian who must**— (2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian;**

Interpretive Guidance § 494.140(c)(2):

The registered dietitian must have one year of professional work experience in clinical nutrition after registration as a dietitian. Experience in clinical nutrition as an intern (prior to registration) would not count toward this requirement, nor would foodservice experience after registration as a dietitian meet this requirement.

V691

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140**(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) and (2):

The social worker employed by a dialysis facility must either:

1. *have a master's degree in social work from a college or university that is accredited by the Council on Social Work Education (CSWE); or*
2. *meet the 1976 experience criteria.*

The CSWE website provides a directory of accredited master's-level social work degree programs.

Licensure requirements for master-prepared social workers in clinical practice vary from state to state. The master's prepared social worker must meet the licensure requirements in the state of practice. Refer to V681. The Association of Social Worker Boards (ASWB) maintains information about social work regulations and State licensure requirements in each State. This online database features reports developed by ASWB to provide an understanding of social work regulations across states and provinces.

The curriculum of masters-level programs in schools accredited by the CSWE is tailored to the candidate's chosen career goals and area of specialization. Their education program includes courses in human behavior, family dynamics, diagnosis, mental health treatment, conflict management, and ethics. Therefore, any one whose degree is from a school accredited by the CSWE is presumed to have a "specialization in clinical practice."

Staff who do not meet the 1976 experience criteria, e.g. bachelor's prepared social workers, may function as assistants under the supervision of the qualified social worker. Non-MSW social workers that function as assistants to the MSW may provide entry-level services, for example: assisting with transportation arrangements; providing information and helping patients apply for Medicare, Medicaid and other insurance benefits to ensure payment for care; and locating resources to assist in payment for adequate nutrition, housing, and medications. Bachelors-prepared social workers functioning as assistants to the MSW may not perform social work duties specified by the CfCs, for example: assessment of psychosocial needs, develop psychosocial plans of care, provide counseling to patients and families, evaluate family and other support systems, and participate as the social worker in the facility's QAPI program.

The grandfather clause at § 494.140(d)(2) applies to very few social workers, as it only applies to those social workers who have worked in dialysis or transplant facilities since September 1, 1975, and who had at least two years of social work experience on September 1, 1976, when the original ESRD Conditions for Coverage became effective.

Any ESRD social workers who do not have 2 years of experience prior 1976 must have a master's degree in social work.

The qualified social worker, through this grandfather clause, must have a consultative relationship with a master's-prepared social worker. A "consultative relationship" can be demonstrated through a written agreement that outlines the established relationship between the two professionals. The agreement should include any supervision responsibilities, training, and mentoring opportunities. In this instance, a non-MSW social worker remains accountable for all aspects of their professional judgement, assessments, and decisions. They are expected to consult with the MSW when additional knowledge and skills are required to address a dialysis patient's needs.

V692

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.140*(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) and (2):

A "patient care (dialysis) technician" (PCT) means any person who provides direct care to patients and who is not classified as another professional, e.g., nurse, dietitian, or social worker. A biomedical technician or dialysis assistant would be classified as a PCT if they have responsibility for direct patient care or to set up machines for patient use. A technician who maintains or "takes down" machines after use without direct patient contact is not considered a PCT under these regulations.

PCTs must meet requirements of the applicable State for education and training to provide patient care in dialysis facilities, including any State requirements related to practice standards, certification or registration.

V693

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.140(e) Standard: Patient care dialysis technicians. Patient care dialysis technicians must*— (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):

There must be a training program for patient care dialysis technicians (PCTs), approved by the medical director and governing body and directed by a registered nurse. The training program may be conducted at the facility or at another location. Successful completion of a training program provided outside of the hiring facility, e.g. community or corporate-based programs are acceptable if the program is consistent with the requirements at this standard, i.e. the required components are included; the program is under the direction of a registered nurse; and, the program has been approved by the medical director and governing body.

All PCT's who are not yet certified under a State certification program or a national commercially available certification program (V695) must have successfully completed the approved training program before independently providing patient care. "Successfully completed" means the PCT will have completed all didactic portions of the course and demonstrated competency in the knowledge and skills provided by the training.

Experienced PCTs (i.e. employed as a PCT for more than 2 years), who do not have documentation of having completed a training program in accordance with the specifications at § 494.140(e)(3), may still satisfy the requirement by:

1. *Successfully completing a facility's written exam(s) over the required content, and*
2. *A skills checklist completed by observation of the PCT's skills by a registered nurse.*

Successful completion of these exam(s) and competency testing would not negate the need for these experienced PCTs to achieve certification within18 months of being hired as a dialysis patient care technician, as required by § 494.140(e)(4). Facility policies and procedures should define the curriculum, length of training course, and the method for determining successful completion of the course.

V694

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.140(e)(3)*. . . 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)-(viii):

The training program must include the subjects referenced in the regulation, at a minimum.

V695

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140(e) Standard: Patient care dialysis technicians. Patient care dialysis technicians must— **(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) and (ii):

PCT certification can occur under the aegis of either a national, commercially-available program or a State program.

At the time of publication of these regulations (April 15, 2008, 73FR20369), there were three national commercially-available certification programs: the Certified Clinical Hemodialysis Technician (CCHT) examination offered by the Nephrology Nursing Certification Commission (NNCC), the Board of Nephrology Examiners for Nursing and Technology (BONENT) exam, and the National Nephrology Certification Organization (NNCO) exam. Additional national certification programs may become available subsequent to the publication of this guidance.

These national, commercially-available certification programs require a patient care dialysis technician to successfully pass a standardized certification examination in a proctored environment, and maintain certification through current work experience and continuing education.

State certification programs which have a formal certification and competency program (including standardized tests, which reflect the content listed in the regulation, administered in a proctored environment by an independent examiner) that is specific to patient care dialysis technicians can satisfy this requirement. A "standardized test" is one developed and tested to validly and reliably measure the knowledge required to demonstrate competency in the area. If the state requires certification by a national commercially-available certification program, this regulation expects continued certification under the requirements of the national commercially-available program.

Patient care technicians hired after October 14, 2008 must be certified within 18 months of their hire date as a patient care technician. If a patient care technician changes jobs from one dialysis facility to another before becoming certified, the time they were

employed in the first facility will count toward the 18-month deadline for certification unless they had a gap in employment as a patient care technician of more than 18 months.

A reuse technician or a water treatment technician who does not provide direct patient care does not require certification as a patient care dialysis technician. The training curriculum for persons performing hemodialyzer reprocessing is delineated under the Condition for reuse of hemodialyzers and bloodlines at V308. The training for persons responsible for operating and testing the water treatment and dialysate preparation systems is addressed under the Condition for water and dialysate quality at V260. If a reprocessing technician or water treatment technician changes positions to become a patient care technician, they must be certified in 18 months from the date they begin the new PCT position.

V696

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.140**(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):

Any staff member who operates the water treatment system must complete a training program approved by the medical director and the governing body prior to independently performing water treatment system tasks. Refer to V260 in the Condition for water and dialysate quality for additional requirements related to training for the persons operating the water/dialysate systems.

V710

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.150 Condition: Responsibilities of the medical director.

Interpretive Guidance § 494.150:

This Condition defines the role the facility medical director is expected to assume to ensure the delivery of quality patient care and clinical outcomes. Most deficient practices identified in the delivery of quality patient care and patient clinical outcomes are most appropriately cited under the Conditions pertinent to the practice (e.g., infection control practices, lack of patient assessment or plan of care implementation). Citation of these standards or this Condition should be considered when deficient practices are pervasive, the results of the deficient practices are egregious, or the deficient practice identified is not covered under other Conditions.

Determine compliance with this Condition by patient and staff interviews, review of clinical and QAPI records and review of survey findings related to care delivery, patient assessments and plans of care, water and dialysate quality, reuse, and QAPI.

Examples of Condition level noncompliance include, but are not limited to:

- *Serious and/or pervasive problems/trends identified in the quality of care delivery, QAPI activities; and,*
- *Significant deficient practices in patient care policy and procedure development or implementation in which a lack of involvement and oversight by the medical director was a contributing factor.*

V711

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.150 – **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:

Each dialysis facility must have a single medical director who meets the qualifications under the Condition for personnel at V682 identified as responsible for carrying out the duties of this position.

The position of medical director may not be shared by several physicians. The governing body and medical director may designate other physicians to direct different program components in that facility (e.g., home hemodialysis program, home peritoneal program), as long as all components ultimately report to the facility medical director and are under the same QAPI and governing body oversight.

These regulations do not preclude the medical director from also serving as the chief executive officer/administrator of the facility (refer to V752), as long as the responsibilities of both positions are fulfilled.

The medical director is expected to be actively involved and devote sufficient time to fulfilling the following responsibilities:

1. *Oversight of the facility,*
2. *Delivery of patient care, and*
3. *Outcomes in the facility (e.g., to attend and contribute during interdisciplinary meetings for their patients, to participate in performance improvement plans, and to be involved in the education of staff).*

Refer to the Conditions for infection control (V144); water and dialysate quality (V177, V179); reuse of hemodialyzers and bloodlines (V305, V309, V311, V361); and governance (V766, V767) for medical director oversight responsibilities specific to those areas. Generally, unless they are serious or pervasive, findings in those areas should be cited at the more specific tags rather than at this tag.

V712

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.150 – . . . **Medical director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program.**

Interpretive Guidance § 494.150(a):

While these regulations charge the facility governing body with the responsibility for allocating necessary staff and resources for the QAPI program (refer to V756), the medical director is assigned operational responsibility for the QAPI program. Operational responsibility includes, but is not limited to: review of quality indicators related to improved patient health outcomes and monitoring this data on a continual basis as is required by the Condition for QAPI; education of facility and medical staff in the QAPI objectives; reviewing the method of prioritizing the importance of improvement projects; inclusion/encouragement of all staff in participating towards achievement of QAPI goals; communication with the governing body regarding the needs identified by QAPI; and, participating in the evaluation of the effectiveness of performance improvement plans/activities.

Materials documenting the QAPI program should include evidence of active participation and oversight by the medical director (e.g., discussion of issues, guidance and contribution to the development of performance improvement plans, assessment of the effectiveness of those plans).

V713

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.150 – . . . Medical director responsibilities include, but are not limited to, the following: **(b) Staff education, training, and performance.**

Interpretive Guidance § 494.150(b):

The medical director is responsible for ensuring that facility staff members receive the appropriate education and training to competently perform their job responsibilities.

"Performance" refers to how a staff member fulfills their job duties and executes their required tasks. It is the responsibility of the medical director to have procedures in place which routinely assess the competency of staff members to carry out their assigned duties

(e.g., to adequately monitor the patient and the dialysis process, to provide needed social services), and follow facility policy regarding expected performance.

Refer to other Conditions in these regulations for specific requirements for staff education, training and/or competency:

- *V132 in Infection control;*
- *V260 in Water and dialysate quality;*
- *V308, V309 in Reuse;*
- *V693, V694, V696 in Personnel qualifications; and*
- *V760 in Governance.*

Generally, these more specific tags should be used rather than this tag if the problem identified in staff education, training or in the performance of assigned responsibilities is related to one of these areas.

V714

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.150*(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):

Written patient care policies and procedures are essential references for clinical staff and should reflect current practices at the facility. The patient care policies and procedures should address all areas of patient assessment and care delivery for the dialysis modalities provided, and these policies and procedures should reflect both these regulations and current practice standards, as well as adherence to equipment manufacturers' instructions for use.

There must be evidence that the medical director reviewed and approved the patient care policies and procedures and any revisions as they are made. Corporate-owned or corporate-managed facilities may use standard policies and procedures developed by the corporation. There should be a mechanism for the facility medical director to have input into the policies and procedures, and to have some authority to individualize corporate policies to address unique facility situations.

Policies are expected to be adequate, accurate, and up-to-date.

V715

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.150(c) Policies and procedures. The medical director must*— (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):

The medical director is responsible for implementing policies and procedures for all staff. This includes holding medical staff accountable for complying with facility policies and procedures, such as updating plans of care, signing verbal orders, and being knowledgeable about the QAPI targets, as well as working to achieve those targets with their patients. In reviewing the performance of the medical staff, the medical director should consider using currently-available methods, such as practitioner profiles, to review and evaluate performance.

The medical director is responsible for ensuring that the facility has an established policy regarding patient admissions to the facility. Policies for patient admission should address the expectation for an initial assessment by a member of the medical staff (i.e., physician, APRN or PA) before the initiation of the patient's first dialysis treatment in the facility. The initial assessment, which may be a review of the patient's medical record or may be conducted in person, allows the medical team to develop the admission treatment orders and recognize any urgent patient medical needs (e.g., anemia with Hgb < 10g/dl, fluid overload, hyperkalemia) that require immediate action.

Note: The initial evaluation, which occurs prior to the patient's initial dialysis treatment upon admission, is separate and distinct from the routine pre-treatment assessment which occurs prior to each dialysis session.

Orders for treatment must be in place prior to the initial treatment, as well as a patient evaluation by a registered nurse for any immediate needs. At the time of publishing these regulations (April 15, 2008, 73FR20369), according to the American Nephrology Nurses' Association, the minimal nursing evaluation prior to initiating treatment for a patient new to the facility should include:

1. *Neurologic: level of alertness/mental status, orientation, identification of sensory deficits*
2. *Subjective Complaints*
3. *Rest and comfort: pain status*
4. *Activity: ambulation status, support needs, fall risk*
5. *Access: assessment*
6. *Respiratory: respirations description, lung sounds*
7. *Cardiovascular: heart rate and rhythm; presence and location of edema*
8. *Fluid gains, blood pressure and temperature pre-treatment*
9. *Integumentary: skin color, temperature and as needed, type/location of wounds*

Note that other parts of these regulations address adherence to policies and procedures as applicable to specific Conditions, e.g., infection control at V142, water and dialysate

quality at V259, reuse at V306, and physical environment at E-0013. Generally, these more specific tags should be used for deficient practices identified in those areas.

V716

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.150(c) Policies and procedures. The medical director must— (2) Ensure that—
(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):
The medical director must monitor and review each involuntary patient discharge to ensure that the facility IDT follows the discharge and transfer policies and completes the steps required under the Condition for governance at V766 and V767.

The records of any patients who have been involuntarily discharged must show evidence of compliance with each of the requirements detailed at V767, including evidence that the medical director, as well as the patient's attending physician, signed the order for involuntary discharge.

V725

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170 Condition: Medical records.

Interpretive Guidance § 494.170

This Condition requires the facility to maintain complete and accurate records and to protect them against loss and unauthorized use. The requirements apply to both hard copy and electronic health records.

Compliance with this Condition is determined by observation, interview, and review of medical records.

Condition level noncompliance should be considered when there are serious and/or pervasive problems identified with the accuracy, completion, accessibility, and/or protection of patients' medical record information.

V726

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170 – **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

Medical records includes printed or electronic information such as, but not limited to, patient consents, histories and physicals, medication reports, radiology reports, laboratory reports, dialysis treatment orders, patient assessments, patient plans of care, treatment records, and progress notes regarding the condition and care of the patient. Each patient's medical record, whether hard copy, electronic, or a combination of both, should include complete and pertinent information about the condition of the patient, assessments by the IDT , updated plans of care, all interventions and treatments prescribed and delivered, and details of any events occurring with the patient during the course of treatment. No matter what format, the record of care must be readily accessible to every authorized member of the healthcare team so that care can be coordinated to best meet the needs of the patient.

The facility must create and maintain a complete and accurate record of care for every patient that is unique for that patient. Each patient's medical record should clearly portray the patient, the care provided by the facility personnel, and the outcomes of that care.

V731 in this Condition and V599 under the Condition for care at home also address the records of home patients.

V727

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170**(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) and (2)(i)-(v)

The medical record system must protect the privacy and security of all patients' medical record information. The medical records system must ensure that records 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, controlled accessibility and protection of the records.

Electronic medical records systems must be designed to prevent accidental loss or destruction of medical record information (e.g., have an automated backup system), and should have safeguards to prevent alteration of entries without notation of the alteration (e.g., a late entry should be indicated as such). Facility personnel should have sufficient knowledge of electronic system functions to ensure their ability to safeguard records on that system in the event of a problem, including backup of electronic medical records and restoring data. Staff members should be aware of the facility's plan to ensure uninterrupted maintenance of the patient's medical record in the event of a computer failure. Staff members should be able to provide a printed copy of requested portions or the complete current medical record without significant delay (e.g., less than one hour for a portion of the record, less than four hours for the complete current record).

The accumulation of records for a patient treated several times a week for years can become voluminous. The current working chart may contain recent treatment records, and a year of patient assessments, plans of care, progress notes, orders, lab reports, etc. Older records of current patients may be stored in a convenient and secure location where they can be readily accessed as needed. Electronic storage of records is permissible if a secure means to protect the integrity of the record and the privacy of the patient is provided.

The facility policy for stored medical records should ensure prompt retrieval. Facility policy should address how staff members access records that are stored offsite, and the expected time to retrieve them.

In the event of loss of medical records due to unavoidable circumstances, (i.e., natural or man-made disaster) there should be evidence in the QAPI documentation of the event of what records were lost/destroyed, and what steps were taken to prevent similar losses in the future. The facility must have a plan for protecting medical records in an emergency (e.g. transport, secure in place, redundant backup, continuous automatic off-site backup), and for minimizing loss.

Facility policy and practices must reflect the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements for paper and electronic medical records. HIPAA allows release of protected health information (PHI) in certain emergency circumstances, and for the continuity of health care. Also refer to the Condition for patients' rights at V455.

Facility policy should address release of a patient's protected health information to third parties.

V728

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170(a) Standard: Protection of the patient's record. The dialysis facility must—
(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)

Medical records must contain written authorization for health information release prior to release of any medical records that require the patient's/designee's authorization for release.

42 CFR § 494.170(a)(2)(v) authorizes access and review of patient records to state and federal surveyors and ESRD Networks, including making copies of medical records offsite for official purposes. Standards at §489.53(a)(13) requires a provider/supplier to permit copying of records or other information by, or on behalf of CMS, as necessary to determine compliance with Medicare requirements. Failure to permit copying of information can be the basis for termination.

V729

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170**(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):

"Completed promptly" for current (active) patient records means that each clinical event is recorded as soon as possible after its occurrence, care interventions are recorded when provided, and other pertinent patient health information (e.g. assessments, plans of care, progress notes, medication administration, labs, radiology reports, medical orders) is recorded in a timeframe that provides other IDT members with an up-to-date picture of the status of the patient at all times (see also V730).

Facility policy must identify timeframes for the completion of medical records (e.g. signing of verbal orders, completion of discharged patients' records). The medical record system must have a method for identification of the author, date and time of each entry. The author's identification may be by written signature, initials, computer key, or other code. If initials or computer codes are used as signatures, there must be a means to identify the author of the entry. Rubber stamp signatures are not permitted, as there are no means to identify the author with such a method.

V730

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170(b)**(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)

"Centralized" means that the patient's health information is maintained in a common location, such as in a "chart" or electronic record system. At the time of publication of these regulations (April 15, 2008, 73 FR 20369), many facilities maintained a combination of hard copy and electronic records. If part or all of the record is maintained electronically, each member of the IDT must be familiar with and able to access those areas of the patient record they would need to use to stay current with the patient's plan of care. The system in place must allow the members of the IDT to promptly access the most current information about the patient and their treatment.

Dialysis treatment records (i.e. "flow sheets") are the primary means of documenting the daily care of hemodialysis patients. These records should contain complete information about the treatment, such as pre- and post-treatment assessments, vital signs, vascular access in use, pre and post treatment weights, machine parameters and safety checks (e.g. alarm tests, dialysate pH and conductivity, dialysis prescription delivered (i.e. dialyzer, dialysate components, blood and dialysate flow rates, length of treatment), medications given, any clinical events that occurred during the treatment, and, any actions taken and responses to those actions.

V731

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170(b)**(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)

The facility should have a system to maintain and regularly review treatment records kept by all home patients (including those whose equipment and supplies are furnished by a durable medical equipment (DME) supplier) and to incorporate those records into the patient's medical record.

Refer to V599 if deficient practices in the content or maintenance of individual home dialysis patients' records are identified. Use this tag if there are facility-wide issues related to the records for multiple home patients.

V732

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170 **(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)

Note that some states have more stringent requirements for medical record retention. Retention requirements begin after the patient is no longer on census at the facility.

These retention requirements also apply to the records of machine maintenance, dialyzer reprocessing/reuse, water treatment, and dialysate preparation, as each of these records is part of the medical record for the patients on service at the time those records were completed. Documentation of these processes is retained in logs rather than individual patient records. Since many patients are treated on the equipment each day, determination of the retention period may be difficult. Facility policy should address retention of these records.

V733

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.170**(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):

The facility is responsible for transfer of requested patient medical record information to the receiving facility within 1 working day from the date of transfer. The intent is to maintain continuity of care whenever patients leave the facility temporarily (e.g., vacation, business, hospitalization), or transfer permanently to a new facility.

V750

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180 Condition: Governance.

Interpretive Guidance § 494.180

This Condition addresses the overall management of the facility. It requires that an identifiable governing body demonstrate responsibility for the operation of the facility, including fiscal management, staff training and coverage, medical staff appointments and coverage, and the QAPI program. This Condition also holds the governing body accountable for establishing an internal grievance process; decreasing the potential for involuntary discharge of patients; emergency coverage and backup plans for dialysis; electronic data submission; and the relationship of the facility to the ESRD Network.

Compliance with this Condition is determined by patient and staff interview, observations, and review of records. Because the governing body is responsible for the

total operation of the facility, the responsibility of the governing body must be considered when serious problems in other Conditions are identified.

Examples of Condition-level noncompliance include but are not limited to:

- *Major problems with care and safety of patients, patient rights, or operations;*
- *Failure to follow the requirements for involuntary patient discharge;*
- *Failure to respond to network requests for corrective action plans for problems identified by the network;*
- *Failure to submit required data electronically; and,*
- *Noncompliance with another Condition for Coverage if the governing body has some responsibility for the deficient practices.*

V751

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180 – **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:

"Identifiable" means that the individual or individuals who are responsible for the conduct and oversight of the operations of the facility are identified in writing. This may be demonstrated in governing body bylaws or minutes, or in ownership documents.

Terminology related to ownership:

- *"Hospital-based" ESRD facility is a separately certified ESRD facility that is an outpatient department of a hospital and meets the ESRD CfCs at 42 CFR part 494. A hospital-based facility is owned and administered by a hospital or CAH and is physically located on a hospital campus. See also 42 CFR §413.174(c) and SOM section 2272. An ESRD facility physically located inside a hospital but owned by another entity, such as a dialysis corporation, would not be considered "hospital-based."*
- *"Satellite facility" renal dialysis facility is a hospital-owned and hospital-administered ESRD facility but is not located on the hospital campus. A satellite facility is surveyed separately and has its own CMS certification number (CCN).*
- *"Corporate entity" means owned by a group, individual or company; generally these facilities are part of a multi-facility group numbering from several to hundreds of facilities.*
- *"Physician-owned" means owned by a physician through a sole proprietorship, limited liability company, or corporation; may be one or multiple facilities.*

The governing body bylaws should clearly define the ownership of the facility. In some cases, the owner has a contract with another entity for management of the facility. If so, this relationship should be clear in the governing body records of the facility.

Facilities that are part of a dialysis organization with multiple widespread facilities must have a local governing body designated to guide the day-to-day operation of the facility. The governing body may consist of one person or a group of persons. It should be clear in the governing body records who constitutes the governing body and who has the legal authority and responsibility for the governance and operation of the specific facility.

V752

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180**(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)

The qualifications for chief executive officer (CEO) or administrator are not specified in these regulations, but should be defined in facility policy, and include sufficient educational and practical experience to fulfill the responsibilities listed in this section. The governing body or its designee must appoint the selected individual to this role. This position may be held by a member of the staff who is holding a different role, e.g., nurse manager, the medical director, as long as the duties of each role are accomplished.

V753

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(a)**(1) Staff appointments;**

Interpretive Guidance § 494.180(a)(1)

The governing body, through the CEO or administrator, is responsible for the appointment of medical staff including physicians and non-physician practitioners (i.e., advanced practice registered nurses and physician assistants). These appointments must be documented, typically in the minutes of the governing body or in the applicable credential file.

V754

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(a)**(2) Fiscal operations;**

Interpretive Guidance § 494.180(a)(2)

The governing body, through the CEO or administrator, is responsible for maintaining sound fiscal operations. Issues which could indicate problems with fiscal operations include (but are not limited to) missed doses due to a lack of prescribed medications, broken equipment, deterioration of the physical plant, or insufficient staff.

V755

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(a)**(3) The relationship with the ESRD networks; and**

Interpretive Guidance § 494.180(a)(3)

The ESRD Networks are CMS contractors assigned responsibilities via a Statement of Work to:

- *Collect and analyze data on ESRD patients and their outcomes of care, including the information that allows patients to be enrolled into the ESRD Medicare benefit program;*
- *Provide education and oversight to improve the quality of care delivered to dialysis and kidney transplant patients;*
- *Support facilities in developing and maintaining an effective QAPI program; and,*
- *Respond to complaints and grievances*

At the time of publishing these regulations (April 15, 2008, 73FR20369), there were 18 ESRD networks, each covering a specified geographic area.

A signed agreement between the facility and the applicable network is required prior to the initial certification survey. The CEO or administrator receives and acts on correspondence from the ESRD network and should promptly respond to any request from the applicable networks.

Additional requirements related to networks are found at V772.

V756

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(a)**(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):

Requirements for the minimum professional membership in the QAPI process are delineated at V626. If those professional members are not given enough time or support to participate in QAPI activities, this tag should be considered. Routine absence of a member in QAPI committee engagements and/or inability to meet certain performance improvement goals may be an indication that necessary staff and/or resources are not adequately assigned for the facility's QAPI program due to competing responsibilities. There must be communication between the medical director and the governing body regarding QAPI. The governing body must provide resources (e.g., time, staff or funding) for QAPI audits, staff education, refurbishing, etc. as needed to support correction of identified problems. The facility CEO or administrator assigned by the governing body should review information related to significant problems identified and their causes, and provide guidance and support for proposed needed corrections.

V757

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180**(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):

There must be sufficient numbers of qualified and trained staff on duty while patients are on dialysis in-center to meet the individualized needs of the patients. Consideration should be given to the acuity and care needs of patients, staff experience and areas of expertise when evaluating the adequacy of staffing. Sufficient numbers of staff must be present in the treatment area to be able to see every patient during treatment (including lunch breaks, shift change, etc.[refer to V407]); to deliver routine care, patient assessment and monitoring per facility policy; and to promptly respond to and address patient needs (such as changes in physical or mental condition) and machine alarms. Staffing assignments and schedules should demonstrate a pattern of sufficient staff coverage to ensure safe patient care.

Facilities are expected to meet any applicable State regulations that identify specific patient-to-staff ratio requirements. Failure to comply with those State patient-to-staff requirements may be cited at this tag.

V758

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(b)(1) – . . .**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):

A dialysis patient's clinical needs may change rapidly, necessitating attention and intervention from the members of the IDT. When a dialysis facility has staffing limitations that impact the patient's access to care, the governing body is expected to make diligent efforts to secure appropriate staffing. If the nurse manager, social worker, dietitian or other required or necessary position not available, the governing body must make some provision for temporary coverage in order to ensure patient clinical needs are met. If the facility "shares" the social worker or dietitian with multiple clinics, or requires professional staff to perform non-clinical tasks, it must not negatively impact the time available to provide the clinical interventions required to achieve the goals identified in the patient's plan of care. The facility CEO or administrator is responsible to ensure the professional support staff members have sufficient time available in the facility to meet the clinical needs of in-center and home dialysis patients.

V759

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(b)**(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):

There must be a registered nurse (RN) on duty and available at all times when in-center dialysis patients are being treated. This requirement is based upon data in the nursing literature which demonstrates a positive correlation between the availability of professional nursing service and patient outcomes.

If only one RN is on duty, that RN is expected to spend the majority of their time on the treatment floor. Short personal breaks away from the treatment floor are acceptable. A RN must be on-duty whenever patients are present, including the beginning and end of the treatment day.

In some cases, the RN who is on duty may not be qualified under these regulations as a "charge nurse" See V686-V687. In those instances, if allowed under the applicable State nurse practice acts, a qualified licensed practical nurse or qualified licensed vocational nurse may function in the charge role.

V760

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(b)**(3) All staff, including the medical director, have appropriate orientation to the facility and their work responsibilities; and**

Interpretive Guidance § 494.180(b)(3):

The CEO or administrator is responsible to ensure that each member of the staff receives an orientation to the facility, their job duties, and how to do the work assigned. While the orientation of employees should be documented in their personnel files, the orientation of physicians and non-physician practitioners (i.e., advanced practice registered nurses and physician assistants) should be documented in their credential files and include evidence of understanding and agreement to medical staff bylaws, policies and procedures, and responsibilities related to QAPI.

V761

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(b)**(4) All employees have an opportunity for continuing education and related development activities;**

Interpretive Guidance § 494.180(b)(4):

Continuing education programs should be offered to all staff to help them maintain and improve their knowledge, skills, and licensure, if applicable. "Continuing education" includes internal training programs, as well as external professional educational programs.

These regulations also include specific requirements regarding the provision of staff in-services and continuing education relating to infection control at V132; water & dialysate quality at V260; emergency preparedness training, testing and patient orientation at E-0036, and personnel qualifications at V693, V694, and V696.

If the deficient practice identified is related to one of the areas above, the citation should occur for that specific tag.

V762

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180**(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):

Privileges for physicians and non-physician practitioners (i.e., advanced practice registered nurses and physician's assistants) are granted by the facility's governing body based on the individual practitioner's qualifications and performance. The facility must define the requirements for practice at the facility in accordance with any applicable State laws. The medical staff credential files must include evidence the individual meets those requirements, including current licensure in the applicable State. Refer to V681 for issues related to professional licensing.

If the State has more stringent licensure requirements for ESRD facilities regarding medical staff appointments, and those requirements are not met, those findings may be cited at this tag.

V763

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(c) Standard: Medical staff appointments. The governing body— **(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) and (3):

The governing body must inform members of the medical staff of all aspects of the facility's QAPI program, including the requirement to participate in efforts to improve the quality of medical care to their patients. These efforts must be reflected both in documentation of the QAPI program and in the medical records of individual patients. It is not required that all members of the medical staff attend all the QAPI meetings.

Examples of the lack of medical staff adherence to facility policies or goals would include physician(s) not participating in the development of the plan of care, or not addressing poor patient outcomes with a change in the plan of care.

Medical staff who are not informed indicates this requirement is not met. For medical staff not compliant, refer to V715 under the Condition for medical director.

V764

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180**(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)
Each separate physical location for dialysis services must be certified separately, and all approved services for a particular facility must be provided on the premises of that location (with the exception of dialysis care at home). Hospital-based facilities may be located on the same campus of the hospital, with various services (e.g., home training vs. in-center dialysis) being provided in different rooms or areas, but sharing the same address on that campus.

All services provided by the facility must be under the direction of the same professional staff and governing body. Training and support for home dialysis must be provided by a facility certified for those services. On occasion, some home training may be provided in the patient's home to meet the needs of the patient and/or caregiver.

Training for care at home is discussed at V582 through V585. Home patients may see their physicians or a non-physician practitioner (i.e., advanced practice registered nurse or physician assistant) in their offices instead of seeing these practitioners at their dialysis clinics. In-center patients may, on occasion, see their practitioner in their offices, while periodically seeing their practitioner during treatment at the dialysis facility. This requirement can be found under the Condition for patient plan of care at V560.

V765

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.180*(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) and (3)

The facility's policies and procedures must describe all available grievance procedures to the patient which must include the ability to file an oral or written grievance with the facility. The facility must inform the patient and/or the patient's designated representative (also called "designee") of its internal grievance process. Refer to the requirement at V465 under the Condition for patients' rights.

Each facility must implement a process to ensure that there will be no reprisal or denial of services for any patient who files an internal grievance and the grievance procedure will be clearly explained to patients. The existence of grievances should not be viewed negatively, as this would be an indication that patients understand the internal grievance process and believe that filing a grievance will not result in reprisal or denial of services. Lack of grievances does not indicate a lack of an internal grievance process.

The facility's grievance process should ensure those grievances involving situations or practices that place patients or staff members in immediate danger (e.g. the patient's grievance brings attention to hazardous environmental conditions) are prioritized as needing immediate attention and resolved in a timely manner as to avoid any injury or harm to the patients and staff members..

The facility's process must include clearly defined timeframes for a grievance to be acknowledged, investigated, and addressed. Timeframes should be sufficient to conduct an investigation yet ensure that the grievance is addressed in a timely manner.

The patient/designee should be informed of the status of the investigation periodically, and when resolution is attained or considered attained by the facility. Each grievance should demonstrate a completed cycle of reviewing the grievance and reporting back to the patient.

V766

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180**(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) and (3)

Involuntary discharge or transfer should be rare and preceded by demonstrated effort on the part of the IDT to address the problem in a mutually beneficial way. The facility must have and follow written policies and procedures for involuntary discharge and transfer.

If any patients have been involuntarily discharged or transferred since the later of either October 14, 2008 (the effective date of these rules, 73 FR 20370) or the facility's last survey, surveyors will review those patients' medical records to ensure compliance with these regulations and facility policy. See also requirements under Conditions for Patients' rights at V468 and V469.

The medical director must be informed of and should approve any involuntary discharge or transfer of a patient. A facility may involuntarily discharge or transfer a patient only for those reasons listed in this standard and at V767. The medical director must ensure that the reasons for any involuntary discharge or transfer are consistent with this requirement.

If a facility involuntarily discharges or transfers a patient for nonpayment of fees, there should be evidence in the patient's medical record that the facility staff (e.g., billing personnel, financial counselor, or social worker) made good faith efforts to help the patient resolve nonpayment issues.

Requirements for enrolling and maintaining active enrollment status in the Medicare program include reporting changes of a supplier's enrollment information to CMS within specified timeframes. These requirements are established at 42 CFR 424.516(e). In the event a facility ceases to operate, the governing body must notify CMS, the State survey agency, and the applicable ESRD Network. The facility's IDT must assist patients in obtaining dialysis in other facilities. In accordance with § 494.180(f)(4)(iv), the facility must document its attempts to place the patient in another dialysis facility.

If the discharge or transfer is necessary for the patient's welfare, the patient's medical record must include documentation of the medical need and reasons why the facility can no longer meet that need.

V767

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(f) Standard: Involuntary discharge and transfer policies and procedures. …The medical director ensures that no patient is discharged or transferred from the facility unless – **(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)-(v) and (5)

Patients should not be discharged for failure to comply with facility policy unless the violation adversely affects clinic operations (e.g., violating facility rules for eating during dialysis should not warrant involuntary discharge). Patients should not be discharged for shortened or missed treatments unless this behavior has a significant adverse effect on other patients' treatment schedules. A facility may evaluate the patient (who shortens or misses treatments) for any psychosocial factors that may contribute to shortening or missing treatments; for suitability to home dialysis; or, as a last resort to avoid inconveniencing other patients, may alter the patient's treatment schedule or shorten

treatment times for patients who persistently arrive late. Patients should not be discharged for failure to reach facility-set goals for clinical outcomes. CMS does not evaluate compliance by solely determining whether a patient or patients reached the expected targets. Rather, compliance means that a plan of care has been developed by the IDT, is individualized, addresses barriers to meeting the targets, and has been implemented and revised as indicated.

Note: the above examples are intended to be informative and by no means are an exhaustive list of behaviors that should warrant a facility to further evaluate the patient's behavior rather than to involuntarily discharge the patient.

In the event facility staff members believe the patient may have to be involuntarily discharged, the IDT must reassess the patient with an intent to identify any potential action or plan that could prevent the need to discharge or transfer the patient involuntarily. The reassessment should focus on identifying the root causes of the disruptive or abusive behavior and result in a plan of care aimed at addressing those causes and resolving unacceptable behavior.

Evidence must be on file to substantiate that the patient received notification at least 30 days prior to involuntary discharge or transfer and that the ESRD Network was also notified at that time. While the early notice to the State survey agency is not required, facilities may choose to notify the patient, network and the State survey agency at the same time. A 30-day notice is not required in the case of imminent severe threat to safety of other patients or staff. The State survey agency and network would need to be notified immediately if the use of the abbreviated involuntary discharge procedure is necessary.

There must be a written order in the patient's medical record, signed by the attending physician, and the medical director for the facility to involuntarily discharge or transfer a patient. If the reason for discharge is the physician's determination to no longer care for a particular patient and there is no other physician on staff available or willing to accept the patient, generally the state practice boards for physicians require the patient be given some notice to avoid a charge of patient abandonment. The facility would need to follow this regulation as to reassessment, 30 day notice, attempts for placement, etc. during the physician's period of notice to the patient.

Because the goal of contacting another dialysis facility is for continuity of care, the HIPAA Privacy Rule does not require patient consent to contact that other dialysis facility. However, it does limit sharing of protected health information to medical records requested by the other provider or for continuity of care purposes.

Good faith efforts should be made to find the closest facility to the patient's residence that will accept the patient in transfer. The applicable patient's medical record must include evidence of those placement efforts.

An "immediate severe threat" is considered to be a threat of physical harm. For example, if a patient has a gun or a knife or is making credible threats of physical harm,

this would be considered an "immediate severe threat." An angry verbal outburst or verbal abuse is usually not considered to be an immediate severe threat. In instances of an immediate severe threat, facility staff may utilize "abbreviated" involuntary discharge or transfer procedures. These abbreviated procedures may include taking immediate protective actions, such as calling 911 and asking for police assistance. In this scenario, there may not be time or opportunity for reassessment, intervention, or contact with another facility for possible transfer. After the emergency is addressed and staff and other patients are safe, staff must notify the patient's physician and the medical director of these events, notify the State agency and ESRD Network of the involuntary discharge, and document this contact and the exact nature of the "immediate severe threat" in the applicable patient's medical record.

At the time of publication of these rules (April 15, 2008, 73 FR 20369), each facility had received a copy of an interactive program developed by the ESRD Networks on Decreasing Dialysis Patient Provider Conflict (DPC) that addresses proactive techniques to resolve such issues before progression to involuntary discharge. As part of the ESRD Network responsibilities and the agreement between the facility and ESRD Network, strategies and mitigation steps have been developed by the Networks to handle complex relationships between provider and patient, and avoid involuntary discharges. ESRD facilities seeking more information on decreasing patient-provider conflicts and involuntary discharges can find information on the Network websites or by contacting the ESRD Networks directly.

V768

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.180*(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):

The facility must provide written information to all patients, including home patients, regarding who to call and how to obtain emergency medical care when away from the dialysis facility. The patients should be able to contact a call service for a responsible staff member, physician, or on call staff for dialysis-related emergencies 24 hours a day, 7 days a week. In cases of need for emergent medical care (e.g., severe chest pain, loss of consciousness, or uncontrollable bleeding), patients should be instructed to call 911 for immediate medical care.

Instructions for obtaining medical care will vary depending on the event and should be appropriate to the emergency condition.

V769

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(g)**(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):

There must be a listing available of physicians' names and contact numbers and a call schedule if physicians rotate this responsibility. Every facility should have a written plan for physician coverage during illness, vacations, and holidays.

V770

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180(g)**(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) and (ii):

In order to protect dialysis patients who may need emergent hospital services, there must be an agreement with a hospital that can provide inpatient dialysis care, furnish emergency dialysis services, as well as routine care. This could be in the form of a letter from the hospital acknowledging their agreement to this requirement, or a more formal document signed by representatives of both the dialysis facility and the hospital. The hospital does not have to be certified as an ESRD provider, but must be able to provide inpatient dialysis treatment as well as emergency care and other hospital services to meet the patient's needs.

It is not required or expected that every patient admission would be to the hospital with whom the agreement is signed.

V772

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180**(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), and (3)(i)-(iv):

Beginning February 1, 2009, all dialysis facilities must electronically submit data to allow patient enrollment in and disenrollment from the ESRD benefit program, assessment of clinical outcomes, and claims processing.

The facility must electronically submit the required information at the specified intervals, which vary depending on the data element. Data required to be submitted electronically includes: cost report data; administrative data (such as changes in key staff and changes in patient treatment modality); forms such as the CMS-2728 (ESRD Medical Evidence Report Medicare Entitlement and/o Patient Registration) and CMS-2746 (ESRD Death Notification); and, clinical performance data on all patients regardless of payment source, at the frequency determined by CMS. The clinical performance measures required for submission are determined by the Secretary of HHS, and any changes to these measures will be developed through a standardized process. Additional information on clinical performance measures for ESRD facilities can be found here: ESRD Quality Incentive Program.

V772

(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

§ 494.180**(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):

The ESRD facility must respond promptly within any specified deadlines to requests for information, data, or corrective action plans from its ESRD Network. The facility must participate in network projects and activities aimed at addressing identified needs and improving quality of care in the individual facility or the network-wide area. Facilities

may contact their ESRD Network to obtain the most current copy of their network's goals and objectives.

At the time of publication of these regulations (April 15, 2008, 73FR20369), the goals of ESRD Networks were to:

- *Improve the quality and safety of dialysis-related services provided for individuals with ESRD;*
- *Improve independence, quality of life, and rehabilitation (to the extent possible) of individuals with ESRD through encouragement of transplantation, use of self-care modalities (e.g., home peritoneal dialysis, home hemodialysis, and in-center self-care), as medically appropriate, through the end of life;*
- *Encourage and support collaborative activities to ensure achievement of these goals through the most efficient and effective means possible, with recognition of the differences among providers (e.g., independent, hospital-based, member of a group, affiliate of an organization) and the associated possibilities/capabilities; and,*
- *Improve the collection, reliability, timeliness, and use of data to: measure processes of care and outcomes; maintain the patient registry; and support the ESRD Network program.*

V773
(Rev. 246; Issued: 08-17-26; Effective: 08-17-26; Implementation: 08-17-26)

***§ 494.180*(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):

The governing body of the ESRD facility must report to the State survey agency a full and complete listing of any individuals with ownership of 5% or more of the facility.

Any change in ownership must be reported to the State survey agency in a timely manner.

Part II - The ESRD Core Survey Process

Overview

Section 1881(b)(1) of the Social Security Act (the Act) requires facilities to be approved to participate in the end-stage renal disease (ESRD) program. The regulations at 42 CFR Part 494 specify the Conditions that facilities must meet to achieve and maintain approval.

The ESRD survey process represents the relevant areas and issues that should be surveyed/reviewed under each regulation, and in some cases, the methods that should be used to survey those areas and issues. The use of these protocols will promote consistency in the survey/review process. The protocols also ensure that a facility's compliance with regulations is reviewed in a thorough, efficient, and consistent manner so that, at the completion of the survey, surveyors have sufficient information to make compliance decisions.

This survey protocol is designed around survey tasks that involve observing areas and actions, interviewing patients and staff, and reviewing records and documents. The core survey process is designed to directly observe patient care and assess key areas of patient management, infection control, and facility operations. It should be used for all initial and recertification surveys. During an initial survey, the core survey process should be used, along with additional key considerations provided in each applicable task.

Method and Structure of the ESRD Core Survey
The ESRD core survey process is organized by survey tasks specific to the dialysis facility environment and the care of ESRD patients, along with the corresponding core survey worksheets associated with each task.

The "core" activities and guidance for each ESRD core survey task are listed, followed by a list of survey "triggers" pertinent to that area of review. Supplemental procedures reviewing home dialysis services in a long-term care or nursing home setting are included.

***Reviewing Dialysis in Nursing Homes**: The survey protocol includes additional survey activities and guidance that address dialysis services provided by the ESRD facility to residents in a nursing home setting. These sections will be labeled as "Home Dialysis in LTC". The survey team should schedule on-site visits to nursing homes, including, at a minimum, direct observations of machine preparation, initiation of dialysis, vascular access care, and discontinuation of dialysis. In the event that only one patient is receiving services in a nursing home, the ESRD surveyor may need to conduct their observations over multiple days to observe both initiation and disconnection.*

Please note that nursing home, long-term care facility, and long-term care setting are used interchangeably throughout this survey protocol and the corresponding survey worksheets.

If, during the onsite visit at a nursing facility, ESRD facility surveyors identify concerns about the quality of the care provided to a nursing home resident(s) that is unrelated to dialysis facility requirements or dialysis-related concerns that overlap with existing nursing home requirements, those concerns should be communicated to the appropriate SA authorities for a possible nursing home complaint investigation.

***Triggers** are prompts during a surveyor's observations that may warrant a deficiency citation or indicate the need for further investigation to determine the depth of*

noncompliance. Further investigation may be limited to the specific issue or may include expanding that survey task, referred to as "extending" the task. Guidance for extending a core Survey task appears after the applicable tasks or triggers in the core survey process.

Throughout this ESRD core survey document, ***reference documents*** *are listed where applicable ESRD core survey worksheets are available to guide the surveyor during the survey task. A compilation of the ESRD Core Survey Worksheets can be found in the Addendum.*

Data-driven Survey Process
The Dialysis Facility Report (DFR) identifies areas of clinical performance compared to the national average. The comprehensive DFR is updated annually, with select data measures updated quarterly throughout the fiscal year. The clinical data from the DFR will be used to determine measures that are below the national benchmark and incorporate them as ***data-driven focus areas*** *throughout the dialysis facility survey. Surveyors should review the most recent DFR to appropriately evaluate data elements to include in the ESRD Core Survey.*

ESRD Core Survey Tasks:

Task 1 – Pre-survey Preparation
Task 2 – Introductions
Task 3 – Environmental Flash Tour
Task 4 – Entrance Conference
Task 5 – Observations of Hemodialysis Care and Infection Control Practices
Task 6 – Patient Sample Selection
Task 7 – Water Treatment Room and Dialysate Review
Task 8 – Dialyzer Reprocessing/Reuse Review (if applicable)
Task 9 – Dialysis Equipment Maintenance Review
Task 10 – Home Dialysis Training and Support Review
Task 11 – Medical Record Review
Task 12 – Patient Interviews
Task 13 – Personnel Record Review
Task 14 – Personnel Interviews
Task 15 – Quality Assessment & Performance Improvement (QAPI) Review
Decision Making
Exit Conference

Task 1: Pre-Survey Preparation

Reference Document: *Core Survey Data Worksheet*

General Purpose: *Surveyors must analyze clinical data and facility information prior to entrance to prepare for and determine the preliminary data-driven focus area(s) to be*

reviewed during the survey. Data-driven focus areas are clinical measures (e.g., anemia management) in which the facility's results for that given measure are determined to be lower than the national average.

***Initial Survey Key Consideration**: Inform the facility that it must submit to the SA evidence of acceptable water and dialysate quality (i.e., cultures/endotoxins, product water chemical content) for hemodialysis and notify the SA when the facility has admitted at least one patient in each requested dialysis service/modality.*

- ***Review the CMS-3427 Form:** Before an ESRD initial or recertification survey, review applicable Forms CMS-3427 on file to determine if the ESRD facility has patients who receive their dialysis treatments at a nursing home and plan the survey team composition and schedule to accommodate onsite visit(s) to the nursing home(s). The review of dialysis services in a nursing home should be considered an extension of the ESRD Core Survey and, as such, will require additional survey time.*

- ***Review** the most current Dialysis Facility Report (DFR) along with the most current QDFR. The comprehensive DFR contains detailed information on patient characteristics, treatment patterns, hospitalization, mortality, and transplantation patterns in Medicare-certified dialysis facilities. The QDFR is a one-page document that contains key data elements from the facility's comprehensive DFR to be reviewed during Pre-Survey Preparation and guides the identification of the preliminary data-driven focus areas. Follow the instructions in the most current QDFR to compare facility characteristics to the national average. If the facility's outcome in a clinical area is worse than the national average, include that area as a preliminary data-driven focus area. If a facility has clinical outcomes that are better than or equal to the national average, a review of that clinical measure and management thereof is not required.*

    - *The most recent data reflected in the DFR can be up to eight (8) months old.*
    - *During the Introductions task, surveyors should request that the facility submit more recent data and compare it with the data from the most recent DFR. This will allow the surveyor to determine whether improvements were made for any clinical indicator reported during the time period not covered in the DFR.*
    - *The final data-driven focus area(s) will be confirmed after it is determined that a clinical indicator has outcomes lower than the national average and has not improved after reviewing the facility's more recent clinical outcomes report.*

- ***Review the facility complaint and survey history** for the past 12-18 months. Look for trends in patient and/or staff complaint allegations and survey deficiency citations.*

- ***Copy the "Entrance Conference Materials List"** from the ESRD Core Survey Data Worksheet, Section II, for the current fiscal year. This will be presented to the facility*

administrator or person in charge during "Introductions." Gather other documents needed to conduct the survey (e.g., Form CMS-3427, survey worksheets).

- ***Obtain contact information of the respective ESRD Network.*** *To ensure the survey remains unannounced, surveyors may not contact the network until they are on-site for the survey. Surveyors will contact the appropriate representative for the respective ESRD network after entering the facility to inquire about any quality concerns, information regarding involuntary discharges and transfers, and to ask about the receipt of any patient complaints. Network contact information is available on each individual Network's website.*

Task 2: Introductions

General Purpose*: The Introductions task is conducted to announce the survey, introduce the survey team, and inform the facility administrator (or a key person in the facility if the administrator is unavailable) about the purpose of the survey and the anticipated timeline. Explain that the survey will include observations within the facility, record reviews, and interviews with patients and staff. Inform the staff that they will have the opportunity to discuss areas and provide additional information. This introduction should be extremely brief to allow you to observe tasks as quickly as possible.*

Contact the administrator (or the person in charge if the administrator is unavailable) *and present them with the "Entrance Conference Materials" list (Section II of the Core Data Worksheet). This list includes several documents that will be reviewed during the survey. The materials should be submitted to the survey team within the timeframes identified on the form. Information and documents collected from this list will be required when determining the patient sample selection and for surveyor reference during the Entrance Conference.*

Also, surveyors will request that the facility submit its clinical outcomes report, which represents data more recent than the time period covered in the DFR. This data will be used to determine the final data-driven focus areas.

The administrator (or person in charge if the administrator is not available) should also be given a copy of the CMS-3427 ("End Stage Renal Disease Application and Survey and Certification Report") to be completed by the facility staff and submitted to the survey team by Day 2 of the survey. A review of the CMS-3427 completed by the facility during the survey will be done to confirm that the information on the form is accurate and consistent with the information available to CMS.

Task 3: Environmental "Flash" Tour

General Purpose: *Observe the patient care-related areas for an initial assessment of conditions that may have an immediate impact on patient safety, such as infection*

control, physical environment hazards, serious lapses in equipment and building maintenance, and the availability of emergency equipment. Surveyors should request that the facility appoint a staff member to accompany them during the flash tour.

Observe the following patient-related areas of the facility as listed:

- *Patient treatment area (for in-center dialysis)*
- *Water treatment/dialysate preparation area*
- *Reuse room (if applicable)*
- *Home dialysis treatment area*

This is a "flash" tour of the patient-related areas, looking for observable indicators of patient safety concerns. It begins immediately after the Introductions task.

Additional in-depth guidance from the surveyor is provided below for each area.

***In-center dialysis patient treatment area - Observe** the general environment and atmosphere of the treatment area. Observe a sample of 25% (minimum of 3) dialysis stations with patients undergoing treatments. Observe the patient, their vascular access, and the surroundings of the dialysis station. This is a "flash" look, and not a verification of their dialysis prescription delivery, which is done during "Observations of Hemodialysis Care and Infection Control Practices." Observe the availability and functionality of emergency resuscitation and evacuation equipment.*

***Triggers for citation or further investigation of concerns**:*

- *Equipment is not used in accordance with the manufacturer's instructions for use, for example, dummy drip chambers present in the patient treatment area (V400, 403)*
- *Patients' vascular accesses covered, not consistently uncovered/corrected by staff (V407)*
- *No Registered Nurse (RN) on duty (V759)*
- *Evidence of poor staffing, e.g., machine alarms not answered, patients not regularly monitored, no dietitian or social worker currently on staff (V757)*
- *Blood spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood (V122)*
- *HD machine transducer protectors wetted with blood not changed - observe/interview staff regarding the practice of inspecting the internal transducer for blood prior to machine use for another patient (V120)*
- *Insufficient space to prevent cross-contamination and use emergency equipment (V404)*
- *Absence of functional emergency resuscitation equipment (i.e., AED/defibrillator, oxygen, suction, emergency medications, Ambu bag); emergency evacuation equipment insufficient or unavailable (E-0028)*
- *Hemodialysis machines in observable poor repair (e.g., alarms not functional, missing components) (V403)*

- *If dialyzer reuse, germicide odors are noticeable in the patient treatment area (V318)*
- *Disrespectful communication, e.g., rude, demeaning, harassing, name calling, loudly calling out weight; disrespectful or punitive actions toward patients, e.g., physical or chemical restraints, involuntary seclusion (V452, V627)*
- *Failure to offer patients confidentiality when discussing their condition/treatment; failure to protect the patients' confidentiality by allowing exposure of patients' sensitive body parts during procedures (V454)*

***Water treatment/dialysate preparation area - Observe** the carbon system, the chlorine testing equipment and reagents, and current day/shift total chlorine test results. Look at the alarm/monitoring systems for the reverse osmosis (RO) and/or deionization (DI) components, and the dialysate concentrate proportioning ratios listed on the packaging.*

***Triggers for citation**:*

- *Carbon system: absence of 2 or more carbon beds, with sampling port between (V192), current shift total chlorine test not done, testing reagents not sensitive to 0.1mg/L total chlorine, expired or don't match testing equipment (V196)*
- *RO: absence of functioning water quality monitor; no audible alarm in patient treatment area (V200)*
- *DI (if present): absence of functioning resistivity monitor, no audible AND visible alarm in patient treatment area, absence of automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis stations if resistivity falls <1 megohm, DI not monitored twice/day (V202, V203)*
- *Water distribution equipment in observable disrepair or contaminated state, e.g., the presence of algae or discoloration of water (V403)*
- *Acid and bicarbonate dialysate concentrates of different proportioning ratios present - interview staff regarding the use of the different concentrates and verify that only matching ratios are used with machines programmed to that ratio (V249)*
- *Acid or bicarbonate dialysate concentrate mixing and distribution equipment in observable disrepair or contaminated state, e.g., algae (V403)*

***Reuse room - Observe** the condition of the reprocessing equipment, dialyzer storage, and dialyzer refrigerator, if present.*

Triggers for citation:

- *Stored reprocessed dialyzers aesthetically unacceptable, e.g., header caps with blood, leaking, port caps off (V343)*
- *Stored dialyzers not protected from unauthorized access (V321); Not within the germicide manufacturer's temperature range (V345)*
- *Reprocessing room or equipment in observable disrepair (V318, V403)*
- *Dirty dialyzers kept at room temperature >2 hrs. before reprocessing (V331)*

- *Dialyzer refrigerator temperature not monitored (V331)*

Home dialysis training area - Observe *the physical environment, infection control, availability of emergency equipment, and the method for summoning immediate assistance.*

Triggers for citation or further investigation of concerns:

- *Insufficient space in patient training area to prevent cross-contamination and provide emergency care if >1 patient trained at a time (V404)*
- *Insufficient methods to provide patient privacy (V406)*
- *Blood or PD effluent spills not immediately cleaned; equipment and/or surfaces visibly spattered with dried or wet blood or PD effluent (V122)*
- *Absence of functional, immediately available emergency resuscitation equipment (E-0028)*
- *Absence of a method for summoning immediate assistance for the patient or solitary staff (V402)*

Extending *the "flash" tour to other areas of the facility**:** If pervasive concerns are identified during the flash tour of the above four clinical areas, consider examining other patient-related areas of the facility, such as the waiting room, patient bathrooms, supply storage room, hazardous waste storage, and laboratory area. Examples which may suggest a serious lack of environmental maintenance that has the potential to impact patient safety include:*

- *Large areas of water damage*
- *Presence of mold in patient-related areas*
- *Uneven/broken floor surfaces creating multiple trip hazards where patients ambulate (V401, V402)*

TASK 4: Entrance Conference

Reference Document: *Entrance Conference Worksheet*

General Purpose*: The Entrance Conference is held at the conclusion of the flash tour and is conducted with the administrator or designee and any other staff the administrator selects for participation. During the Entrance Conference, the lead surveyor should provide details regarding the expectations, workflow, and approximate timeline for conducting the survey.*

Obtain *and review documentation submitted by the facility, including current facility-specific clinical data related to performance and outcomes. Using this data, identify any trends and determine how the facility is performing in comparison with the preliminary focus areas. If the facility is currently meeting thresholds in an area where the DFR review indicated problems, performance improvement may have taken place. Upon*

validation of the improvement, you may choose not to include that as a final data-driven focus area for review.

Ask the administrative person, or their designee, the facility-specific questions from the "Entrance Conference Questions" worksheet.

***Home Dialysis in LTC**: To facilitate planning for on-site visits to nursing homes, the following information should be requested (also noted in the Entrance Conference Materials List) at the time of the ESRD survey entrance conference:*

- *List of all nursing homes with which the ESRD facility has a current written agreement to provide dialysis services and the address for each nursing home, including how treatments are provided in each distinct nursing home, i.e., in the patient's private room, in a common area, or both.*
- *The names of all patients currently receiving dialysis services from the ESRD facility at each nursing home.*
- *The modality and treatment schedule (including the scheduled times for the hemodialysis treatments) for each nursing home resident named above.*
- *Names and credentials (e.g., RN, PCT) of any nursing home personnel who deliver the residents' dialysis treatments.*
- *A copy of the written agreement between the ESRD facility and each nursing home.*

Task 5: Observations of Hemodialysis Care and Infection Control Practices

***Reference Document:** Observations of Care and Infection Control Worksheets*

***General Purpose:** Make general observations about overall patient care practices related to the safety of the facility, comfort of the patient/staff interactions, and technical aspects of dialysis.*

This task will focus on patient safety in infection control, equipment operation, the use of reprocessed dialyzers, and patient assessment.

Depending on a facility's unique schedule and your travel requirements, you may arrive during the start of the dialysis procedure, at the initiation or conclusion of a patient shift, or while a treatment is being conducted. Each time presents unique opportunities to view special aspects of the dialysis treatment. If possible, conduct observations on different days, shifts, and with different staff. It may be possible to observe several of the procedures at one dialysis station during the changeover between patient shifts.

During start up times, you can view equipment preparation (preparing dialysate, assembling the extracorporeal system, priming the dialyzer and extracorporeal circuit)

and the pre-dialysis assessment of the patient (weighing the patient, taking the blood pressure, taking the patient's pulse, assessing heart and lung sounds, taking the patient's temperature, communicating with the patient, evaluating the vascular access). Whenever you arrive, you will be able to observe staff documentation of these actions as they occur.

When the shift starts, you can observe the staff placing a needle into a fistula or graft access and checking reused dialyzers for patient identification.

During a treatment, you will note the staff monitoring patients (taking vital signs, performing safety checks, monitoring the general condition of the patient), giving medications and solutions, and monitoring equipment.

At the end of a treatment, you can observe the staff discontinuing dialysis, taking vital signs, and cleaning equipment.

In order to facilitate a comprehensive and thorough review, while making efficient use of the surveyor's time, this task consists of observations in the following four (4) areas:

- *The direct care staff delivering care*
- *Medication preparation and administration*
- *Facility isolation practices*
- *Dialysis treatment prescription delivery*

Observe the direct care staff delivering care *– Using the applicable observational checklists from the "Observations of Hemodialysis Care and Infection Control Practices" worksheet, conduct at least two (2) separate observations, at random, of each of the procedures listed below:*

- *Initiation of Hemodialysis with Central Venous Catheter (CVC) (CVC) (Checklist 1)*
- *Central Venous Catheter Exit Site Care (Checklist 2)*
- *Discontinuation of Hemodialysis with Central Venous Catheter (Checklist 3)*
- *Initiation of Hemodialysis with Arteriovenous Fistula (AVF) or Arteriovenous Graft (AVG) (Checklist 4)*
- *Discontinuation of Hemodialysis with AV Fistula or AV Graft (Checklist 5)*
- *Cleaning and Disinfection of the Dialysis Station (Checklist 6)*
- *Preparation of the Hemodialysis Machine/Extracorporeal Circuit (Checklist 7)*
- *Dialysis Supply Management and Contamination Prevention: This checklist should be completed after the surveyor has conducted the above critical observations (Checklist 9)*

Observe each procedure listed above one at a time, to ensure focus on that activity.

Triggers for citation:

- *Observed breaches in infection control patient care practices:*
  - *Poor hand hygiene and glove use practices (V113)*
  - *Supplies taken to the station are not disposed of, disinfected, or dedicated to that patient (V116)*
  - *Clean dialysis supplies not protected from potential contamination (V119)*
  - *Breaches in aseptic practices for CVC (V147) or AVF/AVG care (V550)*
- *Not adequately disinfecting the HD station & equipment between patients (V122)*
- *Not using dialysis equipment and supplies in accordance with manufacturer's instructions for use, for example, not priming reprocessed or dry pack dialyzers and using dummy drip chamber to set up HD machine for patient treatment (V336, V352, V400, 403)-Use of dummy drip chamber during patient treatment bypasses safety mechanisms innate to the dialysis machine and has been determined to be a serious risk to patient safety. This observation should be considered an Immediate Jeopardy.*
- *Not testing hemodialysis machine alarms per manufacturer's DFU (V403)*
- *Not testing dialysate pH/conductivity with an independent method per manufacturer DFU, or lack of staff knowledge of acceptable parameters for pH/conductivity (V250)*
- *Not performing reprocessed dialyzer germicide tests (V350, V353) or patient/dialyzer identification by 2 people (V348) when patient is at the station*
- *Not assessing patients before and after treatment or monitoring during treatment according to facility policy (V504, V543, V550, V551, V715)*

Observe medication preparation and administration: *Use the applicable observational checklist 8 to observe this process. Conduct 2 observations of different staff preparing and administering medications for 1-2 patients.*

Triggers for citation:

- *Medications not prepared in a clean area away from the dialysis stations (V117)*
- *Single-dose medication vials punctured more than once or used for multiple patients (V118)*
- *Multi-dose medication vials punctured with a previously used syringe or needle (V143)*
- *Poor aseptic technique when dispensing and administering intravenous medications from vials and ampules (V143)*
- *Medications for multiple patients taken to a patient station (V117)*
- *Medications prepared and/or administered by unqualified personnel (V681)*
- *Not disposing of needles in a sharps disposal container (V121)*

Review facility isolation practices: *If there is a Hepatitis B positive (HBV+) patient on in-center hemodialysis at the facility:*

- ***Observe*** *the isolation room/area and the equipment and supplies contained within it. If possible, observe the care delivery for an HBV-positive patient to observe direct care procedures as described in the section above. Observe for separation of care practices from the HBV-susceptible patients.*
- ***Review*** *staff/patient assignments for the current week, looking at which patients are concurrently assigned to the staff caring for HBV-positive patients.*
- ***Ask*** *the staff on duty how staff assignments are made when the facility census includes HBV+ patient(s).*

Note: If the dialysis facility does not have any patients requiring isolation, the surveyor should ensure that the facility is prepared to provide isolation services as needed or has an isolation waiver on file.

Triggers for citation:

- *HBV+ patient(s) not isolated (V110, V128)*
- *Observed breaches in infection control practices when caring for HBV+ patients (V113, V116, V117, V119, V121)*
- *Staff assigned/delivering care to HBV+ patients and HBV negative patients on the same shift - Investigate the extent of the practice (V110, V131). (**Note:** Exceptions to this should be rare. If this occurs, the facility's efforts to avoid this situation should be clearly explained to the surveyor. Examples of such efforts are to schedule patients in a manner to avoid overlap between HBV+ and HBV-susceptible patients or scheduling HBV+ patients on shifts when there are 2 RNs on duty so that one RN may access the HBV+ patient's vascular access and administer their medications, while the other RN does so for the other patients. Emergency medical situations may be a justifiable exception.)*
- *Isolation equipment not dedicated for use on HBV+ patients (V130)*
- *HBV negative patient(s) dialyzed in the isolation room/area when an HBV+ patient is on in-center HD census (V110, 128, 130)*

Verify dialysis treatment prescription delivery: *Select a sample of 4-5 patients who are actively receiving their dialysis treatment during this review.* ***Review*** *and compare the dialysis prescription delivery (dialysate, dialyzer, blood flow rate, dialysate flow rate) to patients' dialysis orders for each observation of care. The dialysis prescription being delivered should be consistent with the physician's treatment order.*

Trigger for citation:

- *1 or more patients not dialyzed on ordered prescription, e.g., wrong dialysate, dialyzer type, blood flow rate, dialysate flow rate (V543, 544)*

Task 6: Patient Sample Selection

Reference Document: *Patient Sample Selection Worksheet*

General Purpose*: Surveyors should select a patient sample that represents the complexities and services provided at the facility. Whenever possible, select patients who are in the facility during the time of the onsite survey. This will enable the surveyor to validate information obtained through the Medical Record Review task, as well as gather information from the patient regarding their perception of the quality of care and their understanding of their plan of care.*

Initial Survey Key Consideration*: Dialysis facilities requesting initial approval may have a small patient census. If there are fewer than five patients, include all patients in the sample selection. Surveyors may review closed medical records, if available, when selecting samples.*

Home Dialysis in LTC*: When an ESRD facility has patients on their current census receiving home hemodialysis (HD) or peritoneal dialysis (PD) treatments in a nursing home under a written agreement, the ESRD survey team will include on-site visits to the nursing home(s) as part of the ESRD survey. The total number of nursing home onsite visits will be guided by the number of agreements established with the dialysis facility (see the table below). Refer to the table below for guidelines on the total number of on-site visits. If an ESRD facility provides dialysis services to residents in more than one nursing home, surveyors should review any available clinical information at the time of the entrance conference to identify indicators of poor outcomes, which can assist in selecting nursing homes and nursing home residents for the sample. If no concerns are identified, the nursing homes and residents may be selected at random.*

Use the following three sources when selecting the patient sample:

- *ESRD Core Survey Worksheet: Patient Roster*
- *Information obtained from the Entrance Conference Materials List*
- *Observations of Care*

Use entrance conference materials gathered from the facility to identify dialysis recipients that represent criteria from the Patient Roster, such as "unstable," "recent admission, and "hospitalization." Record selections on the Patient Roster, which displays patient information and the reason for sampling.

Sample Selection Size

Surveyors should select a patient sample size that accurately represents the facility's patient volume and the range of clinical services provided.

Attempt to include in-center hemodialysis patients from different days/shifts to determine whether there are trends in deficient practice.

Use the table below to determine the sample selection size:

A	B	C	D
Facility Census	Patient Sample Size (minimum)	Number of Nursing Home Agreements	Number of Nursing Home Visits*
1 to 50	5	1-10	2
51 to 100	7	11-20	3
101-150	10	20+	4
>150	15		
*If the dialysis facility offers home dialysis services in the nursing home in addition to in-center dialysis, select an additional two patients (minimum) from each nursing home visit. If the dialysis facility only offers home dialysis services in the nursing home, use Column B to determine patient sample size.			

If the dialysis facility census includes fewer than five patients, which may occur for facilities requesting initial approval, it should include all patients for review.

Surveyors may expand the patient sample to include additional patients at their discretion if quality of care and safety concerns related to dialysis care and services are identified during the survey.

Additional guidance for review criteria is found below:

- ***Unstable:*** *Surveyors should look at IDT involvement, functionality, and coordination for assessing and planning care for unstable patients, i.e., the most fragile patients. "Unstable" is defined at §494.80(d)(2) as patients with "(i) [e]xtended or frequent hospitalizations; (ii) [m]arked deterioration in health status; (iii) [s]ignificant change in psychosocial needs; or (iv) concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis."*
- ***New admission <90 days:*** *Surveyors should look at facility processes for assuring timely evaluation and appropriate care of patients new to the facility before and during their first treatment and first weeks at the facility. Pull at least one sample.*
- ***Observed patients:*** *You may also sample patients you have observed during the Observations of Care task, with possible concerns during the survey.*
- ***Complaints:*** *Patients who have filed or are involved in a complaint should be included in the patient sample. All named patients in a complaint investigation should be reviewed.*
- ***Involuntarily discharged (IVD) in the past 12 months, if applicable****: Surveyors should review documentation in the medical record to confirm IDT's reassessments, ongoing problem(s), and actions taken to resolve the problem(s) before the patient's involuntary discharge. Review all records of patients who have been involuntarily discharged. Note: Do not include patients who voluntarily or involuntarily transferred to other dialysis facilities.*

- ***Home Dialysis in LTC****: The purpose of conducting the on-site nursing home portion of the ESRD survey is to verify that:*
  - *Dialysis is being administered in a safe and sanitary environment.*
  - *Treatments are administered by qualified, trained, and competent dialysis administering personnel.*
  - *Coordination between the ESRD facility and the nursing home is occurring to ensure that the nursing home residents on dialysis receive quality care and timely and appropriate interventions to optimize their dialysis outcomes.*

TASK 7: Water Treatment Room and Dialysate Review

Reference Document: *Water Treatment and Dialysate Review Worksheet*

General Purpose*: Verify that the facility monitors the quality of the water used in treatments and the equipment used in water treatment.*

Review critical water treatment components with on-site staff routinely responsible for the activity and daily monitoring of the facility's water treatment system.

Tour of the water treatment room

Observe

- *The required water system components of the water treatment room (carbon tanks, RO unit, audible and visual alarms, DI requirements, if applicable) are present.*
- *Total chlorine test being performed and interview staff to assess their knowledge of the test and allowable limits.*
- *Chlorine testing is performed before the first shift of patient treatment and repeated before each shift, or at least every four hours.*
- *Maximum allowable level of 0.1mg/L total chlorine.*
- *Chlorine "breakthrough" procedure.*
- *Amount of carbon in the system (empty bed contact time- EBCT).*

Triggers for citation:

- *Absence of 2 carbon beds with a sample port in an outpatient water treatment system is citable on identification and should be considered an immediate jeopardy situation. Absence of 2 or more carbon beds with a sample port between (V192)*
- *Insufficient carbon empty bed contact time (<10 minutes total EBCT) or equivalency documentation for block carbon used with portable RO-verify this by interview and/or record review-surveyors are **not** expected to calculate EBCT (V195)*
- *Observed total chlorine test result >0.1mg/L; test done incorrectly or with incorrect reagents/equipment (V196)*
- *Staff assigned to total chlorine testing have inadequate knowledge of testing procedure, maximum allowable level of 0.1mg/L total chlorine, and/or breakthrough procedures (V260)*

Extending *may include an additional observation of another staff member conducting the chlorine test, or additional staff interviews.*

Observe the reverse osmosis (RO) unit for the following*:*

- *Water quality monitoring*

- *Monitoring RO function by % rejection*
- *Product water quality by total dissolved solids (TDS) or conductivity.*
- *The alarm system must be audible. No visual alarm is required for the RO unit.*
- *Interview with designated water treatment staff to assess their knowledge of the facility's water quality monitoring system. Refer to the Water and Dialysate Review: Observation and Interview worksheet.*

Note that if block carbon is used to supply dechlorinated water to a portable RO unit, there must be evidence from the manufacturer that the system attains equivalency to the 10-minute EBCT requirement, based on performance data of the block carbon. In addition, there must be one dual-block carbon system per portable RO unit, and each portable RO unit must supply one hemodialysis machine, per the manufacturer's directions. If the facility uses a continuous online chlorine monitor, inquire about periodic (daily on treatment days) validation testing using an alternative method.

Trigger for citation:

- *RO percent rejection and product water conductivity or TDS not monitored and recorded daily, water quality alarm non-functional, not audible in patient treatment area (V199, V200)*

***Extending** should include an interview with the technical administrative staff. **Note** that the absence of acceptable water treatment monitoring methods of the facility's RO function is citable upon identification. If the water treatment components appear in observable disrepair, consider reviewing the pre-treatment and water distribution components for compliance with the applicable V-tags (V188-V191, V198-V215).*

***Observe the deionization (DI) and resistivity monitor and alarm,** if present.*

If DI is present or included in a back-up plan, observe for the presence of:

- *Functional, continuous resistivity monitor after the DI system, with an audible and visual alarm in the patient treatment area*
- *Presence of an automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis stations*
- *Ultrafilter (UF) after the DI system*

***Interview** facility staff about the DI system and determine if there is a plan to utilize DI as a backup. **Ask** about the following:*

- *How is monitoring conducted?*
- *What is the minimum allowable resistivity level?*
- *What actions are taken when resistivity falls <1 megohm? (i.e., STOP dialysis).*

Note: *DI should not be used as the primary water purification component in a centralized water treatment system, except as a temporary emergency backup due to RO failure (V205).*

Triggers for citation: *(Note if DI is part of a backup plan, all of the triggers below are applicable)*

- *Absence of functional resistivity monitor or alarm; alarm not audible* ***or*** *visible in the treatment area; resistivity not monitored/recorded at least twice per treatment day (V202, V203)*
- *Absence of a functional automatic divert-to-drain or automatic stop valve to prevent unsafe water flow to the dialysis machines (V203)*
- *Staff unaware of accurate monitoring, minimum allowable resistivity of 1.0 megohm, or actions for DI tank exhaustion (i.e., stop dialysis) (V260)*
- *No ultrafilter in-line post DI (V204)*

All *of the above DI triggers are citable on identification, due to the serious safety hazard that poorly managed and monitored DI systems pose to patients.*

Initial Survey Key Consideration*: Chemical analysis for contaminants should be conducted when the Reverse Osmosis (RO) and Deionization (DI) systems are installed, when the membranes are replaced, and at least annually thereafter to ensure that AAMI limits are met. (V201, V206)*

Interview the person responsible for microbiological sampling and monitoring *of water and dialysate regarding the following:*

- *System disinfection*
- *Sample sites*
- *Collection methodology*
- *Sample timing (before disinfection)*
- *How often dialysate cultures are done for each HD machine*

Interview the person responsible for bicarbonate and acid dialysate concentrate mixing *regarding the following:*

- *Verification of proper mixing*
- *Testing of acid concentrate*
- *Bicarbonate concentrate time frame for use (24 hours or per manufacturer's DFU)*
- *"Spiking" (inserting additives) into individual dialysate containers*

Initial Survey Key Consideration*: New bicarbonate concentrate systems must be tested weekly for one month to ensure compliance with maximum/action levels of bacteria and endotoxins (V242).*

Triggers for citation:

- *Water/dialysate samples not drawn before disinfection (V254); sampling methods not per Conditions for Coverage (CfCs) (V252, V253, V255, V258)*
- *Water distribution system not disinfected at least monthly (V219)*
- *Each HD machine has not been cultured at least annually (V253)*
- *Staff unaware of correct dialysate concentrate mixing, acid concentrate batch testing, "spiking", duration of bicarbonate usability, etc. (V229, V233, V235, V236, V260)*

Review facility documentation of oversight of water & dialysate systems *in the following areas:*

Chemical and microbiological monitoring

- *Total chlorine testing - every 2 months*
- *RO monitoring by % rejection and product water quality by TDS or conductivity,* ***NOT*** *all gauge and component readings – every 2 months*
- *If DI present or has been used in the past 12 months, 2 months of resistivity readings at least twice per treatment day*
- *Product water chemical analysis – every 12 months*
- *Microbiological monitoring of water, including in the reuse room, and dialysate; both colony-forming units (CFU) and endotoxin units (EU) - every 6 months*
- ***Practice audits of the operators' compliance with technical procedures*** *- Look at 12 months of facility documentation of observations of staff conducting water testing, dialysate mixing, dialysate pH/conductivity testing, etc. (V260)*

Triggers for citation:

- *Total chlorine results exceeding 0.1mg/L without documentation of appropriate actions taken (V197)*
- *Failure to complete chemical analysis of product water at least annually (V201)*
- *Irregularities, trends of omitted tests (V178, V180, V196, V199, V200, V202, V203, V213, V252, V253)*
- *Microbiological results of water or dialysate exceeding action or maximum levels without documentation of appropriate actions taken (V178, V180)*
- *Practice audits of staff conducted less than annually (V260)*

If deficiencies are observed in the logs, interview technical and administrative staff and include a review of an equal number of additional logs, e.g., two (2) more months of total chlorine logs or RO logs, or 12 more months of chemical analysis.

Home Dialysis in LTC: *A review of water treatment and dialysate monitoring will be conducted at the dialysis facility after the survey team's on-site visit to the nursing home.*

The ESRD facility is responsible for ensuring that the water and dialysate for nursing home hemodialysis equipment meet the quality standards outlined in the ESRD Conditions for Coverage. The documentation of water and dialysate quality used in hemodialysis machines in the nursing home must be maintained at the ESRD facility. Although duplicate records may be kept at the nursing home, the ESRD surveyor must conduct this review at the ESRD facility to ensure that ESRD technical personnel are available to facilitate the review.

Review the water and dialysate quality results during the "Review of water/dialysate logs" in the Core Survey task. Verify that the tests listed below were performed by the ESRD facility and that corrective actions were taken as appropriate by the ESRD facility pursuant to the results of the tests. Additional information about each test is available in the Water Treatment and Dialysate Review Worksheet.

- *Total chlorine*
- *Product water conductivity/TDS*
- *Product water chemical analysis*
- *Microbial surveillance of water*
- *Microbial surveillance of dialysate*

TASK 8: Dialyzer Reprocessing/Reuse Review (If Applicable)

Reference Document: *Dialyzer Reprocessing and Reuse Worksheet*

General Purpose*: To ensure, through observations, interviews, and record reviews, that the reprocessing of each dialyzer is done appropriately and consistently.*

Initial Survey Key Consideration*: New facilities or facilities that add dialyzer reprocessing must validate the safety of the water supply to the reprocessing system by testing for bacteria (microbial content) and pyrogens (endotoxins) weekly for at least three (3) months. Less frequent testing, but not less than monthly, may be appropriate if there is a documented history of at least three (3) months of results consistently below the required levels. (V314)*

Observe the following high-risk components of dialyzer reprocessing, and interview *the reuse technician, as indicated:*

- ***Transportation of used/dirty dialyzers*** *to the reprocessing area—how promptly reprocessing occurs; if refrigerated, ask about refrigeration procedures and maximum refrigeration time. Dialyzers must be reprocessed within two hours of use.*
- ***Pre-cleaning procedures****—If manual pre-cleaning, header removal/cleaning, and/or reverse ultrafiltration are conducted, observe these processes for 1-2 dialyzers and interview about the procedures, the water source for pre-cleaning, and the maximum allowable water pressures at the pre-rinse sink.*
- ***Infection control considerations****: Ensure appropriate personal protective equipment is used for dialyzer reuse. Verify the presence of designated clean and dirty areas to minimize the risk of cross-contamination.*

Interview the reuse technician *about the facility procedures for the following:*

- *Germicide mixing*
- *Storage and spill management*
- *Dialyzer labeling/similar names warnings*
- *Reprocessing procedures*
- *Dialyzer refrigeration and storage*

Review the documentation of facility oversight of dialyzer reprocessing/reuse program *in the following areas:*

Quality Assurance (QA) audits - Review *12 months of facility documentation of the following reuse observational audits. For clarification about the audits, you may need to interview a technical administrative person, instead of the reuse technician:*

- *Observations of reprocessing procedures -each reuse technician observed at least semi-annually*

- *Observations of preparation of dialysis machines with reprocessed dialyzers for patients' treatments, i.e., germicide tests, priming, two-person identification of patient/dialyzer quarterly*
- *Dialyzer labeling, including similar names labeling, quarterly*
- ***Reprocessing equipment preventative maintenance**—Briefly review 12 months of documentation to verify adherence to the manufacturer's directions for daily calibration of automated equipment (this may be located on a daily "start-up" log) and routine maintenance procedures.*
- ***Reuse the adverse events/dialyzer "complaint" log. Look at the last** 12 months for actions taken in response to occurrences possibly related to reprocessing.*

Triggers for citation:

- *Improperly performed dialyzer pre-cleaning, header removal/cleaning (V334)*
- *Water used for pre-cleaning dialyzers is not purified to AAMI standards (V333)*
- *Absence of a functional water pressure gauge at the pre-cleaning sink (V332)*
- *Germicide not stored, mixed, or handled per manufacturer's DFU (V319, V321, V339)*
- *Reuse tech unaware of requirements in key patient safety areas per interview guide (V309, V319, V320, V328, V330, V345)*
- *Dialyzers not transported in a sanitary manner (V331)*
- *Dirty/used dialyzers left at room temperature for >2 hours before reprocessing (V331)*
- *Reprocessed dialyzers stored for extended periods, i.e., exceed the facility's maximum storage time or are not documented as safe and effective (V345)*
- *QA audits listed above are not done or incomplete - Extend to review all of the required QA audits for reuse (V360-V368)*
- *Reprocessing equipment maintenance and repair activities not documented and/or not per manufacturer's directions (V316, V317)*
- *Noticeably strong germicide odors and/or patient or staff complaints regarding germicide odors- review the last 12 months of ambient air vapor testing for the germicide (V318)*
- *Serious adverse events possibly related to dialyzer reprocessing/reuse, e.g., dialyzing a patient on another patient's dialyzer, without documentation of appropriate actions taken to prevent future similar events (V355-V357, V635)- Extend to include reuse as a focus area for QAPI Review.*

Extending the facility-based reprocessing/reuse review may include Observing the complete dialyzer reprocessing procedures, i.e., pre-rinse, automated cleaning, testing, germicide instillation, and labeling for at least 2-3 dialyzers (V327-V345); and additional interviews with reuse technicians and/or technical supervisory personnel.

Note: *If centralized dialyzer reprocessing is conducted with the dialyzers transported to an off-site location for reprocessing, refer to the current CMS Survey and Certification guidance in the State Operations Manual, Chapter 2, Section 2TASK 9: Dialysis Equipment Maintenance Review*

Reference Document: *Dialysis Equipment Maintenance Review Worksheet*

General Purpose*: To ensure, through interviews, observations, and record reviews, that all dialysis equipment is appropriately maintained by facility staff members who conduct functional, available, and routine preventive maintenance.*

Interview the technician responsible for maintaining the machine or equipment. Ask *about the hemodialysis machine manufacturer's directions for preventative maintenance and repair, as well as the prescribed intervals for preventative maintenance, i.e., per operating hours or calendar.*

Review Preventive Maintenance documentation for:

- *Home Machines – pick three at random from the log*
- *In-center Machines – pick three at random*
- *Reviewing logs to confirm that DFU was followed*

Review *the calibration documentation for the dialysis machine and dialysate pH and conductivity meters based on the manufacturer's DFU. Briefly look at two (2) months of logs for pH and conductivity meters and the most recent documentation of calibration of the equipment/ meters used to conduct the hemodialysis machine maintenance and repairs.*

Triggers for citation:

- *Trends of non-adherence to the hemodialysis machine manufacturer's directions for preventative maintenance (V403)*
- *No calibration of pH and conductivity meters or calibration of equipment meters or calibration not per manufacturer's directions (V403)*
- *Observations of severe lack of maintenance of ancillary equipment, e.g., scales, chairs, infusion pumps, oxygen concentrators, that have the potential to impact patient safety (V403)*

Extending *the review of dialysis equipment maintenance may include reviewing the PM logs for an additional 10% of HD machines, 2-3 additional months of calibration meter logs, or maintenance documentation of equipment in observable disrepair (V403).*

Home Dialysis in LTC: The ESRD facility is responsible for maintaining and repairing the dialysis equipment used at the nursing home. While equipment maintenance and repair documentation may be kept on-site at the nursing home, it must also be maintained at the ESRD facility to ensure proper monitoring and review. Note that

some of the dialysis equipment that may be used for dialysis in the nursing home setting is not maintained by the ESRD facility (e.g. NxStage System One, PD cyclers), and malfunctioning equipment is exchanged by the equipment supplier. It is the responsibility of the ESRD facility to ensure that the equipment exchange occurs in a timely manner.

Review the preventive maintenance logs for the hemodialysis equipment for the sampled nursing home residents. If issues are identified, surveyors should use their discretion to expand the sample. Additional information about dialysis equipment review areas are available in the Dialysis Equipment Maintenance worksheet. Surveyors will review:

- *Conventional HD machines and portable RO units*
- *Non-conventional HD and PD cyclers*

TASK 10: Home Dialysis Training and Support Review

Reference Documents: *Home Dialysis PD Worksheet; Home Dialysis HD Worksheet, Home Dialysis in LTC Worksheet.*

General Purpose*: Surveyors must verify that facilities that provide home dialysis training and support services adequately train and support staff as well as patients/caregivers to facilitate safe and successful home dialysis.*

The survey of a home dialysis-only facility must include all applicable survey tasks, e.g., Pre-survey Preparation, Entrance Conference, Patient Sample Selection, Environmental "Flash" Tour, Water/Dialysate Review, Dialysis Equipment Maintenance (as applicable to the equipment in use), Personnel Record Review, and QAPI Review.

Home Dialysis in LTC*: Surveyors will conduct onsite visits to the nursing homes where home dialysis is provided to nursing home residents. The focus of this review is to ensure that the administration of dialysis treatments and the management of residents receiving home dialysis are consistent with the training and education provided by the dialysis facility. Once on-site, the survey team lead will conduct introductions to:*

- *Explain the purpose of the visit.*
- *Provide an overview of the survey activities that will take place.*
- *Estimate the amount of time to be spent on-site.*

Survey activities that will be performed on-site at the nursing home include:

- *Introductions*
- *Tour of the Nursing Home Environment*
- *Observations of Home Dialysis Care*
- *Nursing Home Medical Record Reviews*
- *Nursing Home Resident (Patient) and Personnel Interviews*
- *Training and Competency Reviews*

Refer to the Home Dialysis in LTC worksheet for additional information about the survey activities that will occur at the nursing home.

Interview the home training nurse(s) *about the home training and support program, including evaluating patient candidacy, training patient/caregivers, verifying patient/caregiver understanding, providing IDT support, and providing QAPI oversight. You may need to interview different home training nurses for home hemodialysis and peritoneal dialysis. Interview questions are provided in the Personnel Interviews worksheet.*

If the opportunity arises during the survey to observe the direct care of home dialysis patients when they are being treated or trained at the facility, look for adherence to infection control standards.

Interviews and medical record reviews *of home dialysis patients are conducted during the tasks for Patient Interviews and Medical Record Reviews.*

Triggers for citation:

- *Home training nurse(s) interview or observation of care identifies concerns about knowledge, infection control practices, or other aspects of the home training program. For infection control concerns, refer to the applicable triggers for infection control listed in the Observations of Hemodialysis Care and Infection Control Practices task.*
- *Patient/caregiver interviews identify concerns about the adequacy of training, competency, and support from the IDT, i.e., registered dietitian, social worker, physician, and home training nurse (V581, 585, 586, 592).*
- *Medical record reviews of home dialysis patients identify concerns related to training or monitoring of home dialysis patients, including monitoring water/dialysate quality for HHD patients, if applicable (V585, 586, 593-595).*
- *The dialysis facility does not evaluate home program outcomes separately in QAPI (V626, 628).*

Extending *the review of the home dialysis training and support program may include reviewing the patient/caregiver training materials (V585), sampling additional home dialysis patients for interview or medical record review and further evaluating the surveillance of the home dialysis environment, i.e., home visits (V589).*

Surveyors may conduct on-site visits to LTC facilities to further evaluate the home dialysis care and services provided to patients in the LTC facility if quality of care and/or safety concerns are identified during the ESRD facility survey or when investigating a complaint directly related to the home dialysis services provided in an LTC facility. Surveyors may also conduct on-site visits to the LTC facility to observe the home dialysis environment when the ESRD facility only provides home dialysis services to residents of LTC facilities and does not have community patients on census.

Note*: The ESRD survey team does not have the authority to review non-dialysis-related care and services provided directly within a Medicare-certified LTC facility. If an on-site visit to an LTC facility is indicated based on survey findings, the review's focus should be directly related to the dialysis care and services provided to residents who are patients of the dialysis facility being surveyed. If at any time during the survey, a concern or issue arises regarding the non-dialysis-related care provided by the LTC facility to a sampled home dialysis patient, the survey team should report this as a complaint to the State Agency survey unit responsible for oversight of the Medicare-certified LTC entity.*

Task 11: Medical Record Review

Reference Documents: *Medical Record Review Worksheets for In-Center HD, PD, and Home HD. For each medical record review, complete a separate Medical Record Review Worksheet.*

General Purpose: *Conduct a focused medical record review to assess the quality of care provided to each sampled patient related to poor outcomes and the final data-driven focus areas. For patients who receive home dialysis services in the nursing home, nursing home medical records will be reviewed on-site. Refer to the Home Dialysis in LTC worksheet for additional guidance.*

Review the current dialysis prescription, medication orders, and dialysis treatment records for all sampled patients. Exclude closed records of patients who were involuntarily discharged.

Guidance for the medical record review for all sampled patients is found below:

- ***In-center HD patients****—Look at 2-3 consecutive weeks of hemodialysis treatment records for machine safety checks, treatments and medications delivered as ordered, blood pressure/fluid management, and patient monitoring per policy.*
- ***Home HD patients****—Look at 2-3 consecutive weeks of hemodialysis treatment records for staff monitoring of the patient's adherence to treatment and medication orders, machine safety checks, blood pressure/fluid management, and recognizing and addressing issues.* ***Note:*** *For sampled home HD patients, review the water/dialysate chemical and microbiological quality documentation, as applicable, for the hemodialysis equipment in use.*
- ***PD patients****—Look at 8-12 consecutive weeks of PD documentation, e.g., flow sheets for staff monitoring the patient's adherence to treatment and medication orders, blood pressure/fluid management, and recognizing and addressing issues.*
- ***Residents receiving home dialysis treatments in the LTC facility****- Along with the other components of the medical record review for home dialysis patients, surveyors should review home training and competency records of personnel who administer home dialysis treatments in the LTC facility to verify that individuals who administer home dialysis treatments have received the appropriate training before performing dialysis care as required under [V582, V586]. The training should be tailored to meet the individual needs of the residents. Following the requirements established at § 494.100(a) for home dialysis training, surveyors should also verify the ESRD facility's method of continuously evaluating and documenting the competency of administering personnel and addressing problems or concerns when identified.*

Data-driven focus areas for the survey*: Review the interdisciplinary team's attention to care and coordination by reviewing patient outcomes and interventions for all sampled patients in the data-driven focus areas. Assess the ESRD facility's actions by looking at*

the physician's orders, interdisciplinary progress notes, patient care plans, and other applicable medical record components.

Expect to see that one or more IDT members monitored the patient's outcome in the identified focus area(s), recognized when the patient was not achieving their goal, and responded with meaningful interventions aimed at improvement/resolution. Verify that if the interventions were unsuccessful, the IDT continued to make improvements by adjusting strategies with alternative interventions.

***Note:** This is a focused review examining facility systems for addressing poor patient outcomes in the data-driven focus areas. You are not expected to **search** each patient's record for all outcomes. If, during your review of the data-driven focus areas, you **discover** poor outcomes for the patient in another area, use your judgment about whether reviewing the additional area would be of value, and follow the guidance in the survey protocol above for that area.*

The remainder of each patient's medical record review should be focused on the criteria for sampling that patient, using the following guidelines:

Guidance for review of anemia management concerns (Patients with Hgb <10 g/dL)

Look for evaluation of the patient for:

- *Treatable causes of anemia, e.g., infection, inflammation.*
- *GI blood loss.*
- *Iron studies such as ferritin and transferrin saturation.*
- *Symptoms of anemia.*
- *Erythropoiesis-stimulating agent (ESA) prescribed or increased; and,*
- *Avoidance of transfusion.*

Guidance for review of fluid management concerns (Patients with >13mL/kg/hr average ultrafiltration rate (UFR) for intradialytic fluid removal)

Review available documentation for the presence of:

- *Interventions that address cause(s) for fluid gains between treatments.*
- *Interventions to mitigate the effects of rapid fluid removal during dialysis (e.g. hypotension, cramping, loss of consciousness).*
- *IDT recognition of the potential risks to the patient posed by both failures to control fluid gain between treatments and consistent rapid fluid removal (>13mL/kg/hour UFR average in any treatment length), and,*
- *Interventions to minimize those risks.*

***Guidance for review of patients sampled as "Unstable"** (described at V520 guidance for §494.80(d)(2) as patients with extended or frequent hospitalizations, marked*

deterioration in health status, significant change in psychosocial needs, or concurrent poor nutritional status, unmanaged anemia, and inadequate dialysis).

- *Plan to review IDT documentation in:*
- *progress notes*
- *physician's orders*
- *assessments and plan of care*
- *Verify that the IDT, including the social worker, uses a standardized mental and physical assessment tool to evaluate the patient's psychosocial status, e.g., age-appropriate Healthcare Related Quality of Life-HRQOL survey*

Note: The IDT process and thoroughness of the patient's assessments and plans of care should be reviewed in detail. Ensure that an assessment of the patient was conducted and that the clinical and/or psychosocial issues contributing to the patient's instability were addressed through an appropriate plan of care interventions. There should be evidence of a functional IDT process, including substantive contributions from and communication among all required IDT members.

Guidance for review of patients sampled as newly admitted (<90 days)
Review *the admission orders, labs, and progress notes. Review the process for ensuring the new patient was appropriately evaluated on admission, prior to the first dialysis treatment, and during their first weeks of care at the facility.*

- *Expect to see that the patient had written orders by a physician or non-physician practitioner (if allowed by state law) and was evaluated by an RN prior to their first dialysis treatment at the facility.*
- *The patient must be evaluated for Hepatitis B and tuberculosis and offered Hepatitis B vaccination and pneumococcal vaccination, if indicated.*
- *The facility staff should have evaluated and addressed the issues related to the patient's labs, fluid management, dialysis-related problems, as well as other clinical, nutritional, and psychosocial needs.*
- *For home dialysis patients and their partners, their training and home dialysis environmental needs must be evaluated and addressed.*

Patients sampled due to observations

- ***Focus*** *review on the circumstances pertinent to the concerns raised from your observations and/or random interview(s) regarding the patient.*

Patients sampled as part of a complaint investigation

- *Follow the applicable complaint investigation process.*
- *To preserve the intention of the Core Survey Patient Sample Selection process, patients sampled as part of complaint investigations must not make up more than 25% of the survey patient sample.*

Patients sampled as involuntarily discharged (IVD)
The primary focus of your investigation into a patient who has been involuntarily discharged should be on the meaningful actions taken by the facility in an attempt to avert the IVD, and to preserve the health and safety of the patient.

Note: *The ESRD CfCs severely limit the option of involuntarily discharging a patient without transferring the patient's care to another outpatient dialysis facility. When one of the criteria for consideration of involuntary transfer/discharge listed at V766 is identified, the facility and ESRD Network are fully expected to exhaust all resources to address the problems and prevent the patient's transfer or discharge. If there is no resolution, the facility must make meaningful attempts to transfer that patient's care to another outpatient dialysis facility. The only exception to this expectation is in the case of an immediate severe threat to the health and safety of others when the facility may utilize an abbreviated IVD procedure.*

Review *the documentation pertaining to the actions taken in an attempt to avert the IVD, to locate and arrange for the transfer of the patient's care to another dialysis provider, and, if all meaningful efforts are unsuccessful, the procedures followed prior to discharging the seriously abusive/disruptive patient. You should* ***interview*** *the facility's qualified social worker, other applicable staff, and the patient to supplement and/or support the medical record review.*

Guidance for review of IVD of the seriously abusive/disruptive patient

Patients' rights protect a patient's right to refuse treatment. Therefore, skipping or shortening treatments and/or failing to meet facility set goals for clinical outcomes, as well as verbal outbursts or verbal abuse that do not present an immediate severe threat, are not acceptable reasons for involuntary discharge.

Review of the medical record and other documentation must show written evidence of/that:

- *The IDT took meaningful actions to attempt to avert the IVD. At a minimum, these efforts must include a full IDT reassessment of the patient involving the professional IDT, the medical director, and patient's attending physician to investigate and determine the root causes of the patient's disruptive or abusive behavior and actions to resolve the issues* ***before*** *considering involuntary discharge of the patient. The facility investigation should include evaluation of the possible roles mental illness, cognitive impairment, cultural or language differences, or staff behaviors and interactions with the patient may play in the patients' problematic behaviors, with interventions implemented to address and resolve the conflict(s).*
- *The facility staff contacted and collaborated with the applicable ESRD Network to resolve the problems, avert the discharge, and, if unsuccessful, facilitate a transfer to another facility.*

- *The facility staff contacted other dialysis facilities, including those outside their corporate parent company, to attempt to transfer the patient before considering IVD.*
- *The facility fully implemented/conducted ALL of the above actions **before** proceeding with the procedures for IVD.*
- *Once the decision for IVD was made, the facility notified the patient at least 30 days before the IVD, notified the applicable ESRD Network, obtained a written physician's order for the IVD that was signed by the medical director and the patient's attending physician, and notified the State survey agency of the IVD.*

Triggers for citation:

- *Lack of evidence of a functional IDT process to monitor, recognize, and address barriers to attaining identified patient outcome goals in one or more clinical and psychosocial areas*
- *Incomplete, inaccurate, inaccessible, or insecure medical records. **Extend** to look at medical records management systems to ensure mechanisms are in place to facilitate the maintenance of complete, accurate, and accessible records on all patients (V726)*
- *Concerns identified in other survey tasks, which can be investigated further through medical record review to support or dispel findings*

Home Dialysis in LTC:
In addition to the dialysis order/prescription and dialysis treatment records reviewed at the nursing home, review information listed below in the ESRD facility medical record of the sampled nursing home patients. Additional survey instructions for each review area is available in the Medical Record Review worksheet.

- *Labs/Indicators*
- *Interdisciplinary Clinical Care*
- *Self-Monitoring Data*
- *Patient Education*

Task 12: Patient Interviews

***Reference Document:** Patient Interview Worksheets for In-Center HD, PD, and Home HD*

***General Purpose**: The surveyor will conduct patient interviews to verify information obtained during observations and record reviews throughout the survey. For patients who receive home dialysis services in the nursing home, on-site interviews with the patient (resident) will be conducted. Refer to the Home Dialysis in LTC worksheet for additional guidance.*

Interview all sampled patients *selected during "Patient Sample Selection." If the sampled patient is unavailable or refuses to be interviewed, replace each patient you cannot interview with an alternative patient. Enter these additional patients on the Patient Roster and document that they were interviewed. Unless their interview indicates a reason to do so, you are not required to review their medical records. Interviews should take approximately 15-20 minutes.*

Patient interviews should be conducted with patients in the facility at the time of the survey. Explain that the interview will be conducted privately unless the interviewee requests otherwise. If an interview cannot be completed in person, the surveyor should request assistance from a facility staff member to reach the patient by phone.

There will be general questions asked of every patient in every interview; however, patient interviews should include questions specific to the patient's condition, reason for admission, quality of care, and knowledge of their plan of care.

Refer to the Patient Interview Worksheet for additional guidance.

Note: For patients sampled due to being involuntarily discharged, some of the Interview Guide "core" questions may not be applicable.

Interview techniques – use plain language, be aware of the patient's level of understanding, and maintain cultural awareness.

Triggers for citation:

- *Home dialysis patient interviews or staff interviews indicate concerns about the training program -* ***Extend*** *to review documentation of patient/caregiver training and demonstration of comprehension (V585, V586)*
- *Patient or caregiver interviews indicate a lack of functional patient education program and patients' rights concerns -* ***Extend*** *review to documentation of patient education and patients' rights*
- *Patients express concerns regarding:*
  - *Patients' rights and responsibilities (V451)*
  - *Education about transplant and all options of dialysis modalities and settings, including those not offered at the facility (V451, V453, V458)*
  - *Disrespectful treatment from staff (V452)*
  - *How to prevent infections and protect their dialysis access (V562)*
  - *The safety and comfort of the physical environment of the facility (V401, 402)*
  - *Disaster preparedness at home and how to evacuate the facility in an emergency Refer to Emergency Preparedness tag at EP-0038 and EP-0040)*
  - *Communication with the IDT and involvement in planning their care (V501, V541)*
  - *Staff proficiency in delivering safe, adequate care (V681, V713)*
  - *Problems due to inadequate numbers of qualified trained staff, e.g., nursing, dietitian, social worker, patient care technicians (V757-759)*

- *Culture of Safety: freedom to report care concerns, ask questions, make suggestions, or file a grievance/complaint without fear of reprisal (V465-V467*
- *Adequate training and IDT support for home dialysis patients and caregivers to facilitate successful home dialysis (V585, V592)*

Be alert to trends of any complaints or triggers and incorporate those "triggers" in each subsequent patient interview.

Task 13: Personnel Record Review

Reference Documents: *Personnel Record Review Worksheet*

General Purpose*: All dialysis facility staff members must meet the applicable scope of practice and State licensure requirements. Additionally, all dialysis facility staff must meet personnel qualifications and demonstrate the competencies necessary to effectively serve the needs of their patients. The surveyor will review personnel files to determine if staff members are licensed (if applicable), have the necessary educational requirements, training, and ongoing competencies required to perform the specific duties of their positions.*
Verify that staff and personnel are licensed, certified, and or permitted in accordance with State and local requirements.

Verify that staff and personnel meet all standards (such as licensure, board certification, and work experience requirements) in accordance with personnel qualifications at §494.140.

Review a sample of personnel files representing staff from each of the disciplines listed below for verification of qualifications, training, and competency:

- *Medical director*
- *Nurse manager*
- *Home dialysis training nurse*
- *Charge nurse*
- *Staff nurse*
- *Patient Care Technician (PCT)*
- *Registered dietitian*
- *Master's-prepared social worker*
- *Water treatment system technician*
- *Reuse technician*
- *Machine/equipment technician*

Audits of personnel practice: *The Core Survey process includes the expectation that the dialysis facility will continuously monitor its operations, including auditing staff competency and compliance with implementation of technical and patient care procedures, to ensure patient safety. The Core Survey supports the requirements of the ESRD CfCs and recommendations of the Centers for Disease Control and Prevention (CDC) in that facility staff must be periodically, but not less than annually, audited through direct observation while performing water testing, dialysate mixing and testing, dialysis equipment operation (V260), dialyzer reprocessing/reuse procedures (V360, V367, V368), and direct patient care infection prevention practices (V132, V142, V147). During the course of the Core Survey, surveyors should expect to see that required staff practice audits are conducted by observers who possess the qualifications and training to evaluate the accuracy of the specific procedure implementation. The practice audit documentation must clearly show that the observed staff demonstrated competency in the*

procedure(s), or what lapses in practice were observed. When lapses in practices are observed, facility documentation must demonstrate evidence of follow-up with investigation and performance improvement actions.

Triggers for citation:

- *Personnel lack required qualifications, training, or competency verification (EP-0038, V681, V684-V696)*
- *PCTs listed with no current certification-check for hire date within 18 months; Note that medical, military, or other approved leave of absence extends the time allowed for certification/recertification (V695)*

Extending *personnel file review may include review of additional personnel files to verify accuracy of the facility-submitted documentation or investigate the extent of personnel qualifications, training, and competency issues.*

Task 14: Personnel Interviews

Reference Documents: *Personnel Interview Worksheets for the Medical Director, Staff Nurse, Patient Care Technician, Dietitian, Social Worker, Administrator, Other Medical Staff*

General Purpose*: The surveyor will conduct personnel interviews to assess staff members' knowledge of their responsibilities in relation to regulatory requirements, as well as facility policies and procedures. Personnel interviews will also aid in clarifying or validating observations throughout the survey process. Note: For patients who receive home dialysis services in the nursing home, nursing home staff will also be interviewed. Refer to the Home Dialysis in LTC worksheet for additional guidance.*

Surveyors should interview personnel associated with concerns identified during the survey process, such as Observations of Care, Medical Record Review, and Patient Interview, to determine and/or support staff competency and compliance with the requirements necessary to perform their duties.

Interviews may be conducted in person or by phone. Tailor the staff interviews to address the specific survey issues and concerns. Surveyors should also utilize the applicable ESRD Core Survey interview worksheets for additional "core" questions. The interview worksheets have been segregated by personnel type.

Home Dialysis in LTC*: The surveyor will interview dialysis facility staff before conducting the nursing home onsite visit. Before visiting the nursing home onsite, ESRD surveyors should interview the home training nurse, social worker, and dietician to gather information regarding the services provided by the ESRD facility to the nursing home and/or the resident(s) of the nursing home. Interview questions are outlined in the Personnel Interviews worksheet.*

Note: The biomedical technician may be interviewed during the Water and Dialysate Review task, and the home training nurse(s) may have been interviewed during the Home Dialysis Training and Support task.

Task 15: Quality Assessment & Performance Improvement (QAPI) Review

Reference Document: *QAPI Review Worksheet*

General Purpose: *Verify that the facility's QAPI program is sufficiently comprehensive and robust to monitor and track all facility operations/services, recognize when performance improvement is indicated, respond with effective actions to attain and sustain improvements, and support a facility-wide culture that ensures optimum patient safety.*

QAPI Scope: *Each facility is required to develop and implement a QAPI program tailored to its specific needs and characteristics. The surveyor must review each facility's QAPI program to determine the presence of active involvement of the professional members of the IDT. At a minimum, members of the QAPI team must include the medical director/physician, a registered nurse, a social worker, and a dietitian. The facility's QAPI program may also include patients, caregivers, and other technical facility personnel.*

Active involvement is demonstrated by the routine presence and participation of QAPI team members in identifying and analyzing facility practices and goals, as well as implementing improvement activities.

The facility is expected to recognize when performance improvement is needed in any area and respond with performance improvement actions tailored to the unique aspects of that facility and its patient population, aimed at achieving improved patient safety and quality of care.

Some dialysis corporations implement a comprehensive corporate-based program. A facility's utilization of a corporate-based QAPI program is not the sole basis for citation. The surveyor must review and determine whether the corporate QAPI program includes:

- *Participation from facility staff members.*
- *Representation of all the dialysis facility's operations and services; and,*
- *Measurable clinical indicators related to outcomes and prevention/reduction of medical errors.*

Preparation for QAPI Review: *Although portions of the QAPI review may occur throughout the survey, the bulk should be conducted toward the end of the survey. Conducting the review after most of the survey is completed allows the surveyor to determine if the facility has identified the same concerns as the survey team and whether performance improvement actions have been initiated to address them.*

Review the facility QAPI documentation for the last six (6) months in the areas listed below.

The QAPI survey review is divided into three Segments:

Segment I: *Facility Monitoring of Care and Operations*
Segment II: *Patient-related Data and Survey Findings*
Segment III: *Culture of Safety*

Segment I: Facility Monitoring of Care and Operations

The review of Segment I is brief and is conducted to verify that the facility's QAPI program has sufficient infrastructure to enable sustainable quality improvement. Specifically, the program framework is designed to continuously monitor all areas of dialysis-related care and services using indicators and performance measures.

The facility's QAPI program should include all the services provided by the facility and be segregated by modality and setting (e.g., in-center conventional HD, in-center nocturnal HD, daily HD, conventional home HD, home PD, in-center PD, HD or PD provided in LTC facilities).

The review of Segment I incorporates two areas:

- *Clinical and operational indicators; and*
- *Oversight of technical operations and practice audits.*

Clinical and Operational Indicators

The facility must measure, analyze and track, at a minimum, all required clinical and quality indicators at §494.110. This includes, but is not limited to the following:

- *Adequacy of dialysis*
- *Nutritional status*
- *Mineral metabolism and renal bone disease*
- *Anemia management*
- *Vascular access*
- *Medical injuries and medical errors identification*
- *Hemodialyzer reuse program, if the facility reuses hemodialyzers*
- *Patient satisfaction and grievances*
- *Infection control*

The facility must identify outcome goals reflecting the most current community standards and best practices. Surveyors should reference current national standards from sources such as the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines produced by the National Kidney Foundation and the recommendations for water and dialysate safety from the Association for the Advancement of Medical Instrumentation (AAMI).

The QAPI documentation must show the active involvement of all personnel necessary to adequately address and resolve problems/issues, including members of the IDT, i.e.,

medical director, nurse manager, master's-prepared social worker (V691), registered dietitian, and other personnel such as technical staff and patient care staff (V626, V628).

***Home Dialysis in LTC**: During the QAPI Review at the ESRD facility, expect to see the inclusion of nursing home dialysis in the QAPI process (V626). Look for:*

- *Evaluation of outcomes for nursing home residents on dialysis at the nursing home: The ESRD facility must track, trend, and analyze data for residents on dialysis from each nursing home with which it has a current agreement.*
- *Performance Improvement: The ESRD facility must identify and investigate any problems/poor outcomes experienced by nursing home residents, develop and implement performance improvement plans, and evaluate the results and plans of action.*
- *Collaboration/coordination: There must be evidence of an effective working relationship between the nursing home and the ESRD facility. Evidence of collaboration and coordination may include, but is not limited to:*

    - *Recurring meetings and bi-directional communication for information exchanges between the ESRD facility and the nursing home leadership/staff.*
    - *Communication plans for reporting adverse events and appropriate interventions; and*
    - *Timely and prompt response to dialysis-related issues.*

Deficiencies related to the roles and responsibilities of the ESRD facility regarding its delivery of ESRD services to nursing home residents should be cited at the corresponding ESRD regulatory citation.

Oversight of Technical Operations and Practice Audits

Technical Operations: Verify the presence of consistent QAPI oversight and performance improvement actions, when indicated, for the following technical areas:

- *Water/dialysate quality (in-center and home hemodialysis)*
- *Dialysis equipment maintenance and repair*
- *Dialyzer reuse*

Practice Audits: If surveyors have observed deficient findings during observations or practice audits during the Personnel Record Review, determine whether the facility successfully maintained oversight by appropriately identifying this lapse, and expect to see an evaluation to determine the cause(s) of the issue and actions taken to resolve it.

Segment II: Patient-Related Data and Survey Findings

***General Purpose**: Surveyors will review the patient-related data maintained by the facility in four critical areas to assess how the facility monitors and implements provisions of care using clinical data. Through this review, the surveyor should assess*

the facility's QAPI activities to identify issues, prioritize areas for improvement, and respond to problematic areas in order to attain and sustain improvements.

Critical review areas include the following:

- *Mortality*
- *Infection prevention and control*
- *Medical errors/adverse occurrence tracking system*
- *Data-driven focus areas (identified through the DFR)*

Mortality review

Review *QAPI activities relating to any patient death trends and evaluation of patient deaths and/or trends, and efforts implemented to address adverse trends potentially related to care received at the facility.*

Review, *with the responsible facility person, the QAPI documentation for evaluating the facility's mortality data. Focus the discussion on the analysis and trending of causes of patient deaths and their relationship to the care received at the facility.*

Ask: *What information do you collect about patient deaths? How does the QAPI Team conduct analyses of individual patient deaths and recognize trends in causes and contributory factors to these deaths? Expect to see evidence that the facility reviewed and evaluated all patient deaths and analyzed trends in causes of patient deaths (V628).*

Expect to see, for identified trends in cause of deaths, that the IDT investigated the issues and conducted QAPI review focused on the aspects of care.

For example, a high rate of deaths due to infection should prompt the facility to review their central venous catheter (CVC) rate, CVC reduction efforts, hospitalization patterns, water/dialysate cultures, and staff compliance with infection control practices.

Infection prevention and control

Review of the facility's program for infection occurrence tracking/trending, vaccination rates, personnel infection control education and visual auditing, and patient education in infection prevention.

Infections are a leading cause of death in dialysis patients, and protection from infection is vital to their health and safety. This QAPI review aims to ensure that the facility's activities support a multifaceted and effective facility-wide program for the prevention, detection, and management/control of infections, with the goal of minimizing or eliminating healthcare-associated infections (HAIs) acquired at the facility.

There are four (4) areas of the infection prevention and control review:

- *Infection Occurrence Tracking/Trending/Surveillance*
- *Vaccination: High-Risk Disease Management*
- *Staff Education and Visual Practice Audits for Infection Control*
- *Patient Education for Infection Prevention*

Infection Occurrence Tracking/Trending/Surveillance

***Review** the infection tracking logs.*

- *All positive culture results, dialysis access, bloodstream infections (BSI), and peritonitis episodes, if applicable, should contain sufficient information for each (i.e., patient name, date, infecting organism, culture site, antibiotic use)*
- *Trends in infections should be recognized, evaluated/investigated, and performance improvement strategies implemented and monitored for effectiveness (V637).*

***Review** the documentation of the facility's dialysis-related infection rates.*

Expect to see that the facility routinely calculates dialysis-related infection rates as applicable to the modalities offered (i.e., hemodialysis vascular access, peritoneal dialysis catheter, peritonitis) using an accepted formula. Vascular access and peritoneal dialysis catheter infection rates are generally expressed as events per 100 patient months [(# of events ÷ total months patients on HD/PD in 12 months) x 100]. Peritonitis rates are either expressed as episodes per patient year at risk [episodes ÷ (total PD patient months ÷ 12 months)] or episodes per 100 patient months; high infection rates and upward trends are recognized, investigated, and performance improvement actions are implemented and monitored for effectiveness (V637).

Vaccination: High-Risk Disease Management

Refer to the facility vaccination information obtained from the Entrance Conference Materials List.

***Request** the QAPI documentation of oversight for surveillance and vaccinations, including, but not limited to:*

- *Hepatitis B patient surveillance: susceptible patients and personnel offered vaccination (V125-V127).*
- *Tuberculosis surveillance of patients on admission or exposure.*
- *Influenza vaccinations are offered to patients and personnel seasonally.*
- *Pneumococcal pneumonia vaccination offered to patients.*
- *New Hepatitis C (HCV) infections (i.e. antibody elevation for facilities that test for HCV) or unexplained ALT elevations; and,*
- *Surveillance and vaccinations offered (if available) of Emerging Infectious Diseases, such as Influenza, Ebola, Zika Virus, COVID-19, and others.*

Expect to see evidence of active QAPI oversight of the high-risk disease surveillance and vaccination programs listed above. If trends or lapses in surveillance or vaccination are identified, verify that the QAPI Team thoroughly investigates the problem, implements performance improvement actions, and monitors them for effectiveness (V637).

Staff Education and Visual Practice Audits for Infection Control

During staff interview, ask the following questions:

- *What are staff taught about the patient care practices for the prevention of infections?*
- *How often are they re-educated in infection prevention?*

During interviews with the training director, ask the following questions:

- *What methods are used to conduct and ensure visual audits are performed on all staff performing clinical and technical functions within the dialysis facility?*
- *How often are the visual audits conducted?*
- *If unsatisfactory results are evident in practice audits, how are corrective actions implemented?*
- *How are staff involved in developing and implementing corrective action(s)?*

***Review** the facility documentation for all visual audits conducted to observe personnel infection control practices while delivering care to patients.*

CDC guidelines for Infection Control Training and Education in dialysis facilities recommend that training and education for all employees at risk for occupational exposure to blood be provided at least annually, given to new employees before they begin working in the unit, and documented. Expect to see evidence of active staff education and at least annual verification of competency of infection prevention and control practices through visual audits of each staff member who provides direct patient care. Competency verification should include, but is not limited to, staff's ability to demonstrate initiation and discontinuation of hemodialysis, vascular access care, medication preparation and administration, and hand hygiene. When lapses in practice were observed by the dialysis facility through their surveillance and monitoring efforts, expect to see evidence of actions taken for improvement and staff involvement during the planning and development of improvement plans. (V637, V132, V142, V147).

Patient Education for Infection Prevention

During interviews with patients and staff, ask the following:

- *How are patients educated about infection prevention?*

- *How are patients encouraged to be engaged and aware of infection prevention practices that both patients and dialysis facility staff should follow? (e.g., changing gloves, hand hygiene, cleaning/disinfecting equipment)*
- *How are patients encouraged to voice concerns about personnel infection control practices?*

Expect to see that the facility's infection prevention and control program includes educating patients and families about strategies for remaining infection-free (V637, V562, V585).

When facility data indicates high rates of infection *or the potential for high rates of infection (for example, high rates of CVC >90 days), or patterns of problematic survey findings in infection control: Ask the following:*

- *What investigations have been conducted into your facility's problematic infection issue?*
- *What QAPI strategies have been implemented to improve the problem?*
- *What improvements have been achieved?*

Expect to see that a facility with high patient infection rates has fully investigated for trends and causes of the infections, including but not limited to staff care practices, water/dialysate, and dialyzer reprocessing sources. For high rates of CVC>90 days, there should be evidence of meaningful strategies implemented for reducing CVC rates. When reductions in infection rates or CVC >90 days are not attained, there should be evidence of revisions and changes in performance improvement actions until improvements are achieved (V637).

Medical error/adverse occurrence/clinical variance tracking and investigation system

Verify the presence of an effective system for responding to events, investigating, and addressing causal or contributory factors to prevent occurrence or recurrence. During this review, the surveyor should "follow" an error/event and the facility's performance improvement actions, as evidenced in the facility system.

The intent of this review is to ensure that there is an effective QAPI system in place for reporting, investigating, and responding to errors/occurrences.

Review the facility error/occurrence log for the past 6 months. Select one error/occurrence from the log. The error/occurrence may be randomly selected or may be pertinent to concerns identified during the survey. Review the investigation and outcome of the error/occurrence with the appropriate facility personnel. The surveyor should determine whether the investigation into the circumstances was thorough, possible cause(s) were investigated, and QAPI actions to prevent future similar occurrences occurred.

Expect to see evidence that the facility thoroughly investigated the error/occurrence by examining the circumstances surrounding it, including interviews with all applicable staff to understand the context, and that these staff members were involved in the development of the resolution plan. There must be evidence that the facility implemented a meaningful action plan to mitigate factors that contributed to the error/occurrence, monitored the plan for effectiveness in preventing recurrence, and, if a similar error/occurrence happened, revised and implemented the revised plan (V634).

The error/occurrence log is not automatically a source for survey deficiency citations. However, if a facility fails to investigate the causes of errors or adverse events, this may indicate a citation.

Data-driven focus areas

Individualize the review of the data-driven focus areas pertinent to this facility survey. In all areas, conduct a detailed review to determine the quality and effectiveness of the facility QAPI actions for addressing problematic areas and attaining and sustaining improvements in outcomes.

See the ESRD Core Survey QAPI Review Worksheet for additional guidance on this review.

***Review** data-driven focus areas and survey findings in more detail with the responsible facility-based person.*

Ask the facility-based person the following questions:

- *How are facility performance improvement activities prioritized?*
- *How did the facility-based QAPI program recognize the focus area problem/issue and investigate the root cause(s)?*
- *What actions were taken for improvement, and how were the actions and subsequent outcomes monitored to ensure improvements were attained and sustained?*
- *If improvements were not attained, what actions were taken?*

For each data-driven focus area and survey finding you reviewed, expect to see evidence that the facility:

- *Prioritized improvement activities to ensure the areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner (V639)*
- *Routinely monitored the focus area, recognized that a problem/opportunity for improvement existed, thoroughly investigated root/multiple causes of the issues, and developed and implemented performance improvement plans (V638)*
- *Monitored the performance improvement plan to attain and sustain improvements, or, if goals were still not achieved, revised the actions until improvements were attained and sustained (Note: repeated entries of "will*

monitor" over several consecutive months without active revisions to action plans is not sufficient evidence of effective QAPI) (V626, 628-637)

Segment III: Facility Culture of Safety

Verifying the presence of a facility-wide culture that promotes and protects patient safety. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/events, open blame-free communication between all levels of staff and patients, and clearly communicated expectations of staff and patients. A facility-wide culture of safety enables staff and patients to participate in ensuring that everyone at the facility is committed to identifying and mitigating risks to patients.

The culture of safety review has two (2) components:

- *Staff participation*
- *Patient participation*

Staff Participation Review

Verify the presence of open communication among all levels of facility staff and encouragement for staff to voice concerns without fear of retribution. The surveyor will review the facility's method for promoting and gathering staff feedback or questions as well as providing information related to expectations among all levels of staff.

There should be evidence that the facility has an organized, facility-based system in place for staff to submit written or verbal suggestions for improvement, communicate concerns about their work environment, and file complaints.

If the surveyor has gathered evidence of staff complaints not being addressed, for example, during staff interviews, confirm with an appropriate member of the QAPI team whether the complaints were received, reviewed, and addressed.

Expect to see evidence that the facility administration educates and encourages staff to make suggestions and voice concerns and complaints about their work environment. There should be evidence that administrative personnel recognize and acknowledge staff concerns in a timely, non-judgmental manner, conduct substantive investigation into the concerns, and include applicable staff in resolution to the issues (V626).

Patient Engagement Review

The surveyor will review the facility's method for promoting and gathering patient feedback. Verify facility participation with all dialysis patients that provide feedback on the overall care and operations at the dialysis facility to promote patient satisfaction. The surveyor should review the facility patient grievance, complaint, or suggestion

system by "following" a patient complaint through the process.

If the patient interviews task indicated a reluctance to voice complaints, follow up with facility-based personnel for further investigation. Review the record to see if the complaints were documented and ask staff whether the complaints were received. Is there a QAPI process that allows patients to complain or submit grievance without fear of retribution?

***Ask:** How are staff taught to respond to patients' concerns? What types of patient concerns do you educate and expect staff to report and record?*

***Ask:** How are patients educated about and encouraged to freely speak up and voice suggestions and complaints/grievances without fear of retribution or retaliation? How are their concerns, verbal or written suggestions, and complaints/grievances recorded and responded to? What is your facility's system for communicating with patients and reporting the resolution to them? (V465, V466, V467)*

***Review** the patient suggestion/complaint/grievance log with the responsible facility-based person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient. You may wish to interview the involved patient about their experience using the facility's patient suggestion/complaint/grievance system.*

Expect to see that facility management and staff encourage patients to verbalize suggestions and concerns, in addition to written complaints/grievances. Staff should be educated on how to respond professionally to patients' verbalized concerns and to report them to their supervisor for recording and follow-up (V636, V765).

There must be evidence that the patient's concern you reviewed was recorded, the circumstances investigated, mutually acceptable resolution reached, and the result communicated to the patient (V636, V465, V765).

Verify that the facility routinely assesses the patients' satisfaction with the facility services and care received and acts upon the identified opportunities to improve care.

***Ask the following:** How do you assess patient satisfaction/perceptions of care at this facility?*
How do you use that information to improve programs or care delivery? (V636)

Triggers for citation:

The QAPI program does not:

- *Administer oversight of all facility operations including monitoring all areas and conducting practice audits as required by the CfC (V260, V362-V368, V403)*

- *Recognize and address risk areas where facility outcomes and/or survey findings indicate performance improvement is needed/indicated (V625-V640)*
- *Follow up on performance improvement plans, resulting in improvements not attained or sustained or recurring similar adverse events (V634, V638)*

Extending *the QAPI review should be considered if there are serious, pervasive deficient practices identified during the survey and were not recognized and/or adequately addressed by the dialysis facility. Extending the QAPI review should include investigating the facility's compliance with the Conditions for Coverage of Medical Director and Governance. This may include interviews with the facility administrator, medical director, and governing body members to determine what administrative failures have contributed to the pervasive problems, through lack of adequate staff and/or resources (V754, V756, V757); lack of staff training and education (V713, V715, V760, V761, V763); and/or lack of involvement or leadership of the medical director (V712, V714).*

Decision Making:

General Purpose: To facilitate communication and collaboration among survey team members regarding potential survey findings and to prepare for the Exit Conference.

- *Meet with the survey team to discuss the survey findings*
- *Refer to reference documents on ESRD decision making*
- *Make copies of evidence as needed to document survey findings*

Exit Conference:

General Purpose: To notify the facility of the concerns identified during the survey, and the preliminary findings of deficient practice.

Verbally present findings in order of severity; do not provide specific V-tags.

Follow relevant SOM & State procedures.

Part III: Surveyor Worksheets

Task 1: Pre-Survey Preparation

ESRD Core Survey Data Worksheet

Facility: _____	***CCN:***
_____	
Surveyor: _____	***Date:***
_____	

Instructions: *Use this worksheet to gather essential information for reviewing the pre-survey and entrance conference tasks.*

Contents: *There are 2 sections of this worksheet:*

- ***Section 1: Pre-survey Preparation and Dialysis Facility Report (DFR) Review*** *(pages 2-4): To review and evaluate the facility outcomes data from the current FY DFR and quarterly DFR (QDFR), as well as facility survey history review, and ESRD Network contacts*
- ***Section 2: Entrance Conference Materials List*** *(pages 5-6): To be copied and given to the facility*

PRESURVEY PREPARATION AND DIALYSIS FACILITY REPORT REVIEW

The following dialysis facility reports are created under contract to the Centers for Medicare & Medicaid Services (CMS) to provide state surveyors and the CMS Location with information on clinical performance and outcomes. Dialysis facility reports contain data pertaining to patient characteristics, treatment patterns, hospitalization, mortality, and transplantation patterns in dialysis facilities.

Dialysis Facility Report (DFR): *Provided as a resource for characterizing selected aspects of clinical experience at a given facility relative to other caregivers in the state, End Stage Renal Disease (ESRD) Network, and across the United States. Since these data could be useful in quality improvement and assurance activities, each state's surveying agency may utilize the DFRs as a resource during their survey and certification process. This report is updated annually.*

Quarterly DFR (QDFR): *The QDFRs for State Surveyors provide quarterly updates of select measures from the DFRs in December, March, and June of each year. These reports are utilized by each state surveyor's agency as a resource during the survey process and guide the pre-survey identification of the preliminary data-driven focus areas*

Download and review *the current FY DFR for the facility. The DFR, QDFR, as well as the State Profiles may be accessed at https://dialysisdata.org/.*

Enter your Username and Password then click "Log in" to log onto the Secure DialysisData.org web site.
The DFR tab contains the current comprehensive FY DFR for all facilities in the respective State or Region.
The QDFR tab contains more recent results of select measures from the FY DFR
The Profiles tab contains the:
State Profile
Confidential Outcomes List

Review how the facility is ranked on the State Profile/Outcomes List. Review the information about the facility on pages 1-3 of the DFR.

Review the most current fiscal year's DFR in conjunction with the facility QDFR. Review each pre-populated data element on the QDFR, which are key aspects of facility performance and assists the surveyor's identification of the preliminary data-driven focus areas during the pre-survey preparation. Note trends in outcomes over the 4-year period. For standardized mortality (SMR) and transplant ratios (STR), the 4-year average is a more consistent measure of facility performance. For standardized hospitalization ratio (SHR) and standardized readmission ratio (SRR) the most recent 1-year measurement is most meaningful.

Review how the facility compares with U.S. Averages. Note declining or improving trends and flag which elements are worse than the U.S. Average. Consider those clinical areas for preliminary data-driven focus areas for the survey.

Preliminary data-driven focus areas based on DFR review:

1. _____ ***4.*** _____
2. _____ ***5.*** _____
3. _____ ***6.*** _____

During the entrance conference:

Review and confirm the preliminary data-driven focus areas by reviewing more recent facility data. This will allow the surveyor to determine whether improvements were made for any clinical indicator reported during the time period not covered in the DFR. The ***final data-driven focus area(s)*** *will be confirmed after it is determined that a clinical indicator has outcomes lower than the national average and has not improved after reviewing the facility's more recent clinical outcomes report.*

Discuss the selection of the data-driven focus areas for the survey with the

administrative person. If SHR &/or SRR on DFR are high, include hospitalization/readmission as a data-driven focus area. If the facility is currently meeting the thresholds in an area where the DFR review indicated problems, performance improvement may have taken place. Upon validation of the improvement, you may choose not to include that as a data-driven focus area for review.

Review of Transplant Waitlist: If the facility DFR and current transplant % is lower than the national threshold, review requested information and gather additional information during the medical record review and patient interviews to ensure patients are being educated and referred as required (V-458, V-513, V-554, V-561).

Final data-driven focus areas for survey:

1. _____ ***4.*** _____
2. _____ ***5.*** _____
3. _____ ***6.*** _____

Review ESRD Facility Survey and Complaint History (12-18 months): *This information may be obtained from facility files maintained by the State Agency, the CMS national database, and in Table 15 of the facility DFR. Note any survey and complaint information in the space provided below.*

Areas of concern:

_____
_____
_____
_____

Contact the ESRD Network: *After entrance into the facility, call the Network to ask about concerns related to involuntary discharges, complaints, and other survey issues related to the ESRD Core Survey process.*

Network person contacted: _____ *Position:*

_____

Is the facility under any special Network quality monitoring? If yes, describe:

_____
_____
_____
_____
_____

Have there been any involuntary discharges or patterns of involuntary transfers from the facility? If yes, how many, and describe any pattern(s) identified:

_____

_____

_____

_____

Have there been patterns of patient complaints about the facility? If yes, describe any pattern(s) identified:

_____

_____

_____

Are there any other concerns you have about the facility that the survey team should be aware of? If yes, describe your concerns:

_____

_____

_____

_____

Areas of concern based on facility survey/complaint history and contact with the ESRD Network:

1. _____ ***4.*** _____

2. _____ ***5.*** _____

3. _____ ***6.*** _____

Task 4: Entrance Conference

ENTRANCE CONFERENCE MATERIALS LIST

***Surveyor**: Make a copy of this list and provide it to the facility-based staff member for submission of requested information.*

***Facility**: Review this list and submit the requested information to the survey team leader. Items must be submitted within the timeframes indicated.*

Timeframe for submission: within 3 hours of receipt of materials list

- *List of current patients by name, separated into modalities.*
- *List of facility key personnel: medical director, administrator, nurse manager, social worker, dietitian, chief technician, and home training nurse(s).*
- *Current in-center hemodialysis patient schedule by days & shifts with any isolation patients identified (seating chart or assignment sheet).*
- *List of patients admitted to this facility within the past 90 days who are currently on census (do not include visiting patients) separated by modality with date of admission.*
- *List of patients who have been designated as "unstable" for any month in the past 3 months, including reason for unstable designation and month.*
- *List of all patients who were involuntarily discharged (not transferred to another outpatient dialysis facility) from this facility in the past 12 months.*
- *List of all discharged patients categorized as "lost to follow up" (i.e., not transferred out or discontinued dialysis) for the past 12 months.*
- *List of home hemodialysis (HHD) or peritoneal dialysis (PD) patients scheduled to be seen at the facility during the survey.*
- *List of all nursing homes with which the ESRD facility has a current written agreement to provide dialysis services and the address for each nursing home, including:*
    - *How treatments are provided in each distinct nursing home, i.e., in the patient's private room, in a common area, or both.*
    - *The names of all patients currently receiving dialysis services from the ESRD facility at each nursing home.*
    - *The modality and treatment schedule (including the scheduled times for the hemodialysis treatments) for each nursing home resident named above.*
    - *Names and credentials (e.g., RN, PCT) of any nursing home personnel who deliver the residents' dialysis treatments.*
    - *A copy of the written agreement between the ESRD facility and each nursing home.*
- *Hospitalization logs with admitting diagnoses listed for 6 months.*
- *List of current patients readmitted to the hospital within 30 days of discharge in past 6 months, separated by modality.*
- *Infection logs for past 6 months.*

- *List of in-center HD patients who are dialyzed with 0 K+ or 1.0 K+ dialysate.*
- *All patients' individual laboratory results for hemoglobin, Kt/V, uncorrected calcium, phosphorus and albumin for the current 3 months; separated by modality.*

Timeframe for submission: End of survey, Day 1

- *Vaccination information*
  - *# of patients who received complete series of Hepatitis B vaccine _____*
  - *# of patients who received the influenza vaccine between August 1 and March 31 _____*
  - *# of patients who received the pneumococcal vaccine _____*
- *Staff schedule for the previous two weeks, organized by days of the week*
- *Policies and procedures for the following:*
  - *Patient care (admissions, transfers, discharge, involuntary discharge, clinical care policies)*
  - *Water treatment*
  - *Dialysate preparation and delivery*
  - *Dialyzer reprocessing and reuse, if applicable*
- *Patient suggestions, complaints, and grievances for last six months*
- *Adverse event documentation for the last six months*
- *QAPI meeting minutes for last 6 months. Include any supporting documentation and/or materials*
- *Copy of any CMS-approved waivers, i.e. medical director, life safety code, and/or isolation room waivers. Note: Life Safety Code waiver cannot apply to dialysis facilities that do not provide an exit to grade (42 CFR 494.60(d)(1)).*
- *Staff practice audits for infection prevention while performing direct patient care. Submit practice audits for most recent 12 months.*
- *Routine maintenance and testing logs for the following water and dialysate components:*
  - *Daily water system monitoring, submit for last two months*
  - *Total chlorine testing, submit for last two months*
  - *Bacterial cultures and endotoxin results (water and dialysate cultures), submit for last 6 months*
  - *Product water chemical analysis, submit for last 12 months*
  - *Staff practice audits for water testing, dialysate mixing and testing, and microbiological sampling, submit for last 12 months*
- *Documentation of the following equipment maintenance:*
  - *Preventative maintenance and repair of hemodialysis machines, submit for last 12 months*
  - *Calibration of equipment for machine maintenance, submit for last 12 months*
  - *Calibration of equipment for dialysate pH and conductivity testing, submit for last two months*
- *Logs for the following dialyzer reprocessing components, if applicable:*
  - *Bacterial cultures and endotoxin results from reuse room sites, submit for the last six months*

- *Preventative maintenance and repair of reprocessing equipment, submit for last 12 months*
- *Reuse QA audits, submit for the last 12 months*

Timeframe for submission: Day 2 of survey

Completed "CMS 3427-End Stage Renal Disease Application and Survey and Certification Report"

Entrance Conference Questions

Facility: _____ *Date:* _____

Instructions: A surveyor must gather preliminary information to aid in their review of a dialysis facility. Ask the facility representative for the information listed below.

FACILITY CENSUS

Current in-center census (hemodialysis only): ____
Number of hemodialysis treatment stations currently in use: _____

FACILITY HOURS OF OPERATION

What time is the facility open? _____
What time do staff arrive? _____
How many patient shifts are there? M/W/F _____ *T/Th/Sa* _____
What time do patient shifts start? _____

FACILITY ISOLATION/INFECTION CONTROL

Does the facility have an isolation room or area? Yes _____ *No* _____
If yes, how many isolation stations are available? _____
If not, does the facility have an active isolation room waiver? Yes _____ *No* _____
Does the facility have a written agreement with a local facility which accepts patients requiring isolation? Yes _____ *No* _____
Name of alternate facility: _____
Number of HBV+ patients on census: _____
Number of patients on census with MRSA and/or VRE: _____
Has the facility had patients (or staff) with Tuberculosis conversions (- to +) in the last 3 years? Yes _____ *No* _____
If yes, was the appropriate State Health Department notified? Yes _____ *No* _____

DIALYZER REUSE

Does the facility reprocess/reuse dialyzers? Yes _____ *No* _____
If yes, name of germicide used: _____
Does the facility use a centralized reprocessing facility? Yes _____ *No* _____
If yes, name of centralized reprocessing facility: _____

HOME DIALYSIS

Does the facility have a home dialysis training and support program? Yes ____*No* _____
If yes, number of patients: Peritoneal Dialysis (PD) ____*Home Hemodialysis (HHD)* ___
If not, how does the facility provide access to this home dialysis?

_____
_____

Does the facility have home dialysis patients receiving services in a nursing home? Yes____ No ____
If yes, number of patients: PD _____ HHD _____ and number of nursing homes where home dialysis services are provided _____
Who administers the home dialysis treatments in the nursing home?
Dialysis facility personnel _____ Nursing home personnel _____ Existing caregiver ___

SPECIAL CONSIDERATIONS
Does the facility have patients on census who weigh less than 30 kg or who are under 18 years of age? Yes _____ No _____

PERSONNEL
Staff members currently in orientation: _____
Does the facility use contracted staff to provide care in the facility? Yes _____ No _____

MEDICAL RECORDS
What system for patient medical records is used? _____
Is part or all of the medical record computerized? Yes _____ No _____

Task 5: Observations of Hemodialysis Care and Infection Control Practices

Facility _____ ***CCN*** _____ ***Surveyor***

_____

This worksheet is intended to guide the surveyor through the Observations of Hemolysis Care and Infection Control Practices in the ESRD Core Survey Process.

There are three parts to this survey task:

- *Observation of care delivery*
- *Review of facility isolation practices*
- *Verification of dialysis treatment prescription delivery*

Observation of care delivery:

Observe the following activities using the applicable observational checklists in this worksheet:

Hemodialysis patient care and dialysis station & equipment preparation: Attempt to capture at least 2 separate observations of each of the procedures listed below. Try to conduct observations on different days and of different staff. It may be possible to observe several of the procedures at one dialysis station during the changeover between patient shifts. Observe each procedure listed below one at a time, to ensure focus on that activity.

- *Initiation of Hemodialysis with Central Venous Catheter (CVC) (Checklist 1)*
- *Central Venous Catheter Exit Site Care (Checklist 2)*
- *Discontinuation of Hemodialysis with Central Venous Catheter (Checklist 3)*
- *Initiation of Hemodialysis with Arteriovenous Fistula (AVF) or Arteriovenous Graft (AVG) (Checklist 4)*
- *Discontinuation of Hemodialysis with AV Fistula or AV Graft (Checklist 5)*
- *Cleaning and Disinfection of the Dialysis Station (Checklist 6)*
- *Preparation of the Hemodialysis Machine/Extracorporeal Circuit (Checklist 7)*
- *Dialysis Supply Management and Contamination Prevention: This checklist should be completed after the surveyor has conducted the above critical observations (Checklist 9)*

Medication preparation and administration: Use observational Checklist 8 to capture two observations of different licensed nursing staff preparing and administering medications. Include two patients in each observation to identify trends in practice and technique.

Facility isolation practices: *Observe the isolation room or area, and the equipment and supplies contained within it. Is the isolation room/area:*

Separated from other in-center stations? (V110, V128)
Equipped with dedicated equipment and supplies for single-patient use? (V110, V130)

Determine if there are any HBV+ patients who will be receiving hemodialysis at the facility during the survey. ***Complete this section if there are HBV+ patients*** *receiving in-center hemodialysis at the facility.*

Review staff assignments to ensure staff member for HBV+ is dedicated to one or more HBV+ or HBV immune patient. Staff should not simultaneously be caring for patients who are HBV susceptible. (V110, V131). Are staff members dedicated?

Yes _____ No _____

(Note: Exceptions to this should be rare. Emergency medical situations may be a justifiable exception.)

Staff members are observed practicing appropriate isolation techniques, e.g. removal of PPE and hand hygiene when entering and leaving the isolation room/area. (V113, V130)

Yes _____ No _____

Notes:

_____

_____

_____

Verification of dialysis treatment prescription delivery: *Complete this section to verify that dialysis treatments being delivered are administered in accordance with the physician's ordered dialysis prescriptions.*

Select four to five patients that are actively receiving hemodialysis treatments during this review.

Observe the following treatment prescription components for each of the selected patients:

Dialyzer
Blood flow rate
Dialysate flow rate
Dialysate

Review the dialysis orders/prescription in the medical record for each of the selected patients. Compare the order with the delivered treatment parameter set on the dialysis machine while the patient is being dialyzed.

Note: If the facility utilizes an electronic medical record, request the facility-based staff member to assist in retrieving the electronic treatment orders/prescription.

Are delivered patient treatment parameters consistent with physician dialysis orders/prescriptions? (V543, V544) Yes _____ No _____

Note: Observational Checklists 1 through 9 are intended to focus observations on the elements/steps of the procedures that would be expected to prevent the transmission of infections and ensure safe operation of dialysis equipment.

Additional Comments:

Checklist 1: Initiation of Hemodialysis with Central Venous Catheter (CVC)

Facility _____ *Surveyor*

_____

Obs. #1: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Obs. #2: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Notes: The patient should wear a mask whenever CVC is accessed. Staff PPE must include a gown, mask, eye protection, and gloves (V115, V113). All antiseptics and disinfectants must be used per the manufacturer's instructions.

ACTION	OBSERVATION 1	OBSERVATION 2
No common tray/cart brought to dialysis station (supplies for only that patient brought to station) (V116)	Yes ____ No ____	Yes ____ No ____
Hand hygiene, don clean gloves (V113)	Yes ____ No ____	Yes ____ No ____
Place clean field under CVC ports (V147)	Yes ____ No ____	Yes ____ No ____
Close the catheter clamps. Disinfect CVC hubs, using an appropriate antiseptic. May perform external disinfection by: Open hub disinfection by wiping the threads and top of uncapped hub with antiseptic, removing any residue/blood and/or. Closed connector devices which have penetrable caps not removed, wipe outside connecting surfaces of device (V147)	Yes ____ No ____	Yes ____ No ____
Connect sterile syringes aseptically to each port to remove indwelling solutions and/or flush with sterile saline; initiate treatment	Yes ____ No ____	Yes ____ No ____
Remove gloves, hand hygiene (V113)	Yes ____ No ____	Yes ____ No ____

Additional Notes:

_____

Checklist 2: Central Venous Catheter Exit Site Care

Facility _____ *Surveyor*

_____

Obs. #1: Patient ID _____*Date/time* _____ *Station #* _____ *Staff*

_____

Obs. #2: Patient ID _____*Date/time* _____ *Station #* _____ *Staff*

_____

Notes: Patient should wear a mask whenever CVC is accessed (V147). Staff PPE must include gown, mask, eye protection, and gloves (V115, V113). All antiseptics and disinfectants must be used per manufacturer's instructions.

ACTION	*OBSERVATION 1*	*OBSERVATION 2*
No common tray/cart brought to dialysis station (supplies for only that patient brought to station) (V116)	*Yes ____ No ____*	*Yes ____ No ____*
Hand hygiene, don clean gloves (V113)	*Yes ____ No ____*	*Yes ____ No ____*
Remove old dressing and discard	*Yes ____ No ____*	*Yes ____ No ____*
Remove gloves, hand hygiene, clean gloves (V113)	*Yes ____ No ____*	*Yes ____ No ____*
Cleanse area around CVC exit site with antiseptic ; allow to dry before applying dressing (V147)		
Sterile dressing applied to CVC exit site; may apply antimicrobial ointment if not contraindicated or chlorhexidine-impregnated dressing if no sensitivity (V147)	*Yes ____ No ____*	*Yes ____ No ____*
Remove gloves, hand hygiene (V113)	*Yes ____ No ____*	*Yes ____ No ____*

Additional Notes:

_____

_____

Checklist 3: Discontinuation of Hemodialysis with Central Venous Catheter

Facility _____ *Surveyor*

_____

Obs. #1: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Obs. #2: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Notes: Patient should wear a mask whenever CVC is accessed (V147). Staff PPE must include gown, mask, eye protection, and gloves (V115, V113). All antiseptics and disinfectants must be used per manufacturer's instructions.

ACTION	*OBSERVATION 1*	*OBSERVATION 2*
No common tray/cart brought to dialysis station; supplies for only that patient brought to station (V116)	*Yes ____ No ____*	*Yes ____ No ____*
Hand hygiene, don clean gloves (V113)	*Yes ____ No ____*	*Yes ____ No ____*
Place clean field under CVC ports (V147)	*Yes ____ No ____*	*Yes ____ No ____*
Reinfuse extracorporeal circuit	*Yes ____ No ____*	*Yes ____ No ____*
Remove gloves, hand hygiene, don clean gloves (V113)		
Close CVC clamps; Disinfect CVC connections with appropriate antiseptic. May perform external disinfection by: *Wiping exterior of connections before disconnecting blood lines: Open hub disinfection wiping threads and top of open CVC hubs, removing any residue/blood after disconnecting blood lines and/or;* *Closed connector devices: wiping exterior of connections before disconnecting blood lines (V147)*	*Yes ____ No ____*	*Yes ____ No ____*
Disconnect blood lines aseptically (V147)	*Yes ____ No ____*	*Yes ____ No ____*
Apply sterile port caps aseptically after post treatment protocol (applicable to closed connector devices when changed) (V147)	*Yes ____ No ____*	*Yes ____ No ____*
Discard unused supplies or dedicate them to that patient; no disposable supplies returned to common supplies (V116)	*Yes ____ No ____*	*Yes ____ No ____*

ACTION	OBSERVATION 1	OBSERVATION 2
Remove gloves, hand hygiene (V113)	Yes ____ No ____	Yes ____ No ____

Additional Notes:

_____

_____

_____

Checklist 4: Initiation of Hemodialysis with Arteriovenous Fistula (AVF) or Arteriovenous Graft (AVG)

Facility _____ *Surveyor*

_____

Obs. #1: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Obs. #2: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Notes: Staff PPE must be gown, face shield or mask/eye protection, and gloves (V115, 113). All antiseptics and disinfectants must be used per manufacturer's instructions.

ACTION	OBSERVATION 1	OBSERVATION 2
No common tray/cart brought to dialysis station (supplies for only that patient brought to station) (V116)	Yes ____ No ____	Yes ____ No ____
Wash skin over access with soap and water or antibacterial scrub (patient or staff may do this-patients should be instructed to wash their access upon entering facility & staff verbally confirm with patient that it was done; for dependent patients, staff must do this before proceeding with skin antisepsis) (V550)	Yes ____ No ____	Yes ____ No ____
Evaluate access; Locate/palpate cannulation sites	Yes ____ No ____	Yes ____ No ____
Hand hygiene (remove gloves, if worn); don clean gloves (V113)	Yes ____ No ____	Yes ____ No ____
Apply antiseptic to skin over cannulation sites and allow to dry; sites not touched again after skin antisepsis, without repeating skin antisepsis (V550)		

ACTION	OBSERVATION 1	OBSERVATION 2
Insert cannulation needles; tape in place; initiate treatment	Yes ____ No ____	Yes ____ No ____
Remove gloves, hand hygiene (V113)	Yes ____ No ____	Yes ____ No ____

Note: This checklist is not intended for use with buttonhole cannulation technique

Additional Notes:

Checklist 5: Discontinuation of Hemodialysis with AV Fistula or AV Graft

Facility _____ *Surveyor*

_____

Obs. #1: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Obs. #2: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Notes: Staff PPE must be gown, face shield or mask/eye protection, and gloves (V115, 113). All antiseptics and disinfectants must be used per manufacturer's instructions.

ACTION	OBSERVATION 1	OBSERVATION 2
No common tray/cart brought to dialysis station (supplies for only that patient brought to station) (V116)	Yes ____ No ____	Yes ____ No ____
Hand hygiene, don clean gloves (V113)	Yes ____ No ____	Yes ____ No ____
Reinfuse extracorporeal circuit; disconnect bloodlines aseptically	Yes ____ No ____	Yes ____ No ____
Remove gloves, hand hygiene, don clean gloves (V113)		
Remove needles aseptically; discard needles in Sharps container at point of use; Needle sites held with clean gauze or bandage using clean gloved hands (patient, staff or visitor) or disinfected clamps (V550, 113)	Yes ____ No ____	Yes ____ No ____
Remove gloves, hand hygiene (V113)	Yes ____ No ____	Yes ____ No ____
When hemostasis is achieved: Hand hygiene, don clean gloves; replace blood-soiled bandage/ gauze on needle sites; Bandage/gauze on each needle site is clean & dry prior to discharge (V550, 113)	Yes ____ No ____	Yes ____ No ____
Discard unused supplies or dedicate them to that patient (no supplies returned to common supplies) (V116)	Yes ____ No ____	Yes ____ No ____
Remove gloves, hand hygiene (patient or visitor who held sites, remove gloves, hand hygiene) (V113)	Yes ____ No ____	Yes ____ No ____

Additional Notes:

_____

Checklist 6: Cleaning and Disinfection of the Dialysis Station

Facility _____ *Surveyor*

_____

Obs. #1: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Obs. #2: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Notes: All items listed in this checklist must be disinfected using an EPA-registered hospital disinfectant prepared and used in accordance with manufacturer's instructions (V122)

Staff PPE must be gown, face shield or mask/eye protection, and gloves (V115, 113)

ACTION	*OBSERVATION 1*	*OBSERVATION 2*
Remove all bloodlines and disposable equipment; discard in biohazards waste; dialyzer for reprocessing: all ports capped, dialyzer and bloodlines transported in a manner to prevent contamination of other surfaces (V122)	*Yes ____ No ____*	*Yes ____ No ____*
Empty prime waste receptacle, if present on machine	*Yes ____ No ____*	*Yes ____ No ____*
Remove gloves, hand hygiene, don clean gloves (V113)	*Yes ____ No ____*	*Yes ____ No ____*
Use disinfectant-soaked cloth/wipe to visibly wet all machine top, front and side surfaces, dialysate hoses, Hansen connectors, and outside surfaces of dialysate concentrate containers (V122)		
Wipe wet all internal and external surfaces of prime waste container and allow to dry if present; prime waste container must be disinfected before used	*Yes ____ No ____*	*Yes ____ No ____*

ACTION	*OBSERVATION 1*	*OBSERVATION 2*
to prepare for another patient's treatment (V122)		
When chair vacated: discard unused disposable supplies (or dedicate to that patient); chair fully reclined, fresh disinfectant cloth/wipe used to visibly wet all external front-facing and side chair surfaces, including down sides of seat cushion and tops of side tables (V116, V122)	*Yes ____ No ____*	*Yes ____ No ____*
Non-disposable items: BP cuff & tubing, TV controls, call button, data entry station and counters around dialysis station wiped wet with disinfectant (V122)	*Yes ____ No ____*	*Yes ____ No ____*
If clamps are used, cleaned of visible blood and disinfected (V116)	*Yes ____ No ____*	*Yes ____ No ____*
Discard cloths/wipes; remove gloves, hand hygiene (V113)	*Yes ____ No ____*	*Yes ____ No ____*

Attention: The previous patient must fully vacate the dialysis station before surface cleaning, disinfection and set up for the next patient begins.

Additional Notes:

Checklist 7: Preparation of the Hemodialysis Machine/Extracorporeal Circuit

Facility _____ *Surveyor*

_____

Obs. #1: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Obs. #2: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Notes: Hemodialysis machines must be operated in accordance with the manufacturer's directions for use for internal function verification and dialysate testing. Artificial dialyzers must be rinsed and tested in accordance with the germicide (if reprocessed) and dialyzer manufacturer's directions for use. Dummy drip chambers must never be used to prepare a machine for patient treatment (V400, V403)

Staff PPE must include gloves; if reprocessed dialyzer, gown, face shield or mask/eye protection (V115, V113, and V320)

ACTION	*OBSERVATION 1*	*OBSERVATION 2*
Reprocessed dialyzer germicide tests done (i.e., presence test before rinsing/priming, absence of residual test prior to treatment initiation) (V350, 353)	*Yes ____ No ____*	*Yes ____ No ____*
Dialyzer rinsed/primed with sufficient saline (note that single use dialyzers not chemically sterilized may require less saline for rinsing than reprocessed dialyzers and chemically sterilized single use dialyzers) (V352, 403)	*Yes ____ No ____*	*Yes ____ No ____*
Dialysate pH and conductivity tested with an independent method; Staff aware of allowable pH range and variation from machine conductivity reading (V250)	*Yes ____ No ____*	*Yes ____ No ____*
Machine alarms and internal functions (e.g., pressure holding test) tested (V403)	*Yes ____ No ____*	*Yes ____ No ____*
Reprocessed dialyzer: patient and dialyzer matched and identified by 2 people while patient is at dialysis station (V348)	*Yes ____ No ____*	*Yes ____ No ____*

Additional Notes:

_____

Checklist 8: Parenteral Medication Preparation and Administration

Facility _____ *Surveyor*

_____

Obs. #1: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Obs. #2: Patient ID _____ *Date/time* _____ *Station #* _____ *Staff*

_____

Notes: Medications must be prepared in a clean area on a clean surface away from dialysis stations (V117).

ACTION	*OBSERVATION 1*	*OBSERVATION 2*
Hand hygiene (V113)	*Yes ____ No ____*	*Yes ____ No ____*
Single dose vials used for one patient only and discarded (V118)	*Yes ____ No ____*	*Yes ____ No ____*
Multiple dose vials are only entered with a new, sterile syringe and needle, labeling with date opened and discarded within 28 days or by manufacturer's instructions (V143)	*Yes ____ No ____*	*Yes ____ No ____*
Wipe stopper with alcohol or other antiseptic (V143)	*Yes ____ No ____*	*Yes ____ No ____*
Withdraw medication into sterile syringe; Label syringe if medication not immediately administered; Medications may be prepared for multiple patients at one time, but administration must be to one patient at a time, leaving remainder of medications in the clean preparation area (V117)	*Yes ____ No ____*	*Yes ____ No ____*
Only individual patient's medications taken to their dialysis station (V117)	*Yes ____ No ____*	*Yes ____ No ____*
Hand hygiene, don clean gloves and other PPE as indicated by potential exposure (e.g., gown and mouth/nose/eye protection if injecting into blood lines) (V113, 115)	*Yes ____ No ____*	*Yes ____ No ____*
Wipe injection port with antiseptic; inject medication (V143)	*Yes ____ No ____*	*Yes ____ No ____*

ACTION	*OBSERVATION 1*	*OBSERVATION 2*
Discard syringe into sharps disposal container Exception: If using a needleless system with no attached needle, disposal into a sharps container is not necessary (V121)	*Yes ____ No ____*	*Yes ____ No ____*
Remove gloves, hand hygiene (V113)	*Yes ____ No ____*	*Yes ____ No ____*

Additional Notes:

_____

Checklist 9: Dialysis Supply Management and Contamination Prevention

Facility _____ *Surveyor*

_____

Observation period #1: Date _____ *Time of observation period*

_____

Observation period #2: Date _____ *Time of observation period*

_____

NOTE: This checklist is intended to be completed after observations of care using checklists 1 through 8 have been completed, to record your observations related to the facility supply management in general throughout that observation periods. Record details of specific stations, staff, and patients involved in the applicable fields below.

ACTION	*OBSERVATION 1*	*OBSERVATION 2*
Supplies are stored and kept in designated clean areas, sufficient distance from dialysis stations to prevent contamination from potentially infectious materials/substances (V119)	*Yes ____ No ____*	*Yes ____ No ____*
Supplies for next patient are not brought to the station before the prior patient's treatment is terminated and applicable piece of equipment (machine, chair) is cleaned/disinfected (i.e., supplies are not placed on or near the machine until it has been "stripped" and surface disinfected) (V119)	*Yes ____ No ____*	*Yes ____ No ____*
Carts or trays containing supplies are not taken to or moved between dialysis stations (V119)	*Yes ____ No ____*	*Yes ____ No ____*
Staff do not store patient care supplies in pockets or on their person (V119)	*Yes ____ No ____*	*Yes ____ No ____*
Non-disposable equipment (e.g., thermometer, pH/conductivity meter, access flow device, O2 saturation meter, blood glucose meter, stethoscope diaphragm/bell end) brought to the dialysis station is disinfected before being returned to a common area or taken to another dialysis station Disinfection=all surfaces wiped visibly wet with EPA-	*Yes ____ No ____*	*Yes ____ No ____*

registered hospital disinfectant and allowed to dry (V116)		
Medication vials are not taken to the dialysis station (V117)	*Yes ____ No ____*	*Yes ____ No ____*
Disposable supplies taken to the dialysis station not used on the patient are discarded or dedicated to that patient and not returned to common supplies (V116)	*Yes ____ No ____*	*Yes ____ No ____*

Additional Notes:

Task 6: Patient Sample Selection - Roster

***Instructions**: Select patients using the criteria provided on the table below. Record patient information in the appropriate fields and mark the appropriate column to indicate the "Reason Sampled". During the Medical Records Review, focus each review on the sampling criteria.*

***Facility:** _____ **CCN:** _____ **Census:** ____ **Date:** _____*

Abbreviations	*Reason Sampled*									
Modality: *ICHD: In-center Hemodialysis* *ICPD: In-center Peritoneal Dialysis* *HHD: Home Hemodialysis* *PD: Home Peritoneal Dialysis* *Survey Method:* *I: Interview* *O: Observation* *R: Record Review*	*Unstable*	*New Admission (<90 days)*	*Involuntary Discharge*	*Home Dialysis in LTC*	*Infection*	*Recent Hospitalization/ Readmission*	*CVC > 90 Days*	*Observation*	*Complaint*	*Random Sample*
Name: *ID:* *Admit Date:* *Modality:* *Method:* *Surveyor:*										
Name: *ID:* *Admit Date:* *Modality:* *Method:* *Surveyor:*										

Name: *ID:* *Admit Date:* *Modality:* *Method:* *Surveyor:*										
Modality: *ICHD: In-center Hemodialysis* *ICPD: In-center Peritoneal Dialysis* *HHD: Home Hemodialysis* *PD: Home Peritoneal Dialysis* *Survey Method:* *I: Interview* *O: Observation* *R: Record Review*	*Unstable*	*New Admission (<90 days)*	*Involuntary Discharge*	*Home Dialysis in LTC*	*Infection*	*Recent Hospitalization/ Readmission*	*CVC >90 Days*	*Observation*	*Complaint*	*Random Sample*
Name: *ID:* *Admit Date:* *Modality:* *Method:* *Surveyor:*										
Name: *ID:* *Admit Date:* *Modality:* *Method:* *Surveyor:*										
Name: *ID:* *Admit Date:* *Modality:* *Method:* *Surveyor:*										

Name: *ID:* *Admit Date:* *Modality:* *Method:* *Surveyor:*										
Name: *ID:* *Admit Date:* *Modality:* *Method:* *Surveyor:*										

Task 7: Water Treatment and Dialysate Review Worksheet

Facility _____ *CCN* _____ *Surveyor* _____
Technician(s) _____ *ID* _____ *Date/Time* _____

Instructions: *Conduct this review with on-site staff routinely responsible for the water and dialysate monitoring and testing. Multiple technicians or staff may need to be interviewed.*

Carbon System and Chlorine Removal	*Trigger*
Observe for presence of two carbon beds, or banks of tanks with sample port in between *Comment: If block carbon is used to supply dechlorinated water to a portable RO unit, there must be one dual block carbon system (two block carbon or one block carbon and one granular activated carbon tank) per portable RO and each portable RO must supply one hemodialysis machine, per manufacturer's directions.*	*V192* *V193*
Empty bed contact time (EBCT) of the carbon system is equivalent to 10 minutes. *Comment: Review documentation of the EBCT for verification. If block carbon is used, there must be evidence from the manufacturer that the system achieves a 10-minute EBCT.*	*V195*
Interview staff to determine how the facility conducts chlorine testing in the water system. *Identify frequency of water testing.* *Identify the maximum allowable result.* *Comment: If the facility is using a continuous on-line chlorine monitor, ask about periodic validation testing with an alternate method.*	*V196* *V260*
Interview staff to determine what actions are taken if maximum allowable level of total chlorine is exceeded *Comment: Maximum allowable limit for total chlorine is 0.1 mg/L.*	*V197* *V260*

Total Chlorine – Water Testing	*Trigger*
Observe staff performing total chlorine testing for the following: • *Appropriate technique* • *Appropriate reagents used for the appropriate sample size* • *Reagents are being used within the expiration date*	*V196*

• *Sensitivity to detect 0.1mg/L of total chlorine* • *For digital meters – meter is zeroed prior to testing* • *For strips – quantitative method for testing is used* *Comment: The sample must be obtained from the sample port after the primary carbon tank.* *Review written instructions for testing prior to staff observations.*	

Reverse Osmosis (RO) and Continuous Water Quality Monitor	*Trigger*
Observe the RO unit and the water quality monitoring system. Confirm presence of continuous water quality monitor and audible alarm to alert staff of poor water quality. *Comment: Demonstration of alarm testing is NOT REQUIRED.*	*V200*
Interview staff to determine water quality monitoring method. Determine set point for the water quality alarm and actions taken if the percent rejection falls below 90% or the water quality exceeds set point.	*V199* *V200*

Deionization (DI)	*Trigger*
Observe for presence of DI system in the water treatment system *Comment: DI system should not be used as the primary water purification component in a central water system, except on a temporary basis due to RO failure (V205)*	*N/A*
Does the facility back-up plan for water system failure include use of DI? *If yes, verify the following:* *Presence of functional, continuous resistivity monitor after the DI system, with an audible and visual alarm in the patient treatment area* *Automatic divert-to-drain component or stop valve to prevent water with resistivity <1megohm from reaching dialysis stations* *Ultrafilter after the DI system* *Interview staff to determine the following:* *DI system monitoring frequency* *Alarm setting for resistivity level* *Actions taken if a DI tank exhausts and water resistivity drops <1 megohm*	*V202* *V203* *V204* *V260*

Disinfection/Water and Dialysate Microbiological Monitoring	*Trigger*
Interview staff to determine the following: *How often the water distribution system is disinfected*	*V219*

When water cultures and endotoxin/LALs are obtained in relation to disinfection, and from which sample site(s)	*V213* *V254*
How often dialysate cultures are taken from each hemodialysis machine	*V253*
Total number of hemodialysis machines cultured each month	*V253*
Method for collecting and testing samples of water and dialysate	*V252* *V253* *V255* *V258*
Action and maximum allowable microbiological levels for product water and dialysate, and actions taken when levels are exceeded	*V178* *V180*

Dialysate Preparation and Delivery	*Trigger*
Dialysate mixing systems must be maintained for safe and functional working conditions	*V403*
If batches of acid dialysate concentrates are mixed on-site, validate the verification testing method	*V229*
If batches of bicarbonate concentrates are mixed on-site, verify the shelf-life of mixed bicarbonate concentrate before it must be discarded	*V233*
Determine whether facility mixes additives to dialysate. If yes, verify the qualifications of staff responsible for mixing additives. Note: some state laws govern who is qualified to handle and mix medications. Violation of the state law could be a citation. *Request concentrate jug(s) that have been mixed with additives and review for proper labeling.*	*V100* *V101* *V235* *V236*

Water and Dialysate Oversight Logs	*Trigger*
Review total chlorine testing logs (past 2 months) and determine: *Trends of omitted tests* *Total chlorine levels exceeding maximum level (greater than 0.1mg/L)* *Improvement actions resulting from abnormal total chlorine levels*	*V196* *V197*
Review RO function monitoring and product water quality (past 2 months) and determine: *Water quality recorded daily (TDS or conductivity)* *Appropriate monitoring of RO % rejection*	*V199* *V200*
Review product water chemical analysis (past 12 months) and verify chemical analysis completed at least annually	*V201*
Review microbiological testing of water and dialysate (past 6 months) and determine: *Monthly testing of cultures and endotoxin levels from identified sites in the water treatment and distribution system, and dialyzer reprocessing room (if applicable)*	*V213* *V253* *V178* *V180*

Dialysate cultures and endotoxin tested from at least 2 hemodialysis machines per month, and each machine cultured at least annually *Appropriate actions taken when culture or endotoxin results exceeded action levels (50 CFU/1 EU) or maximum allowable levels (200 CFU/2EU)*	
If DI is present, or used in the past 12 months, review DI monitoring logs for 2 months and determine: *Resistivity readings recorded at least 2 times a day* *If resistivity level recorded below 1 megohm, verify dialysis was stopped and appropriate actions were taken to resolve problem*	*V202* *V203*

Technical Practice Audits	*Trigger*
Review staff audit logs (past 12 months) and verify achievement of periodic audits, not less than annually, for the following technical procedures: *water and dialysate testing* *dialysate mixing* *dialysate pH and conductivity testing at the point of use (HD machines)*	*V260*

Home Dialysis in LTC	*Trigger*
Total chlorine: Before each treatment for each portable RO unit, and per manufacturer directions for use for any non-conventional HD system for the past two months *For the PureFlow SL, tests must be recorded after preparation of each dialysate batch, i.e., "SAK"/batch, and before the use of that batch of dialysate*	*V196,* *V270-* *V273* *V276* *V277* *V403*
Product water conductivity/TDS: Recorded for each treatment day from each portable RO unit for the past two months	*V199*
Product water chemical analysis: From each portable RO unit for the past 12 months. For PureFlow SL, water chemical analysis is required at the end of the first "PAK" and annually thereafter	*V177* *V201* *V206* *V276* *V277* *V403*
Microbial surveillance of water: For the last six months, including cultures and endotoxin results from each portable RO unit (six separate reports required). Note that only dialysate testing is required for PureFlow SL.	*V178* *V254* *V278* *V594*
Microbial surveillance of dialysate: For the last six months, including cultures and endotoxin results from each conventional and non-conventional HD	*V180* *V276*

machine- at least quarterly for non-conventional machines, monthly for conventional machines, and at the end of the SAK life for the PureFlow SL.	*V278* *V594*

Task 8: Dialyzer Reprocessing and Reuse Worksheet

Facility _____	*CCN*
_____	
Surveyor _____	*ID*
_____	
Reuse Technician _____	*Date/Time*
_____	
Reprocessing Equipment _____	*Germicide*
_____	

Instructions: *Conduct this review with personnel routinely responsible for reprocessing dialyzers, typically the reuse technician(s).*

Observation of Reprocessing Area	*Trigger(s) Identified*
OBSERVE: Does the reprocessing area and equipment appear clean, sanitary and maintained?	*V318* *V403*
OBSERVE: Are there noticeable odors of germicide? If so, ASK: when/how are germicide air levels tested?	*V318*
OBSERVE: Are used/dirty dialyzers reprocessed within 2 hours or refrigerated? Is the refrigerator temperature monitored?	*V331*
OBSERVE: Are reprocessed dialyzers protected from unauthorized access, damage, or contamination?	*V321*

Observation/Interview with Reprocessing Personnel	*Trigger(s) Identified*
Personal Protective Equipment (PPE) *OBSERVE: Are staff using PPE appropriate to the tasks performed and the germicide used?*	*V320*
Germicide *ASK: What are the germicide manufacturer's instructions for proper germicide mixing and storage?* *How long must dialyzers be filled with germicide (dwell time) before they can be used for dialysis?* *How long may a reprocessed dialyzer stay on the shelf (when a patient is absent) before it must be refilled with fresh germicide?* *What are the procedures for germicide/chemical spills?* *Are there equipment and supplies readily available in the event of splashes or spills of chemicals and/or germicide? (i.e., eyewash station, spill kit)*	*V319* *V320* *V321* *V339* *V345* *V349*

Observation/Interview with Reprocessing Personnel	*Trigger(s) Identified*
Dialyzer labeling *ASK: When are patient dialyzers labeled? For patients with same or similar names, how are dialyzers labeled?*	*V328* *V330*
Transportation of dirty dialyzers *OBSERVE: Are used/dirty dialyzers transported in a clean/sanitary manner (all ports capped, not cross- contaminating other dialyzers)?* *If dialyzers are refrigerated, ASK: How soon after dialysis must a dialyzer be reprocessed or refrigerated? What is the maximum time a dialyzer may be refrigerated prior to reprocessing?*	*V331*
Pre-cleaning procedures *OBSERVE: Select a minimum of 2 dialyzers. If header caps are removed, are the dialyzer headers, caps and O-rings cleaned and disinfected appropriately?* *Are water pressures at the pre-rinse sink monitored and maintained within dialyzer parameters?* *Is cross-contamination avoided by disinfecting equipment connections between dialyzers or the use of barrier adaptors?* *ASK: What quality of water is used for pre-cleaning the internal compartments of the dialyzers?*	*V334* *V332* *V331* *V333*

Reuse QA Oversight	*Trigger(s) Identified*
Review: 12 months of the following QA audit results to verify they are routinely conducted:	
Quarterly: *Dialyzer labeling including verification of similar names warnings and appropriate labeling practices*	*V366*
Preparation for dialysis including observations of staff preparing reprocessed dialyzers for use in patients' treatments	*V368*
Semi-annual: *Reprocessing procedures including observations of reprocessing personnel performing dialyzer reprocessing procedures*	*V367*

Reprocessing Equipment Preventative Maintenance and Repair	*Trigger(s) Identified*
REVIEW: 12 months of preventative maintenance and repair logs:	*V316*

Are PM procedures and repairs performed in accordance with manufacturer's directions and recorded by the person performing PM procedures? *Are the automated reprocessing systems calibrated per manufacturer DFU (this may be found in daily "startup logs")?* *Is equipment tested after repairs and before being placed back in service?*	*V317*

Reuse Adverse Occurrences	*Trigger(s) Identified*
Review: 12 months of dialyzer complaint records (significant events, complaints, and/or deviations from expected outcomes) to determine whether appropriate actions were taken in response to serious events related to reprocessed dialyzers	*V355* *V356* *V357* *V635*

Task 9: Dialysis Equipment Maintenance Worksheet

Facility _____	*CCN* _____	*Surveyor* _____
Technician(s) _____	*ID #* _____	*Date/Time* _____

***Instructions**: Conduct this review with the on-site personnel responsible for equipment maintenance to ensure all equipment is maintained and operated in accordance with the manufacturer's recommendations.*

Dialysis Machine Preventive Maintenance (V403)

Conduct an interview with staff/technician(s) responsible for dialysis equipment maintenance. Ask the following questions:

- *What is the total number of hemodialysis machines maintained by the facility?*
- *What hemodialysis machines does the facility maintain?*
- *Are there machines from different manufacturers?*
- *Does the facility maintain home dialysis machines?*

Identify the types of machines used by the facility and record the preventive maintenance directions for use (i.e. maintenance intervals by calendar months, operating hours, or both) in the fields provided below.

Machine type _____ *PM DFU* _____
Machine type _____ *PM DFU* _____
Machine type _____ *PM DFU* _____
Machine type _____ *PM DFU* _____

Review 12 months of PM logs for 10% (minimum of 3) hemodialysis machines maintained by the facility. Sample should represent all machines/manufacturer types used by the facility, including home dialysis machines. Record the dates, operating hours, and type of PM procedures conducted (e.g. quarterly, semi-annually, annually) in the table below.

Machine # or ID & Type	Dates of PM for Past 12 Months	Operating Hours Recorded	PM Procedure

Machine # or ID & Type	*Dates of PM for Past 12 Months*	*Operating Hours Recorded*	*PM Procedure*

Were all sampled dialysis machines maintained according to the manufacturer's DFU for PM? Yes _____ No _____ (V403)

Dialysis Equipment Testing and Calibration

Interview the equipment maintenance technician(s) to determine the manufacturer's DFU for the following:

- *Calibration of dialysate pH and conductivity meters*
- *HD machine PM and repair equipment and/or meters*

Review 2 months of calibration logs for the dialysate pH and conductivity meters used at the dialysis machines prior to patient treatment to determine whether calibration was done according to manufacturer's DFU. Yes _____ No _____ (V403)

Review the most recent calibration document for the equipment/meter used to conduct HD machine PM and repairs to determine whether calibration was done according to manufacturer's DFU. Yes _____ No _____ (V403)

Additional Notes:

_____

_____

_____

_____

_____

_____

_____

_____

Dialysis in LTC:

- ***Conventional HD machines and portable RO units****: Review the last 12 months of preventative maintenance logs and verify the maintenance was conducted per manufacturer's Directions for Use (DFU) (V403)*
- ***Non-conventional HD and PD cyclers****: The ESRD facility must maintain documentation of dialysis equipment identification (e.g., serial numbers) and information regarding the equipment exchanges and recommended routine maintenance per manufacturer's DFU. (V403)*

Additional Notes:

Task 10: Home Dialysis Training & Support Worksheet

Facility _____ *Date/Time* _____
Home Dialysis Training RN(s): _____
Home Modality Type: Hemodialysis ___ Peritoneal Dialysis ___ Surveyor: _____

Instructions: *Conduct interviews with home dialysis training staff to verify that all applicable requirements are applied for home dialysis provisions of care. Interviews should be individualized for each approved home modality, i.e., hemodialysis and peritoneal dialysis.*

Staffing _____ ***(V-590, V-592, V-681, V-685, V-757)***

- *Are there sufficient amounts of trained, qualified staff to meet the medical, nutritional, and psychosocial needs of each HD/PD patient*
- *How do IDT members see and provide services to HD/PD patients? How frequently?*
- *How does the dialysis facility ensure a care coordinator for each HD/PD patient?*

Patient Education_____ ***(V-453, V-458, V-512, V-513)***

- *What information is presented to patients about their options for treatment modality and setting?*
- *How is a patient's abilities, interests, preferences, and goals evaluated?*
- *How are patients with mental illness, cognitive impairment, cultural differences or language barriers educated?*

Patient Candidacy, Training and Competency_____ ***(V132, V585, V586)***

- *How are Home HD/PD candidate/caregiver needs evaluated?*
- *How is patient/caregiver training and competency evaluated for appropriateness? (e.g. ability to perform dialysis at home, training on infection prevention, supply disposal, storing and administering ESAs, symptoms to report, etc.)*

Patient Monitoring_____ ***(V587, V589, V592)***

- *How are HD/PD patients monitored following any training received?*
- *How often are home visits conducted to monitor the patient's home adaptation?*
- *How often are HD/PD flow sheets and treatment records collected?*
- *Who is responsible to review HD/PD flow sheets and treatment records?*

Care Planning _____ ***(V542, V559, V598)***

- *How does the dialysis facility involve the HD/PD patient/caregiver in their plan of care?*
- *How are barriers to goals monitored, recognized, and addressed?*
- *How do patients requiring backup dialysis receive their treatment(s)?*
- *What is the facility's system for ordering supplies and tracking supply usage?*

Home Dialysis in LTC _____

- *What training do the administering personnel receive?* ***(V582-V586, V693-V694)***
- *Who conducts the training?* ***(V685)***
- *How does the ESRD facility verify competency of nursing home personnel providing home dialysis treatments?* ***(V585-V586)***
- *What training do the on-site nurses who supervise the dialysis treatments in the nursing homes receive?* ***(V584, V681)***
- *Do you or another qualified ESRD IDT member conduct periodic site visits for each nursing home resident receiving dialysis and if so, where are these visits documented?* ***(V589, V590)***
- *What system does the ESRD facility have in place for nursing home dialysis equipment, maintenance and repair?* ***(V403)***
- *What provisions are in place at each nursing home to accommodate isolation during dialysis, if needed?* ***(V128, V130, V131)***
- *What is the expected interaction among the ESRD IDT, the nursing home IDT and residents on dialysis in the nursing home? Where is this interaction documented?* ***(V540-V542, V590-V592)***
- *How are interim changes in the nursing home patient's plan of care communicated between the ESRD facility and the nursing home?* ***(V541, V558, V590-V592)***
- *How are the comprehensive patient assessments conducted by the ESRD IDT for the nursing home residents; how are the ESRD facility plans of care then developed for those residents; and how are the ESRD facility plans coordinated with the nursing home plans of care?* ***(V501-V520, V541-V562, V590-V592)***
- *How is home dialysis performed in the nursing home incorporated into the ESRD facility QAPI program?* ***(V626)***

QAPI _____ ***(V628, V637, V756)***

How does the home dialysis training staff actively participate in the QAPI program?

How is data collected, tracked and trended for the Home HD/PD program? (e.g. catheter infections, peritonitis rates, etc.)

Dialysis in the Long-Term Care Setting Worksheet

(To be used onsite, at the nursing home)

Nursing Facility _____ *Date/Time*

_____

Dialysis Location: ☐ Resident Room ☐ Common Area (Den) ☐ Other:

_____

Dialysis Type: ☐ HD ☐ PD ☐ Both Surveyor:

_____

The survey team should use the guidelines in this worksheet for each on-site visit to a nursing home. This worksheet should not be used when conducting survey activities at the dialysis facility. During the on-site visit at the nursing home, the following survey activities will be completed:

- *Introductions*
- *Tour of the Nursing Home Environment*
- *Observations of Home Dialysis Care*
- *Nursing Home Medical Record Reviews*
- *Nursing Home Resident (Patient) and Nursing Home Personnel Interviews*
- *Training and Competency Reviews*

Introductions with the Nursing Home Administration and Staff:

- *Introduce the members of the ESRD survey team to the nursing home administrator or designee in charge.*
- *Explain that the visit is a component of an associated ESRD facility survey, and the purpose of the visit is to determine compliance with the ESRD Conditions for Coverage and not the nursing home regulations.*
- *Explain that any non-dialysis-related quality of care concerns or dialysis-related concerns that overlap with existing nursing home requirements observed during the visit can be shared with the applicable State Survey Agency, with oversight of nursing home compliance with Medicare health and safety standards. Such concerns and findings will not be shared or discussed with the nursing home administrator by the ESRD surveyors.*
- *Provide the Administrator with a general overview of the anticipated survey activity to be performed in the nursing home, including the names of the residents who will be observed during their dialysis treatments and nursing home staff who may be interviewed.*
- *Explain that a review of associated medical records while on site will be done to confirm that ESRD responsibilities are accomplished as required and to evaluate the level of coordination between the ESRD facility and the nursing home.*

- *Provide the Administrator with an estimated amount of time that will be spent on site.*

Tour of the Nursing Home Dialysis Environment
Observe the location where the resident(s) receive their dialysis treatments. This may be in the resident's room or another location in the nursing home. Observe the location where dialysis equipment and supplies, including dialysate concentrates, are stored.

Dialysis administration and patient monitoring during treatments should be consistent with home dialysis education and training provided by the dialysis facility. Further, dialysis facilities are expected to periodically monitor the patient's adaptation to home dialysis by visiting the patient or the resident's home (V589). Unsafe, unsanitary, or disordered/dirty conditions may indicate a lack of dialysis facility monitoring of the resident's adaptation to home dialysis or insufficient competency of home dialysis skills and methods that would otherwise trigger re-education/re-training or removal of the resident as an appropriate candidate for home dialysis when re-education or re-training does not resolve the concerns. Observations indicating non-compliance may include, but are not limited to:

Infection Control Precautions (V585)
- *Unsanitary conditions that may be associated with a dialysis treatment, including, but not limited to, blood spots/spills, dirty dialysis equipment, uncontained infectious wastes, dirty dialysate containers, etc.*
- *Dialysis supplies stored near contamination sources.*
- *Insufficient space between and surrounding resident treatment areas (dialysis machine, chair/bed/water treatment equipment) to prevent cross-contamination, provide personal privacy, or provide emergency care.*

Effective Use of Dialysis Supplies and Equipment (V585, V593)
- *Dialysis equipment in poor repair (e.g., missing components, alarms non-functional, components rusted).*
- *Portable water treatment unit(s) lacking two carbon tanks and sample port between (does not apply to pre-configured systems).*
- *No documentation for chlorine testing after preparation of each new dialysate batch, i.e., SAK, for pre-configured systems.*
- *Resident(s) receiving hemodialysis, but total chlorine test(s) were not performed and/or recorded (as applicable to HD equipment in use) before the start of the current HD treatment(s).*

Ability to handle medical and non-medical emergencies (V585)

Observation of Home Dialysis Care
Observe the direct dialysis care of the sample resident(s). For hemodialysis, use the observation checklists in the ESRD Core Survey "Observations of Hemodialysis Care and Infection Control Practices" worksheet applicable to the

care activities (e.g., Checklist #1 and Checklist #4 to observe hemodialysis initiation with a central venous catheter, arteriovenous fistula, or graft; Checklist #7 to observe the preparation of a conventional hemodialysis machine). Observations of residents receiving hemodialysis include:

- *Set-up.*
- *Initiation of treatment.*
- *Vascular access check.*
- *Discontinuation of treatment.*

Typical hemodialysis treatments can last 2-4 hours; therefore, all required observations do not have to be conducted on the same resident. If the survey team determines observation of peritoneal dialysis care is indicated (e.g., high rates of infection/peritonitis), observe staff connecting/disconnecting the resident to/from the cycler (for automated PD), or performing a manual exchange (for continuous ambulatory PD), and the patient's PD catheter site for signs of infection or improper care.

Observed lapses in infection control techniques may include, but are not limited to:

- *Improper hand hygiene or glove use.*
- *Supplies taken to the individual dialysis location but not disposed of, disinfected, or dedicated to that resident after use.*
- *Clean dialysis supplies are not protected from potential contamination*
- *Lapses in aseptic practices for CVC; AV fistula/graft care; PD catheter care.*
- *Inadequate disinfection of dialysis equipment after treatment.*
- *Improper disposal of infectious waste and effluent.*
- *Staff not wearing appropriate personal protective equipment for the procedure.*
- *Lack of aseptic techniques during medication administration, such as drawing saline flush syringes from single-use containers or single-use bags.*

Concerns with Hemodialysis equipment operation may include, but are not limited to:

- *Testing water for total chlorine with expired reagents. (V196, V403)*
- *Failure to test hemodialysis machine alarms; does not apply to preconfigured machines. (V403)*
- *Failure to use an independent method to test conventional HD dialysate pH/conductivity or lack of staff knowledge of acceptable parameters for pH/conductivity. (There are a variety of devices used to test pH and conductivity. Each ESRD facility may use a different device for this purpose as long as DFUs are followed and appropriate testing strips are used. The ESRD facility must set limits for allowing variability of the independent method and machine reading. (V250)*
- *Failure to prime hemodialyzers according to the manufacturer's DFU. (V403)*

Please note that the expectations/requirements for equipment operation vary depending on the type of hemodialysis equipment in use. If the surveyor is not familiar with the HD

machine and water treatment equipment being used, they may wish to review the manufacturer's Directions for Use (DFU) before conducting the observation.

Concerns with patient monitoring during dialysis may include, but are not limited to:

- *Failure to assess residents before and after dialysis or monitoring during hemodialysis treatment according to ESRD facility policy; (V504, V543, V550, V551, V715)*
- *Failure to monitor vital signs throughout the treatment; (V407, V504, V541)*
- *Failure to maintain visualization of the vascular access throughout the treatment; (V407)*
- *Failure to promptly notify appropriate nursing home and ESRD facility personnel for dialysis-related complications. (V503, V504)*

Resident (Patient) Interviews

Interview the sampled residents who receive their dialysis treatments in the nursing home. If a resident is unable to be interviewed due to physical or mental status, interview a family member/guardian/friend who has contact with the resident and may be familiar with the resident's care experiences in receiving dialysis at the nursing home. If a family member/guardian/friend is not available in person, surveyors should attempt to reach them by phone for the interview.

Interview Questions:

- *How did you decide to get your dialysis treatments here in the nursing home? (V458)*
- *Do you ever have any concerns when receiving your dialysis treatments here at the nursing home? If so, how do staff respond to your concerns? (V465-V467)*
- *Have you ever had problems during your dialysis? Was someone there to assist you? Who assisted you? (V588, V592, V681, V688, V757)*
- *Does your dialysis equipment function well during the treatments? (V403)*
- *Do the staff members providing your dialysis treatments wash their hands and change their gloves when caring for you? (V113)*
- *Is the place where you receive your dialysis treatment clean? (V122)*
- *Do the staff members who provide your dialysis treatments treat you with respect? (V452)*
- *For HD: Do the staff members who provide your dialysis treatments stay with you throughout the entire treatment? (V407)*

Nursing Home Medical Record Review

Review the following sections of the nursing home medical records for the sampled residents receiving dialysis:

- ***Most recent dialysis treatment orders**: Confirm that the dialysis treatment the resident is currently receiving is consistent with the most current physician order for treatment and cross-check later at the ESRD facility to verify that the nursing*

home orders and the treatment are consistent with the most current orders on file at the ESRD.

- ***Dialysis treatment records**: Confirm that the nursing home dialysis treatment record is completed after each treatment with any potential issues or concerns that may need to be reported to the ESRD facility team and there is evidence the information is promptly communicated with the ESRD facility.*
- ***Interdisciplinary progress notes**: Review the last three months of progress notes to confirm communication and collaboration between the nursing home IDT and the ESRD IDT to address each resident's issues with dialysis treatments, events, and clinical and psychosocial outcomes. Communication and collaboration should occur timely between the ESRD facility and nursing home regarding treatment orders, changes in the plan of care, notification of dialysis-related complications, adverse events, and prompt identification and notification of the need to transfer a resident to a higher level of care.*

Dialysis Administering Personnel Interviews

If dialysis treatments are administered by nursing home staff, ask the following questions:

- *What training did you receive to enable you to administer dialysis treatments? (V582-V586)*
- *Who provided the training? (V584, V685)*
- *Who is available to help if the resident has a problem during their treatment? (V592, V681, V688, V757)*
- *Who do you call if you have problems with dialysis equipment? (V403, V588, V598, V757)*
- *What do you do if a resident's machine breaks down during a treatment? (V588, V592, V596, V598, V757)*
- *Do you mix or add electrolytes to dialysate for the treatments? (V235, V233)*
- *How do you disinfect the dialysis machine/equipment, and dialysate jugs (if applicable)? (V122, V243, V244)*

Training and Competency Review at the Nursing Home

The ESRD facility is responsible for training and verifying the competency of all nursing home personnel who administer dialysis treatments. Training should be individualized to reflect the residents' needs. Surveyors should review applicable nursing home personnel records to ensure that personnel who administer dialysis treatments have received the appropriate training before performing dialysis care. Surveyors should also verify the ESRD facility's method for continuously evaluating and documenting the competency of administering personnel. This documentation in the nursing home personnel files will later be compared to competency records maintained by the ESRD facility.

Task 11 Medical Record Review Worksheets

Medical Record Review: In-Center Hemodialysis (ICHD)

Facility _____ *Surveyor* _____

Patient Name _____ *ID* _____

Admit Date _____ *Review Date* _____ *DOB* _____ *Age*_____

HD Access Type: ☐ *Fistula* ☐ *Graft* ☐ *Catheter* ☐ *Catheter > 90 days*

Sampling Criteria _____

Instructions: *Conduct a medical record review for each sampled patient to ensure the dialysis facility provided safe and effective care to meet the needs of the in-center hemodialysis patient.*

This worksheet consists of 2 sections: Section 1 is a review of the patient's treatment and medication records; Section 2 is a review of the facility's management of the patient in areas related to the sampling criteria and the data-driven focus areas.

SECTION 1: DIALYSIS TREATMENT AND MEDICATION RECORDS

A dialysis facility must ensure that dialysis treatments are delivered in a safe and effective manner, and that it maintains adherence to treatment orders and care plans. Review each sampled patient's medical record to determine facility practices of implementation of physician's orders, plan of care, dialysis prescription plan, safety of the hemodialysis treatments, fluid/BP management, and patient monitoring before, during, and after each treatment.

Record the current dialysis treatment and medication orders:

Treatment Order Date _____ *EDW** _____ *Frequency* _____ *days/week*

Dialyzer _____ *Dialysate* _____ *BFR** _____ *DFR**

_____

Treatment Duration _____ hours _____ minutes Heparin/anticoagulant

_____

ESA dose _____ Frequency _____ Iron _____ Vitamin D*

_____

Other meds/treatments

_____

**EDW – Estimated Dry Weight | BFR – Blood Flow Rate| DFR – Dialysate Flow Rate | ESA – Erythropoiesis-stimulating Agent*

Review 3 consecutive weeks of ICHD treatment records. Record only exceptions/variances in the fields below. Check here if no exceptions/variances were noted: _____

Number of treatment records reviewed _____ Time Period: _____ to _____

Safety Checks Not Documented (V585)	*Dates/Comments*
Independent pH/ conductivity (V250)	
Machine alarm check (V403)	
Reuse Dialyzer Checks Not Documented	*Dates/Comments*
Germicide presence (V350)	
Germicide absence of residual (V353)	
2-person Patient/dialyzer ID (V348)	
Adequacy Plan Not Implemented (V544)	*Dates/Comments*
BFR, DFR, time, dialyzer type	
Medications/Treatments not Administered as Ordered	*Dates/Comments*
Anemia management (V547)	
Mineral metabolism (V546)	
Incorrect dialysate(V541)	
Antihypertensive (V543)	
Other	
BP/fluid management (V543)	*Dates/Comments*
Hypertension	
Hypotension	
Dry/target weight not achieved	
Ultrafiltration rate >13mL/kg/hr (review for trends) Note any untoward side effects	
Patient Monitoring	*Dates/Comments*
No assessment pre- or post-dialysis (V543)	
Not monitored per policy (V543)	

Access function and/or care not documented (V550)	
Unusual or adverse events (V634)	

During this review, if trends we identified for the following, citation at the applicable V-tag may be indicated:

- *Omitted machine and dialyzer safety checks;*
- *Facility's failure to monitor the patient and machine per facility policy;*
- *Failure to administer the patient's ordered dialysis prescription or medications*

During this review, if trends were identified in the following areas, determine whether the facility staff recognized the occurrence(s), responded through interventions aimed at improving outcomes, or changed interventions when the expected outcome is not achieved.
Note: A citation (V543) is warranted if there is no systematic care planning for the in-center dialysis patient.

Blood pressure management
Fluid Management
Weight Management

SECTION 2: SAMPLING CRITERIA AND DATA-DRIVEN FOCUS AREAS

The medical record review should be focused to look at facility systems in place to address:

- *Patient-specific needs and poor outcomes*
- *Facility-specific data-driven focus areas*

Review patient assessments, interdisciplinary team involvement, and plans of care relevant to the sampling criteria recorded on the Patient Roster, e.g. Unstable, New Admission, Involuntary Discharge, and Recent Hospitalization. For example, if a patient's sampling criteria is Involuntary Discharge, the surveyor should focus their review on pertinent records which document assessments, reassessments, ongoing problems, and efforts made to resolve the problem.

Additionally, each medical record will be reviewed for the facility's management in areas related to the final data-driven focus areas. For example, if "anemia management" is identified as a final data-driven focus area for the facility under review, each medical record should be reviewed for their management and oversight of the patient's anemia management needs, i.e. can the home dialysis patient/caregiver safely and effectively administer erythropoiesis-stimulating agents (ESAs)?

Note: Clinical areas that are not identified patient-specific needs or facility-specific data-driven focus areas are not required to be reviewed during the medical record review. Surveyors may use their discretion to include such areas during their review. Surveyors

are encouraged to obtain copies of any records that are used as a basis for citation, including those from areas that are not required to be reviewed.

Review medical record documentation, such as physician orders, patient assessment, and plan of care, to ensure:

- *The patient's assessment reflects their current condition;*
- *The plan of care contains measurable and expected outcomes, with timeframes to achieve the outcomes; and,*
- *A plan of care is implemented to address the issues identified in a patient's assessment.*

When the expected outcome(s) have not been achieved, ensure that the facility's interdisciplinary team has adjusted the patient's plan of care to achieve specified goals. (V559)

For each area reviewed in this section, is there evidence that the patient's outcomes has improved and/or their goals are met?
____ If yes, no further review is needed. No deficiency citation is indicated.
____ If no, is there evidence that one or more IDT members were monitoring the patient's outcome in that area; recognized that the patient was not attaining their goal or had a problem in that area; implemented interventions aimed at improvement; and changed strategies if improvement was not achieved or sustained?
____ If yes, no citation is indicated.
____ If no, citation in that outcome area is indicated at the applicable Patient Assessment and/or Plan of Care V-tag.

Additional Comments:

Medical Record Review: Peritoneal Dialysis (PD)

Facility _____ *Surveyor*

_____

Patient Name _____ *ID*

_____

Admit Date _____ *Review Date* _____ *DOB* _____ *Age*

_____

Sampling Criteria

_____

Instructions: *Conduct a medical record review for each sampled patient to ensure the dialysis facility provided safe and effective care to meet the needs of the peritoneal dialysis patient.*

This worksheet consists of 2 sections: Section 1 is a review of the patient's treatment and medication records; and Section 2 is a review of the facility's management of the patient in areas related to the sampling criteria and the data-driven focus areas.

SECTION 1: DIALYSIS TREATMENT AND MEDICATION RECORDS

The review of the PD patient's treatment orders and dialysis treatment records should be focused on the patient/caregiver's adherence to dialysis treatment orders (verified through review of the patient's dialysis treatment records/flowsheets) and how staff members provide oversight of the PD patient's treatments and address issues and trends. Look for documentation of staff action in progress notes, plans of care, etc. Note that timeliness of staff review of PD treatment records depends on when the patient provides them but should be at least every 2 months.

Record the current dialysis treatment and medication orders:

Treatment Order Date _____ *EDW** _____ *APD** _____ *CAPD**

_____

APD cycles/day _____ *Dialysate* _____ *Volume* _____ *Dwell*

_____

CAPD exchanges/day _____ *Dialysate* _____ *Volume* _____ *Dwell*

_____

Heparin/anticoagulant _____ *ESA* dose/frequency*

_____

Other meds/treatments

_____

**EDW – Estimated Dry Weight | APD – Automated Peritoneal Dialysis | CAPD – Continuous Ambulatory Peritoneal Dialysis | ESA – Erythropoiesis-stimulating Agent*

Review 8-12 consecutive weeks of PD flowsheets. Record only exceptions/variances in the fields below. Check here if no exceptions/variances were noted: _____

Number of treatment records reviewed _____ Time Period: _____ to _____

Treatment Delivered Different from Order	*Dates/Comments*
# of CAPD exchanges, volume (V544)	
# of APD cycles, volume (V544)	
Dialysate (V544)	
Anemia management (V547)	
Other parenteral medications	
BP/fluid management (V543)	*Dates/Comments*
Hypertension	
Hypotension	
Estimated dry weight not achieved	
Patient not recording weight/BP	
Staff Monitoring	*Dates/Comments*
Flowsheets not reviewed (V587)	
No flowsheets in the medical record (V587)	
Unusual or adverse events (V634)	

The medical records review should ensure that the home training and support staff effectively recognized problems, responded through interventions aimed at improving outcomes, or changed interventions when the expected outcome is not achieved. Review the questions below to determine whether plans of care were implemented when outcomes and goals were not met.
Note: A deficiency citation is warranted if there is no systematic care planning for the home dialysis patient.

Is there evidence that the home training and support staff monitored the patient's home dialysis through routine review of their treatment records? (V587) Explain

_____

_____

_____

Were trends identified in the patient/caregiver failing to follow the dialysis prescription and parenteral medication orders? Explain

Were trends identified with a patient's blood pressure, fluid or weight management? (V543) Explain

SECTION 2: SAMPLING CRITERIA AND DATA-DRIVEN FOCUS AREAS

The medical record review should be focused to look at facility systems in place to address:

- *Patient-specific needs and poor outcomes*
- *Facility-specific data-driven focus areas*

Review patient assessments, interdisciplinary team involvement, and plans of care relevant to the sampling criteria recorded on the Patient Roster, e.g. Unstable, New Admission, Involuntary Discharge, and Recent Hospitalization. For example, if a patient's sampling criteria is Involuntary Discharge, the surveyor should focus their review on pertinent records which document assessments, reassessments, ongoing problems, and efforts made to resolve the problem.

Additionally, each medical record will be reviewed for the facility's management in areas related to the final data-driven focus areas. For example, if "anemia management" is identified as a final data-driven focus area for the facility under review, each medical record should be reviewed for their management and oversight of the patient's anemia management needs i.e. can the home dialysis patient/caregiver safely and effectively administer erythropoiesis-stimulating agents (ESAs)?

Note: Clinical areas that are not identified patient-specific needs or facility-specific data-driven focus areas are not required to be reviewed during the medical record review. Surveyors may use their discretion to include such areas during their review. Surveyors are encouraged to obtain copies of any records that are used as a basis for citation, including those from areas that are not required to be reviewed.

Review medical record documentation, such as physician orders, patient assessment, and plan of care, to ensure:

- *The patient's assessment reflects their current condition*
- *The plan of care contains measurable and expected outcomes, with timeframes to achieve the outcomes*
- *A plan of care is implemented to address the issues identified in a patient's assessment*

When the expected outcome(s) have not been achieved, ensure that the facility's interdisciplinary team has adjusted the patient's plan of care to achieve specified goals. (V559)

If a patient's medical record identifies poor outcomes related to clinical laboratory values (e.g. anemia, dialysis adequacy, albumin), determine whether the facility has implemented a plan of care to address the issue(s) and review the most current 3 months of laboratory values to determine whether the specified goal(s) have been achieved.

For each area reviewed in this section, is there evidence that the patient's outcomes has improved and/or their goals are met?

____ If yes, no further review is needed. No deficiency citation is indicated.
____ If no, is there evidence that one or more IDT members were monitoring the patient's outcome in that area; recognized that the patient was not attaining their goal or had a problem in that area; implemented interventions aimed at improvement; and changed strategies if improvement was not achieved or sustained?
____ If yes, no citation is indicated.
____ If no, citation in that outcome area is indicated at the applicable Patient Assessment and/or Plan of Care V-tag.

Additional Comments:

Medical Record Review: Home Hemodialysis (HHD)

Facility _____ *Surveyor*

_____

Patient Name _____ *ID*

_____

Admit Date _____ *Review Date* _____ *DOB* _____ *Age*

_____

HD Access Type: ☐ *Fistula* ☐ *Graft* ☐ *Catheter* ☐ *Catheter > 90 days*

Sampling Criteria

_____

Instructions: *Conduct a medical record review for each sampled patient to ensure the dialysis facility provided safe and effective care to meet the needs of the home dialysis patient.*

This worksheet consists of 3 sections: Section 1 is a review of the patient's treatment and medication records; Section 2 is a review of the facility's monitoring of the equipment's water and dialysate quality; and Section 3 is a review of the facility's management of the patient in areas related to the sampling criteria and the data-driven focus areas.

SECTION 1: DIALYSIS TREATMENT AND MEDICATION RECORDS

The review of the HHD patient's treatment orders and dialysis treatment records should be focused on the patient/caregiver's adherence to equipment safety procedures and dialysis orders, how staff members provide oversight of the HHD patient's treatments and address issues and trends. Look for documentation of staff action in progress notes, plans of care, etc. Note that timeliness of staff review of HHD treatment records depends on when the patient provides them but should be at least every 2 months.

Record the current dialysis treatment and medication orders:

Treatment Order Date _____ *EDW** _____ *Frequency*

_____ *days/week*

Dialyzer _____ *Dialysate* _____ *BFR** _____ *DFR** _

_____

Treatment Duration _____ *HD Machine Type*

_____

Heparin/anticoagulant _____ *ESA* dose/frequency*

_____

Other meds/treatments

_____

**EDW – Estimated Dry Weight | BFR – Blood Flow Rate | DFR – Dialysate Flow Rate | ESA – Erythropoiesis-stimulating Agent*

Review 3 consecutive weeks of HHD treatment records. Record only exceptions/variances in the fields below. Check here if no exceptions/variances were noted: _____

Number of treatment records reviewed _____ Time Period: _____ to _____

Safety Checks Not Documented (V585)	*Dates/Comments*
Independent pH/ conductivity (V250)	
Machine alarm check (V403)	
Water total chlorine testing (V595)	
Treatment Delivered Different from Order	*Dates/Comments*
BFR/DFR/dialyzer/time, dialysate (V544) (i.e. clearance/adequacy)	
Heparin/anticoagulant (V544)	
Anemia management (V547)	
Other medications	
BP/fluid management (V543)	*Dates/Comments*
Hypertension	
Hypotension	
Estimated dry weight not achieved	
Patient not recording weight/BP	
Ultrafiltration rate >13mL/kg/hr (review for trends)	
Staff Monitoring	*Dates/Comments*
Treatment records not reviewed (V587)	
No treatment records in chart (V587)	
Unusual or adverse events (V634)	

The medical records review should ensure that the home training and support staff effectively recognized problems, responded through interventions aimed at improving outcomes, or changed interventions when the expected outcome is not achieved. Review the questions below to determine whether plans of care were implemented when outcomes and goals were not met.
Note: A deficiency citation is warranted if there is no systematic care planning for the home dialysis patient.

Is there evidence that the home training and support staff monitored the patient's home dialysis through routine review of their treatment records? (V587) Explain

_____

_____

Were trends identified in the patient/caregiver's failure to follow the dialysis prescription and parenteral medication orders? Explain

_____

_____

Were trends identified with a patient's blood pressure, fluid or weight management? (V543) Explain

_____

_____

Were trends identified with patient/caregiver inappropriately operating the HD machine and equipment or inadequately performing safety checks? Explain

_____

_____

SECTION 2: HOME HEMODIALYSIS WATER AND DIALYSATE QUALITY

The dialysis facility must conduct on-site evaluations of the home dialysis patient's water supply to ensure continued efficacy and safety of the home dialysis treatments. (V593)

Review the last 6 months of the water and dialysate quality applicable to the HHD equipment used for the patient's treatments. The requirements for monitoring the water and dialysate quality for home hemodialysis vary according to the HHD equipment. Determine which equipment is in use, and ask staff or review the equipment directions for use and/or facility procedures to become familiar with the testing requirements for the following:

- *Product water chemical analysis (V594)*
- *Total Chlorine testing (V595)*
- *Bacterial and endotoxin testing for water and dialysate (at least quarterly) (V595)*

Additional Comments:

_____

_____

_____

SECTION 3: SAMPLING CRITERIA AND DATA-DRIVEN FOCUS AREAS

The medical record review should be focused to look at facility systems in place to address:

- *Patient-specific needs and poor outcomes*
- *Facility-specific data-driven focus areas*

Review patient assessments, interdisciplinary team involvement, and plans of care relevant to the sampling criteria recorded on the Patient Roster, e.g. Unstable, New Admission, Involuntary Discharge, and Recent Hospitalization. For example, if a patient's sampling criteria is Involuntary Discharge, the surveyor should focus their review on pertinent records which document assessments, reassessments, ongoing problems, and efforts made to resolve the problem.

Additionally, each medical record will be reviewed for the facility's management in areas related to the final data-driven focus areas. For example, if "anemia management" is identified as a final data-driven focus area for the facility under review, each medical record should be reviewed for their management and oversight of the patient's anemia management needs i.e. can the home dialysis patient/caregiver safely and effectively administer erythropoiesis-stimulating agents (ESAs)?

Note: Clinical areas that are not identified patient-specific needs or facility-specific data-driven focus areas are not required to be reviewed during the medical record review. Surveyors may use their discretion to include such areas during their review.

Review medical record documentation, such as physician orders, patient assessment, and plan of care, to ensure:

- *The patient's assessment reflects their current condition;*
- *The plan of care contains measurable and expected outcomes, with timeframes to achieve the outcomes; and*
- *A plan of care is implemented to address the issues identified in a patient's assessment.*

When the expected outcome(s) have not been achieved, ensure that the facility's interdisciplinary team has adjusted the patient's plan of care to achieve specified goals. (V559)

If a patient's medical record identifies poor outcomes related to clinical laboratory values (e.g. anemia, adequacy, albumin), determine whether the facility has implemented a plan of care to address the issue(s) and review the most current 3 months of laboratory values to determine whether the specified goal(s) have been achieved. Surveyors may reference the Measures Assessment Tool for current national standards.

For each area reviewed in this section, is there evidence that the patient's outcomes has improved and/or their goals are met?
____ If yes, no further review is needed. No deficiency citation is indicated.

____ If no, is there evidence that one or more IDT members were monitoring the patient's outcome in that area; recognized that the patient was not attaining their goal or had a problem in that area; implemented interventions aimed at improvement; and changed strategies if improvement was not achieved or sustained?
____ If yes, no citation is indicated.
____ If no, citation in that outcome area is indicated at the applicable Patient Assessment and/or Plan of Care V-tag.

Home Dialysis in LTC:

Labs/Indicators: *Review the most recent three months of hemoglobin, Kt/V, and albumin, as well as any lab values pertinent to the individual nursing home resident (i.e., an outlier in a data-driven focus area for the survey). Look for frequency of monitoring, recognition when a goal is not met, and actions taken to improve poor outcomes. Review Health-Related Quality of Life (HRQOL) survey results to determine what actions were taken for any identified concerns.*

Interdisciplinary Clinical Care: *Review the last three months of medical record documentation for evidence of:*

- *Communication and collaboration between the ESRD IDT members and the nursing home IDT members (V501, V542, V590, V592)*
- *Timeliness in assessment and care planning for the residents; (V501, V516, V519, V520, V542)*
- *Review of all current medications administered at the nursing home (both by the ESRD facility and the nursing home) to avoid duplicates and contraindications; (V506)*
- *Ongoing monitoring of the resident's current health status (V502)*
- *Nutritional status evaluation and monitoring by a qualified ESRD Dietitian (V509, V503)*
- *Psychosocial and rehabilitation needs evaluation and monitoring, and HRQOL survey administered initially and annually by an ESRD MSW; (V510, V514, V552)*
- *Monthly visits of the resident with a medical practitioner (MD, APRN, PA) treating the resident's ESRD; (V560)*
- *Ongoing consultation with resident/designee by the ESRD IDT (MSW, RD, home training nurse, care coordinator); (V590, V592)*
- *Evidence in the medical record of identification and prompt action(s) relating to dialysis concerns identified during dialysis treatment (V587, V599)*

Self-Monitoring Data: *Verify evidence of review of self-monitoring data and other relevant information (e.g., treatment records, flow sheets, and medications administered) and confirm that an appropriate dialysis facility staff member has reviewed it at least every 2 months. (V587)*

Patient Education: *Look for evidence of resident/designee education regarding all options for dialysis modalities and settings, and information on advance directives. (V457, V458)*

Additional Comments:

_____

_____

_____

_____

_____

Task 12: Patient Interviews Worksheets

Patient Interview: In-Center Hemodialysis

Patient Name _____ *ID* _____ *Date/Time*

_____

Facility _____ *Surveyor*

_____

Instructions*: Conduct patient interviews on in-center hemodialysis patients (ICHD) to ensure pertinent details related to a facility's care and oversight of the ICHD patient are captured. Surveyors should explain the purpose of the interview and ask for the patient's permission to conduct it. Interviews should be conducted by phone or in person (preferred).*

CORE QUESTION	*TRIGGER*
Patient Education *What were you told about other treatment options and their risks and benefits, including those treatment options that are not offered here?* *How did you choose in-center hemodialysis (listen for inappropriate steering to in-center HD for the benefit of the provider)?* *What were you told about your condition and why your kidneys failed?* *What have you been told about the different vascular access types?* *[If the patient has a CVC] How was it decided that you would have a CVC?* *What education have the staff given you about infection prevention, personal care, quality of life, rehabilitation, and your rights and responsibilities?*	*V451* *V458* *V461* *V555* *V562*
Dialysis Treatment *Who reviews your lab values with you?* *How is your dialysis adequacy?*	*V504* *V543* *V544*

Does dialysis usually get you to your weight and blood pressure goal? *If not, do you know why not?* *What has the staff done to help you reach these goals?*	
Care Planning *How are you encouraged to participate in planning your care?* *Does the staff ask and consider your needs, wishes, and goals?* *How does the staff help you address barriers to meeting your goals (targets)? Does the staff discuss dialysis prescription changes with you before making them?*	*V456* *V541*
Patient Rights *Do dialysis staff members treat you with respect and dignity and protect your privacy during training and visits to the facility?* *Has anyone talked with you about your right to have an advance directive such as a living will or durable power of attorney for healthcare decisions?*	*V452* *V454* *V457*
Physical Environment *How clean, comfortable, and safe do you think this facility is?* *Do staff members change their gloves and wash their hands before caring for you?*	*V111* *V113* *V401* *V405*
Patient Grievance *How are you encouraged to speak up and make suggestions or comments about the facility and your care here?* *If you were concerned, how would you file a grievance here or elsewhere?* *How safe from retaliation would you feel voicing a concern, making a suggestion, or filing a grievance?* *If you were afraid of retaliation, could you file a grievance anonymously?*	*V465* *V466* *V467* *V627* *V636*
Staffing *Do you feel staffing levels are adequate enough to meet your needs?* *How often do you have contact with them between appointments?*	*V757* *V758*

Additional Notes

Patient Interview: Peritoneal Dialysis

Patient Name _____ *ID* _____ *Date/Time*

_____

Facility _____ *Surveyor*

_____

***Instructions**: Conduct patient interviews on peritoneal dialysis (PD) patients and/or their caregiver to ensure pertinent details related to a facility's care and oversight of the PD patient are captured. Surveyors should explain the purpose of the interview and ask for the patient/caregiver's permission to conduct the interview. Interviews should be conducted by phone or in person (preferred).*

CORE QUESTION	TRIGGER
Patient Education What were you told about your medical status and other treatment options and their risks and benefits, including those treatment options that are not offered here? How did you choose peritoneal dialysis? What were you told about your condition and why your kidneys failed? How was your training and education individualized to meet your specific and unique needs? What education have the staff given you about infection prevention, disposal of used supplies, quality of life, rehabilitation, and your rights and responsibilities?	V451 V458 V461 V555 V585 V562
Home Training How did the home training nurse determine that you and your caregiver, if applicable, were able to safely and appropriately manage PD treatments at home? How satisfied do you feel with the training you received at this facility? Who is your contact, or care coordinator, at this facility? For patients receiving home dialysis in a long-term care setting: Refer to patient interview questions in Part III: Survey Process for Reviewing Dialysis in Nursing Homes	V586 V590
Care Planning How are you encouraged to participate in planning your care? Have you been informed of your right to refuse or discontinue treatment? Does the staff ask and consider your needs, wishes, and goals?	V456 V541

CORE QUESTION	TRIGGER
How does the staff help you address barriers to meeting your goals (targets)? Does the staff discuss dialysis prescription changes with you before making them?	
Patient Rights *Do dialysis staff members treat you with respect and dignity and protect your privacy during training and visits to the facility?* *Has anyone talked with you about your right to have an advance directive, such as a living will or durable power of attorney for healthcare decisions?*	*V452* *V454* *V457*
Patient Grievance *How are you encouraged to speak up and make suggestions or comments about the facility and your care here?* *If you had a concern, how would you file a grievance here? Have you been informed of external grievance procedures?* *How safe from retaliation would you feel voicing a concern, suggesting, or filing a grievance?* *If you were afraid of retaliation, could you file a grievance anonymously?*	*V465* *V466* *V467* *V636*
Staffing *Do you feel staffing levels are adequate enough to meet your needs?* *How often do you have contact with them between appointments?*	*V757* *V758*
Physical and Mental Health Assessment *Have you been offered an assessment or survey that evaluates your health and lifestyle as well as your energy and activity level?* *If problems were identified on the assessment, how did this facility address them?* *Have you been offered counseling services or referrals for other social services?*	*V552*

Additional Notes

Patient Interview: Home Hemodialysis

Patient Name _____ *ID* _____ *Date/Time*

_____

Facility _____ *Surveyor*

_____

***Instructions**: Conduct patient interviews on home hemodialysis (HHD) patients and/or their caregiver to ensure pertinent details related to a facility's care and oversight of the HHD patient are captured. Surveyors should explain the purpose of the interview and ask for the patient/caregiver's permission to conduct the interview. Interviews should be conducted by phone or in person (preferred).*

CORE QUESTION	TRIGGER
Patient Education What were you told about other treatment options and their risks and benefits, including alternative scheduling options and/or those treatment options that are not offered here? How did you choose Home HD? What have you been told about your condition and why your kidneys failed? Were you trained on how to use, store, and troubleshoot your dialysis equipment? What have you been told about risks and benefits of vascular access types, infection prevention, disposal of used supplies, quality of life, rehabilitation, your rights and responsibilities, who to contact for problems 24/7, and what to do in an emergency or if something prevents you from doing home HD?	V450 V451 V458 V555 V585 V562
Care Planning How are you encouraged to participate in planning your care? Does staff ask about and consider your needs, wishes, and goals? How does the staff help you address barriers to meeting your goals (targets)? Does the staff discuss dialysis prescription changes with you before making them?	V456 V541
Patient Rights Do dialysis staff members treat you with respect and dignity and protect your privacy during training and visits to the facility?	V452 V454 V457

CORE QUESTION	TRIGGER
Has anyone talked with you about your right to have an advance directive such as a living will or durable power of attorney for healthcare decisions?	
Patient Grievance How satisfied are you with your home dialysis therapy? How are you encouraged to speak up and make suggestions or comments about the facility and your care here? If you were concerned, how would you file a grievance here or elsewhere? How safe from retaliation would you feel voicing a concern, suggesting, or filing a grievance? If you were afraid of retaliation, could you file a grievance anonymously?	V465 V466 V467 V636
Home Training How did your training nurse know you (and your care partner, if applicable) ready to do HD at home? Who is your contact (care coordinator) at the facility? How often are your dialysis treatment records submitted to the facility? Who reviews them with you? How satisfied were you with the training you received before going home to do your treatments? For patients receiving home dialysis in a long-term care setting Refer to patient interview questions in Part III: Survey Process for Reviewing Dialysis in Nursing Homes	V585 V586 V587 V590
Staffing Do you feel staffing levels are adequate enough to meet your needs? How often do you see the home training nurse, dietitian, social worker, and physician? Is that enough for you to feel supported in your home treatments? How often do you have contact with them between appointments?	V560 V592 V757
Physical and Mental Functioning Have you been offered a survey that asks how your health and symptoms affect your energy, activity level, and lifestyle? How was the survey and its use explained to you? If problems were identified, how did the staff address them?	V552

Additional Notes

Task 13: Personnel Record Review Worksheet

Review personnel records for all members of the interdisciplinary team to confirm that staff have the appropriate qualifications, credentials, and training requirements to perform their duties. Personnel records should be reviewed for the medical director, physician(s), registered nurses, home dialysis nurses, patient care technicians, registered dieticians, social worker, and others as necessary.

Name	*Position*	*Qualifications*	*Orientation*	*Training Records*	*Training Date(s)*
	ALL	*V681*		*V132*	
	Medical Director	*V682*			
	Physician		*V760*		
	Registered Nurse (RN)	*V684 (nurse manager)* *V686 (charge nurse)* *V688*	*V760*	*V147*	
	Home Dialysis RN (if applicable)	*V685*	*V760*		
	Patient Care Technician	*V692* *V695*	*V760*	*V147* *V693* *V260* *V694*	
	Registered Dietician	*V689* *V690*	*V760*		
	Social Worker	*V691*	*V760*		
	Water Treatment System Technician	*V696*	*V760*	*V260* *V403*	
	Other				
	Other				
	Other				

Reviewer Comments:

_____

_____

_____

_____

Task 14: Personnel Interviews Worksheets

Personnel Interview: Administrator (Optional)

Facility _____ *Date/Time*

_____

Administrator _____ *Surveyor*

_____

***Instructions**: Conduct an interview with the Administrator/CEO to evaluate their role and responsibilities of the facility's care and operations. Interviews should be conducted in person but may also be conducted by phone. Focus the interview on activities related to their duties, as well as concerns identified throughout the survey.*

CORE QUESTION	TRIGGER
Facility Culture *How does this facility promote a culture of safety, which includes encouraging staff to report errors or near-misses, or safety risks?* *What action(s) does this facility take when staff report errors or near-misses?* *How does this facility encourage staff and patients to voice comments and/or suggestions related to improvements at the facility?* *What actions does this facility take when staff or patients submit complaints or grievances?*	*V627* *V634* *V636* *V715* *V765*
Staffing *How does this facility ensure a sufficient number of trained, qualified staff to meet the individual needs of each patient?* *How do you monitor and address staffing issues, such as staff turnover, at this facility?* *How do you work with the governing body to ensure there are sufficient numbers of qualified staff to meet patients' needs?*	*V757*
Staff Development *How does this facility promote continuing education and opportunities related to professional development to its employees?*	*V761*
Quality Assessment and Performance Improvement (QAPI) *How does this facility ensure adequate staff and resources are allocated for its quality improvement program?*	*V756*

CORE QUESTION	TRIGGER
How is QAPI information shared with the governing body for review?	

Additional Notes:

_____
_____
_____
_____
_____
_____
_____

Personnel Interview: Medical Director

Facility _____ *Date/Time*

_____

Medical Director _____ *Surveyor*

_____

Instructions*: Conduct an interview with the medical director to evaluate their role and responsibilities in the facility's care and operations. Interviews should be conducted in person but may also be conducted by phone. Focus the interview on activities related to the medical director's duties and concerns identified throughout the survey.*

CORE QUESTION	TRIGGER
Staffing How do you monitor and address staffing issues, such as staff turnover, at this facility? How do you work with the governing body to ensure there are sufficient numbers of qualified staff to meet patients' needs?	V757
Staff Education How do you ensure that all staff at this facility are appropriately trained and competent to perform their job responsibilities, including PCTs as well as water treatment and reprocessing technicians (if applicable)?	V309 V696 V713
Care Planning How does this facility ensure that patient plans of care are individualized, and patients are encouraged to participate in their care planning?	V456 V541
Adverse Events When and how are you alerted of adverse events/occurrences or problems at the facility?	V634 V639

CORE QUESTION	TRIGGER
What is your role regarding the review of occurrences and taking actions to prevent recurrence?	
Infection Control *How are staff (including medical staff) and patients educated about infection prevention?* *How does this facility monitor staff member adherence to infection control policies & procedures?*	*V130* *V131* *V132*
Modality Education *What is this facility's process for ensuring that every patient receives fact-based unbiased education about transplant and all possible dialysis modalities and settings?* *What is this facility's process for referring candidates for transplant evaluation? What actions does the facility take in the event that the patient elects dialysis modalities and settings not offered here?*	*V458* *V553* *V554*
Admission, Transfer, Involuntary Discharge *What actions does this facility take to prevent situations that risk the involuntary transfer or discharge of a patient?* *How do you work with the interdisciplinary team and patient care staff to resolve issues of concern?* *How do you ensure that the interdisciplinary team follows admission/discharge/transfer policies and procedures?*	*V715* *V716* *V766* *V767*
Quality Assessment and Performance Improvement (QAPI) *What is your role in the QAPI program and/or QAPI activities?* *How do you ensure that the QAPI team regularly monitors all required/appropriate quality metrics and segments the data for each modality and dialysis setting?* *What is the QAPI process at this facility for data analysis and identification of areas needing improvement?* *How are these areas prioritized and addressed for performance improvement?*	*V626* *V628* *V712*

Additional Notes:

Personnel Interview: Nurse (Nurse Manager, Charge Nurse, Staff Nurse)

Facility _____ *Date/Time*

_____

Name _____ *Role* _____ *Surveyor*

_____

***Instructions**: Conduct an interview with the nurse manager, charge nurse, and staff nurse(s) to evaluate their roles and responsibilities in the facility's care and operations. Interviews should be conducted in person but may also be conducted by phone. Focus the interview on activities related to the nurse's duties and concerns identified throughout the survey.*

CORE QUESTION	*TRIGGER*
Staffing *Does this facility have a sufficient amount of trained, qualified staff to meet patients' medical, nutritional, and psychosocial needs?* *How and how often do dietitians, social worker, and the patients' nephrologists see and provide services to patients?* *How are direct care staff members routinely scheduled to address vacations, sick calls, etc.?*	*V757* *V758*
Patient Education *What information are patients, and their caregiver(s) provided about their options for transplant and dialysis modalities, including those that may not be offered by the facility?* *How are a patient's abilities, interests, preferences, and goals evaluated?* *How do you educate patients who have mental illness, cognitive impairment, cultural or language differences?* *What topics are included in your patient and their caregiver(s) education program?*	*V453* *V458* *V512* *V513* *V562*
Care Planning *How does this facility ensure that patient plans of care are individualized, and patients are encouraged to participate in their care planning?* *How does the facility monitor, recognize, and adjust the plan of care to address patients' barriers to meeting goals (targets), including learning barriers?*	*V456* *V542* *V559*
Patient Monitoring *How and how often are in-center dialysis patients monitored before, during, and after dialysis?* *How do you supervise patient care provided by direct care staff?*	*V503* *V504* *V543*

CORE QUESTION	TRIGGER
How are patients' dialysis treatment records reviewed for accuracy? *What is the facility system for monitoring patients' fluid management and fluid removal during dialysis?*	
Infection Control *What training have you received for infection prevention and control?* *How does this facility monitor staff member adherence to infection control policies & procedures?* *What precautions do you and direct care staff take when caring for an HBV+ patient?* *How are staffing assignments made when HBV+ patients are scheduled?*	*V130* *V131* *V132*
Quality Assessment and Performance Improvement (QAPI) *What is your role in the QAPI program and/or QAPI activities?* *What is the QAPI process at this facility for data analysis and identification of areas needing improvement?*	*V626* *V628* *V712*
Emergency Preparedness *What training do you have in dealing with patient emergencies and cardiac arrest?* *What are patients taught about emergency disconnection and evacuation from the facility, and about preparing for disasters?* *How do you determine and keep track of which patients need more help with evacuation?* *How would you contact a physician in an emergency?*	*E-0038V769*
Home Training Nurse: • *What qualifications are required of the individual(s) who deliver dialysis treatments in the nursing home?* • *What training does the individual receive?* • *Who conducts the training?* • *How does the ESRD facility verify the competency of an individual(s), e.g., nursing home staff that provides dialysis treatments?* • *What training do the on-site facility nurses who supervise the dialysis treatments in the nursing homes receive?* • *Do you or another qualified ESRD IDT member conduct periodic site visits for each nursing home resident receiving dialysis, and where are these visits documented?* • *What system does the ESRD have in place for nursing home dialysis equipment maintenance and repair?* • *What provisions are in place at each nursing home to accommodate isolation during dialysis if needed?*	*V128* *V130* *V131* *V403* *V540-V562* *V582-V586* *V589* *V590* *V681* *V685* *V688* *V626* *V692-V695*

CORE QUESTION	TRIGGER
• *What is the expected interaction among the ESRD IDT, the nursing home IDT and residents on dialysis in the nursing home? Where is this interaction documented?* • *How are interim changes in the nursing home patient's plan of care communicated between the ESRD facility and the nursing home?* • *How are the comprehensive patient assessments conducted by the ESRD IDT for the nursing home residents; how are the ESRD facility plans of care then developed for those residents; and how are the ESRD facility plans coordinated with the nursing home plans of care? (V501-V520,* • *How is home dialysis performed in the nursing home incorporated into the ESRD facility QAPI program?*	

Additional Notes:

Personnel Interview: Social Worker

Facility _____ *Date/Time*

_____

Social Worker _____ *Surveyor*

_____

***Instructions**: Interview the social worker(s) to evaluate their role and responsibilities in the facility's care and operations. Interviews should be conducted in person but may also be conducted by phone. Focus the interview on activities related to the social worker's duties and concerns identified throughout the survey.*

CORE QUESTION	*TRIGGER*
Patient Education • *How do you educate and counsel patients and families, including those with learning barriers, about coping with kidney failure and dialysis, lifestyle and treatment options, following their treatment plan, and rehabilitation?* • *How do you work effectively with patients who have mental illness, cognitive impairment, cultural or language differences?*	*V453* *V562*
Psychosocial Assessment – In-Center Dialysis • *What psychosocial issues do you address with in-center patients?* • *How do you assess in-center patients' need for and availability of family and other support systems?* • *If you have in-center nursing home patients, how do you communicate and collaborate with NH staff to address psychosocial needs?*	*V514* *V552*
Psychosocial Assessment – Home Dialysis • *How do you assess patients' need for and availability of family and other support systems when determining candidacy for home dialysis?* • *What psychosocial issues do you address with home patients, including those on dialysis in nursing homes, if applicable?* • *How does this facility ensure that medical supervision by the interdisciplinary team is equivalent to that of in-center dialysis patients?* • *How do you communicate and collaborate with NH staff to meet psychosocial needs, if home dialysis services are provided in the NH?*	*V514* *V552* *V592*

CORE QUESTION	TRIGGER
Care Planning • *How do patients at this facility participate in their plan of care?* • *How do you monitor, recognize, and address patients' psychosocial needs and barriers?* • *What standardized mental and physical assessment tool does this facility use to measure each patient's psychosocial status?* • *When is this assessment conducted?* • *What percentage of patients were excluded in the last year and why? What are your refusal and annual completion thresholds?* • *How do you collaborate with the patient and team to overcome barriers to their goals and clinical targets?*	*V456* *V510* *V542* *V552* *V559*
Home Dialysis in LTC • *Who do you communicate with at the nursing home, and how often?* • *How often do you see nursing home residents on dialysis, and where is this documented?* • *When and how do you assess the nursing home dialysis residents, and how is that assessment coordinated with the nursing home psychosocial assessment?*	*V500-V520* *V542* *V588* *V590-V592*

Additional Notes:

Personnel Interview: Registered Dietitian

Facility _____ *Date/Time*

_____

Registered Dietician _____ *Surveyor*

_____

***Instructions**: Conduct an interview with the Registered Dietitian (RD) to evaluate their role and responsibilities in the facility's care and operations. Interviews should be conducted in person but may also be conducted by phone. Focus the interview on activities related to the dietitian's duties and concerns identified throughout the survey.*

CORE QUESTION	*TRIGGER*
Staffing • *How often are nutritional services requested for in-center and home dialysis patients?* • *Do you feel you are able to meet the nutritional needs of each dialysis patient? If not, why?* • *How do you work effectively with patients who have mental illness, cognitive impairment, cultural or language differences?*	*V681* *V757* *V758*
Patient Education • *How do you educate and counsel patients and families, including those with learning barriers, about their renal diet, labs, nutritional status and any other individual needs?* • *How do you work effectively with patients who have mental illness, cognitive impairment, cultural or language differences?* • *What education is provided to patients related to adjustments to their diet and fluids in the event they cannot receive their dialysis treatment(s), for example during an emergency or disaster?* • *What education is provided to patients and families when changes are made to their modality and settings? For example, switching peritoneal dialysis to hemodialysis or between standard and longer or more frequent dialysis?*	*V453* *V545* *V562*
Care Planning • *What are your responsibilities for monitoring lab test results?*	*V505* *V509* *V545*

CORE QUESTION	*TRIGGER*
• *What is your responsibility if the patient's lab results are outside the identified goals?* • *What areas related to nutritional needs are addressed with in-center patients, including diet on dialysis days? Home dialysis patients?* • *For dialysis services provided to nursing home patients, either in-center or in the nursing home, how do you communicate and collaborate with NH staff to meet the patient's nutritional needs and goals?*	*V559* *V592*
Home Dialysis in LTC • *Who do you communicate with at the nursing home, and how often?* • *How often do you see nursing home residents on dialysis, and where is this documented?* • *When and how do you assess the nursing home dialysis residents and how is that assessment coordinated with the nursing home psychosocial assessment?*	*V500-V520* *V542* *V588* *V590-V592*
Quality Assessment and Performance Improvement *How do you participate in QAPI?* *What facility-level nutritional and other data do you bring to QAPI meetings?*	*V626* *V630* *V631* *V756*

Additional Notes:

Personnel Interview: Patient Care Technician

***Instructions**: Conduct an interview with the patient care technician(s) (PCT) to evaluate their role and responsibilities for patient care. Interviews should be conducted in person but may also be conducted by phone. Focus the interview on activities related to PCT duties and concerns identified throughout the survey.*

CORE QUESTION	*TRIGGER*
Staffing *Does this facility have a sufficient amount of trained, qualified staff to meet patients' medical, nutritional, and psychosocial needs?* *Is a registered nurse always on duty when patients are in the dialysis facility receiving treatments?*	*V681* *V757* *V759*
Patient Monitoring *How and how often are in-center dialysis patients monitored before, during, and after dialysis?* *When would you notify a nurse if a patient has a problem?* *What is the facility's system for determining what each patient's fluid removal parameters are?*	*V503* *V504* *V543*
Interdisciplinary Care *What is your role and the responsibilities of patient care at this facility?* *How and to whom would you report patients' interest in, and the need for, education about other treatment modalities?* *What type of patient issues would you refer to members of the interdisciplinary team, i.e. social worker, dietician, nurse?*	*V458* *V509* *V510* *V694*
Infection Control *What training have you received for infection prevention and control?* *What precautions do you and direct care staff take when caring for an HBV+ patient?* *How are staffing assignments made when HBV+ patients are scheduled?*	*V113* *V130* *V131* *V132*

Additional Notes:

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Task 15: Quality Assessment & Performance Improvement Worksheet

*Facility*_____ *CCN*_____ *Date* _____ *Surveyor*_____ *Facility Staff* _____

Instructions: *Each facility is required to develop and administer a QAPI program that is individualized to their facility and its unique needs. The surveyor must review each facility's QAPI program to determine the presence of active involvement of the professional members of the IDT. This includes the medical director/physician, a registered nurse, a social worker, and a dietitian. The facility's QAPI program may also include patients, caregivers, and other technical facility personnel.*

Some dialysis corporations implement a comprehensive corporate-based program, however, the facility's utilization of a corporate-based QAPI program is not the sole basis for citation. The surveyor must review and determine whether the QAPI program includes:

- *Participation from facility staff members*
- *Representation of the dialysis facility's operations and services*
- *Measurable clinical indicators related to outcomes and prevention/reduction of medical errors*

Preparation for QAPI Review: *Although portions of the QAPI review may occur throughout the survey, the majority of the QAPI review should be conducted toward the end of the survey. Conducting the review after most of the survey is completed allows the surveyor to determine if the facility has identified the same concerns as the survey team, and what performance improvement actions they have taken to address them.*

Prior to conducting the QAPI review, the survey team should communicate, discuss the survey findings, and list the ***focus areas*** *to be reviewed during Segment II in the spaces provided below:*

1.	*4.*
2.	*5.*
3.	*6.*

The QAPI review is divided into three Segments of review:

Segment I. Facility Monitoring of Care and Operations
Segment II. Patient-related Data and Survey Findings
Segment III. Culture of Safety Review

Segment I. Facility Monitoring of Care and Operations: *Verify that the facility QAPI program has sufficient infrastructure, and continuously monitors all areas as expected. The review of Segment I includes the following two areas:*

- *Clinical and operational indicators*
- *Oversight of technical operations and practice audits*

Segment II. Patient-related Data and Survey Findings: *Review the patient-related data in four critical areas to assess how a facility monitors and implements provisions of care with the use of clinical data. Through this review, the surveyor should assess the facility's QAPI activities for recognizing issues, prioritizing, and responding to problematic areas to attain and sustain improvements. Review of Segment II includes the following four areas:*

- *Mortality review*
- *Infection prevention and control*
- *Medical error/adverse occurrence tracking system*
- *Data-driven focus areas and survey findings*

Segment III. Culture of Safety Review: *Verify the presence of a facility-wide culture that promotes and protects patient safety. The primary components are a robust and proactive system for reporting and addressing errors/risks, open blame-free communication between all levels of staff and patients, and expectations of staff and patients are clearly communicated. Review of Segment III includes the following two areas:*

- *Staff engagement*
- *Patient engagement*

Review the facility-based QAPI documentation for the most recent six months in the areas listed in Segments I, II, and III below. Interview the responsible facility-based person.

Segment I: Facility Monitoring of Care and Operations

Clinical and Operational Indicators

Review the facility-based QAPI documentation to verify that the facility's QAPI program includes active involvement of all expected administrative, patient care and technical staff and that the QAPI program monitors at a minimum all the expected areas of patient clinical management and facility operations (§ 494.110).

Data must be segregated by dialysis modality and setting (e.g. HD, PD, nocturnal, in-center, home). Note that not all areas are required to be monitored monthly.

This is not a detailed review, but a brief look at the facility's QAPI summarizing documentation. Review of the facility QAPI performance improvement activities is conducted in more detail during Segment II.

Clinical indicators of performance and outcomes to be routinely monitored include (§ 494.110 (a)(2):

Dialysis adequacy (V629)	*Dialyzer Reuse QA audits & adverse events (V635)*
Nutritional status (V630)	*Patient satisfaction & grievance/complaints (V636)*
Mineral metabolism and bone disease management (V631)	*Infection prevention & control (V637)*
Anemia management (Hgb, transfusions, TSAT%, ferritin) (V632)	*Vascular Access – HD (V633)* *PD Access – (V633)*
Medical Injuries and Medical Errors Identification: In-center Hemodialysis and Home Dialysis (V634) *Cardiac arrest at facility* *Death during dialysis* *Error in dialysis treatment prescription delivery* *Medication errors, omission, adverse reactions* *Transfusion reactions* *Incorrect reprocessed dialyzer set-up or used* *Blood loss* *Chlorine/fluoride breakthrough* *Machine malfunction with treatment interruption* *Patient transfer to hospital* *Patient falls/injuries* *Vascular access events: infiltration, clotting, excessive bleeding, infection* *Intra-dialytic symptoms: hypotension with loss of consciousness, chest pain, severe cramping, nausea/vomiting, pyrogenic reactions* *Staff incidents and injuries: needle sticks, blood/body fluid exposure, non-adherence to procedures, patient abuse/disrespect*	

Additionally, the facility's QAPI program should maintain oversight of routine activities occurring in the facility for identification of concerns, investigation of causal or contributory factors, and implementation of improvement activities to correct or mitigate the problem(s).

Clinical and technical areas identification of concerns include:

Water and dialysate quality (V628)	*ESRD Network relationship/communication (V772)*
Dialysis equipment maintenance and repair (V628)	*Mental health/psychosocial assessment, for example health-related quality of life (HR-QOL) survey (V628)*
Personnel qualifications	*Mortality*
Physical plant safety "rounds" audits (V628)	*Morbidity: hospitalizations, admitting diagnoses, readmissions within 30 days (V628)*

Is the facility routinely monitoring and trending all of the expected areas, and segregating data by modality and setting (HD, PD, nocturnal HD, in-center, home)? (V626, V628)
Explain:

_____
_____
_____

Do outcome goals reflect community standards?(V628)
Explain:

_____
_____
_____

Does QAPI documentation show active involvement of all on-site personnel necessary to adequately address and resolve problems/issues, including all members of the interdisciplinary team, i.e., medical director, nurse manager, masters-prepared social worker, registered dietitian, and other personnel such as technical staff and patient care staff? (V626, V628)
Explain

_____
_____
_____

Technical Operations and Practice Audits

Review the facility QAPI documentation to ensure routine oversight is maintained in the areas listed below:

AREA FOR REVIEW	*DESCRIPTION*
Water and Dialysate Quality	*Includes in-center and home dialysis Review: water and dialysate cultures/endotoxin results monthly; product water chemical analysis annually; and microbiological monitoring as indicated for the equipment in use (V628) Audits at least annually of facility staff mixing dialysate concentrates, testing batches of acid concentrate, testing dialysate pH/conductivity, testing water for total chlorine and microbiological sample collection, and operating equipment (V260)*
Dialysis Equipment	*Review of dialysis machine, equipment and ancillary equipment maintenance and repair monthly (V628)*
Reuse	*Review and verify that all required reuse QA audits are conducted at the applicable intervals and adverse occurrences related to reuse are addressed (V635)*

Does the QAPI program indicate areas mentioned above were conducted at the required intervals?
Explain:

_____

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If problems were identified in the reviews and audits above, did the facility act to resolve the problem(s) and attain improvements?
Explain:

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Note: Instances where improvement activities are continued despite no change or a decline in performance is not evidence of an effective QAPI program. For example, sustained elevations of water and dialysate culture levels addressed with disinfection for several months despite no change in culture levels would not be indicative of an effective performance improvement activity.

Additional Notes:

_____

Segment II. Patient-related Data and Survey Findings
Review the mortality, infection prevention and control, and medical error/adverse occurrence investigation systems (i.e., critical priority areas). Review of data-driven focus areas and survey findings should be individualized and relevant to the current survey being conducted.

In all areas, conduct a detailed review to determine the quality and effectiveness of the facility QAPI actions for addressing problematic areas and attaining and sustaining improvements in outcomes.

Mortality Review

Review QAPI documentation for the evaluation of facility mortality events. Review should be conducted with the responsible facility-based personnel. Discussions with facility staff should focus on the analysis of causal factors for patient deaths and its relationship to the care received at the facility.

Ask: What information does your facility collect following a patient death event? What is the facility's method for conducting the analysis of individual patient deaths?

Is there evidence of patient death evaluation and analysis of the causal and/or contributory factors? (V628)
Explain:

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_____

If a facility's DFR indicates mortality outcomes worse than the national average, review the following additional areas:

- *Method and result(s) of investigation into causal and/or contributory factors related to death events.*
- *Identification of trends in factors related to death events.*
- *Performance improvement actions to address and improve mortality ratio.*

There may be situations in which a patient misses their provider visit in a given month. However, if there are patterns of missed visits, the IDT is responsible for the patient's care, and as such, should determine its impact on the patient's health and safety. Facility attempts to follow-up should me evidenced. For example, if a patient is defined as "unstable" in accordance with § 494.80(d), and has a pattern of missed monthly visits, documentation must be evidenced in the medical record that addresses the IDT's oversight of the patient's care.

Infection Prevention and Control

Review the QAPI documentation for evaluating facility infection control events. Discussions should focus on the facility's program for the prevention, detection, and

management/control of infections, with the goal of minimizing or eliminating healthcare-associated infections (HAIs) acquired at the facility.
There are four areas of this review:

1. *Infection occurrence tracking/trending surveillance*

   Ask: *What types of infections do you record? What information do you record about each infection? What is the facility hemodialysis vascular access infection rate? What is the facility peritoneal dialysis catheter infection rate? What is the facility peritonitis rate?*

   Review: *The infection tracking logs.*
   Are all positive culture results, dialysis access infections, blood stream infections (BSI), and peritonitis episodes, if applicable recorded with sufficient information for each (i.e., patient name, date, infecting organism, culture site, antibiotic use)?

   Is there evidence that trends in infections were recognized, evaluated/investigated, and performance improvement activities implemented and monitored for effectiveness? (V637)

   Review: *Documentation of facility dialysis-related infection rates.*
   Does the facility routinely calculate dialysis-related infection rates as applicable to the modalities offered (i.e. hemodialysis vascular access, peritoneal dialysis catheter, peritonitis) using an accepted formula?

   Is there evidence that high infection rates and upward trends were recognized, investigated, and performance improvement actions implemented and monitored for effectiveness?

2. *Vaccination: high-risk disease-specific management*
   Refer *to the facility vaccination information obtained from the Entrance. Conference Materials list.*

   Ask: *The responsible facility-based person to show you the QAPI documentation of oversight for surveillance and vaccination for:*
   - *Hepatitis B patient surveillance and susceptible patients and personnel offered vaccination*
   - *Tuberculosis surveillance of patients on admission or exposure*
   - *Influenza vaccinations offered to patients and personnel annually*
   - *Pneumococcal pneumonia vaccination offered to patients*
   - *New Hepatitis C (HCV) infections (i.e. antibody elevations for facilities that test for HCV) or unexplained ALT elevations; HCV surveillance/routine testing including testing on admission.*

   Is there evidence of active QAPI oversight of the above high risk disease surveillance and vaccination programs? (V637, V125-V127)

If lapses in surveillance or vaccination were identified, did the facility take meaningful actions to investigate the problem, implement performance improvement plans, and monitor their effectiveness? (V637)

If HBV conversions, other notifiable diseases or outbreaks were identified, were they reported to the local health department? (V637)

3. *Staff education and visual practice audits for infection control*
   ***Ask**: What are staff taught about infection prevention practices? How often are they re-educated in infection prevention? What methods do you use to visually audit patient care staff infection control practices? How often are the visual audits of patient care staff conducted? If you identify a problem during an audit, how do you involve staff in developing and implementing the solution?*

   ***Review:** The documentation of visual audits of personnel infection control practices while delivering care to patients.*

   Is there evidence of active staff education and at least annual verification of competency for infection prevention and control by visually auditing each direct care staff providing care to patients (e.g. initiation and discontinuation of hemodialysis, vascular assess care, medication preparation and administration, hand hygiene, etc.)? When lapses in practices were observed, were actions taken toward improvement? Were the involved staff included in the investigation into issues surrounding the practices, and development and implementation of improvement plans, rather than just counseling or reeducating? (V637, V132, V142, V147)

4. *Patient education for infection prevention*
   ***Ask:** How are patients educated about infection prevention? How are patients encouraged to be engaged in knowing what infection prevention actions (e.g., changing gloves, hand hygiene, cleaning/disinfecting equipment) they and staff should be follow? How are the patients encouraged to speak up if they have concerns about personnel infection control practices?*

   Does the facility's infection prevention and control program include educating patients and their families about strategies for remaining infection-free? (V637, V562, V585)

For facilities with high rates of infection, high rates of CVC >90 days, or patterns of survey findings in infection control:
***Ask:** What investigation have you conducted into your facility's problematic infection issue? What QAPI strategies have you implemented to improve the problem? What improvements have you achieved?*

Is there evidence that the facility recognized and acted upon their poor infection outcomes? (V637)

When reductions in infection rates or CVC >90 days rates were not attained, did the QAPI Team revise and change the performance improvement actions until improvements were achieved?

MAKE ONE COPY OF THIS PAGE FOR EACH FOCUS AREA YOU WILL REVIEW

Data-driven focus areas and survey findings areas: *Using your list of QAPI focus areas from page 1 of this worksheet.*

Review *those data-driven focus areas and survey findings areas in more detail with the responsible facility-based person.*

Ask*: How do you prioritize facility performance improvement activities? How did the facility-based QAPI Team recognize the focus area problem/issue and investigate the root/multiple cause(s)? What actions did you take for improvement, and how were the actions and subsequent outcomes monitored to assure improvements were attained and sustained? If improvements were not attained, what actions did you take?*

Focus Area:

- *Is there evidence that the facility prioritized performance improvement activities to ensure areas with the highest potential for impacting patient safety were given priority and aggressively addressed in a timely manner?*

- *Did the facility routinely monitor the focus area, identify the issue, or recognize that a problem or opportunity for improvement existed?*

- *Did the facility thoroughly investigate root/multiple causes of the issue and develop, implement, and monitor performance improvement plans?*

- *Does the current QAPI documentation show that improvements have been attained and sustained?*

If yes to all above questions: no further review is needed for that focus area or survey concern/finding. The facility QAPI response was effective; no citation at QAPI is indicated

If improvements were not achieved and the outcome goals in the focus area are not currently being met, is there evidence that the facility revised, implemented, and monitored the revised QAPI actions?(Note that repeated entries of "will monitor" without active revisions to action plans are not sufficient evidence of effective QAPI) (V626, 628-637)

Segment III: Facility Culture of Safety

Verifying the presence of a facility-wide culture that promotes and protects patient safety. The primary components of a culture of safety are a robust and proactive system for reporting and addressing errors/events, open blame-free communication between all levels of staff and patients and clearly communicated expectations of staff and patient. A facility-wide culture of safety enables staff and patient participation to ensure that everyone at the facility is committed to identifying and mitigating any risks to patients.

The culture of safety review has two (2) components:

- *Staff participation*
- *Patient participation*

Staff Participation Review

Verify the presence of open communication among all levels of facility staff and encouragement for staff to voice concerns without fear of retribution. The surveyor will review the facility's method for promoting and gathering staff feedback or questions as well as providing information related to expectations among all levels of staff.

There should be evidence that the facility has an organized, facility-based system in place for staff to submit written or verbal suggestions for improvement, communication of concerns about their work environment, and complaints.

If the surveyor has gathered evidence of staff complaints not being addressed, for example during staff interviews, confirm with an appropriate member of the QAPI team whether the complaints were received, reviewed, and addressed.

Expect to see evidence that the facility administration educates and encourages staff to make suggestions and voice concerns and complaints about their work environment. There should be evidence that administrative personnel recognize and acknowledge staff concerns in a timely, non-judgmental manner, conduct substantive investigation into the concerns, and include applicable staff in resolution to the issues (V626).

Patient Participation Review

The surveyor will review the facility's method for promoting and gathering patient feedback. Verify facility participation with all dialysis patients that provide feedback on the overall care and operations at the dialysis facility to promote patient satisfaction. The surveyor should review the facility patient grievance, complaint, or suggestion system by "following" a patient complaint through the process.

If the patient interviews task indicated a reluctance to voice complaints, follow up with facility-based personnel for further investigation. Review the record to see if the complaints were documented and ask staff whether the complaints were received. Is

there a QAPI process that allows patients to complain or submit grievance without fear of retribution?

Ask: *How are staff taught to respond to patients' concerns? What types of patient concerns do you educate and expect staff to report and record?*

Ask: *How are patients educated about and encouraged to freely speak up and voice suggestions and complaints/grievances without fear of retribution or retaliation? How are their concerns, verbal or written suggestions, and complaints/grievances recorded and responded to? What is your facility's system for communicating with the patient and reporting the resolution to him/her? (V465, V466, V467)*

Review *the patient suggestion/complaint/grievance log with the responsible facility-based person. Select one patient suggestion/complaint/grievance to review how it was investigated, resolved, and the result communicated to the patient. You may wish to interview the involved patient about their experience using the facility patient suggestion/complaint/grievance system.*

- *Expect to see that facility management and staff encourage patients to verbalize suggestions and concerns, in addition to written complaints/grievances. Staff should be educated how to respond professionally to patients' verbalized concerns and to report them to their supervisor for recording and follow up (V636, V765).*
- *There must be evidence that the patient's concern you reviewed was recorded, the circumstances investigated, mutually acceptable resolution reached, and the result communicated to the patient (V636, V465, V765).*

Verify that the facility routinely assesses the patients' satisfaction with the facility services and care received and acts upon the identified opportunities to improve care.

Ask the following: *How do you assess patient satisfaction/perceptions of care at this facility?*
How do you use that information to improve programs or care delivery? (V636)

Triggers for citation:

The QAPI program does not:

Administer oversight of all facility operations including monitoring all areas and conducting practice audits as required by the CfC (V260, V362-V368, V403)

Recognize and address risk areas where facility outcomes and/or survey findings indicate performance improvement is needed/indicated (V625-V640)

Follow up on performance improvement plans, resulting in improvements not attained or sustained or recurring similar adverse events (V634, V638)

Extending *the QAPI review should be considered if there are serious, pervasive deficient practices identified during the survey and were not recognized and/or adequately addressed by the dialysis facility. Extending the QAPI review should include*

investigating the facility's compliance with the Conditions for Coverage of Medical Director and Governance. This may include interviews with the facility administrator, medical director, and governing body members to determine what administrative failures have contributed to the pervasive problems, through lack of adequate staff and/or resources (V754, V756, V757); lack of staff training and education (V713, V715, V760, V761, V763); and/or lack of involvement or leadership of the medical director (V712, V714).

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R246SOMA	08/17/2026	Revisions to the State Operations Manual (SOM) Appendix H, End-Stage Renal Disease (ESRD) Program Interpretive Guidelines and Survey Procedures	08/17/2026	N/A
R200SOMA	02/21/2000	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 (ESRD), 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	02/21/2000	N/A
R01SOM	05/21/2004	Initial Release of Pub 100-07	N/A	N/A