CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12575	**Date: April 11, 2024**
	Change Request 13587

SUBJECT: Internet Only Manual Updates to Publication 100-04 to Implement Updates to Policy (Inpatient Rehabilitation Facility (IRF))

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update the Medicare manual Pub. 100-04 with regard to IRF policy changes made within the IRF Final Rule (FR) FY2024 [88FR 68494], specifically, to note the updates to the modification to the regulation, § 412.25 (c)(1), for IRF units to become excluded and paid under the IRF PPS. Additionally, CMS Regional Office (RO) was updated to Office of Program Operations and Local Engagement (OPOLE) and clarifying language was added around the presumptive compliance guidance.

EFFECTIVE DATE: July 12,2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 12,2024
Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	03/140.1/Medicare IRF Classification Requirements
R	03/140.1.1/Criteria That Must Be Met By Inpatient Rehabilitation Facilities
R	03/140.1.2/Additional Criteria That Must Be Met By Inpatient Rehabilitation Units
R	03/140.1.3 /Verification Process Used To Determine If The Inpatient Rehabilitation Facility Met The Classification Criteria
R	03/140.1.5/Changes in the Status of an IRF Unit
R	03/140.2.5.1/Area Wage Adjustments

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical

direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 12575	Date: April 11, 2024	Change Request: 13587

SUBJECT: Internet Only Manual Updates to Publication 100-04 to Implement Updates to Policy (Inpatient Rehabilitation Facility (IRF))

EFFECTIVE DATE: July 12,2024
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I. GENERAL INFORMATION

A. Background: This Change Request (CR) updates the Medicare manual with regard to IRF policy to update content to reflect new IRF policies finalized in the Fiscal Year (FY) 2024 IRF Prospective Payment System (PPS) final rule (88FR 68494).

B. Policy: This CR updates the Medicare manuals to conform with recent rulemaking, specifically, to amend the requirements currently in regulation § 412.25(c)(1) to allow a hospital to open a new IRF unit anytime within the cost reporting year, as long as the hospital notifies the CMS RO (OPOLE) and Medicare Administrative Contractor (MAC) in writing of the change at least 30 days before the date of the change. Additionally, if a unit becomes excluded during a cost reporting year, this change would remain in effect for the rest of the cost reporting year.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13587.1	Contractors shall be aware of the updates to Pub 100-04, Chapter 3.	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13587.2	Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.	X				

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

140.1 - Medicare IRF Classification Requirements

(Rev.12575; Issued:04-11-24; Effective: 07-12-24; Implementation: 07-12-24)

Section 1886(j) of the Social Security Act (the Act) provides for the implementation of a prospective payment system (PPS) under Medicare for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation unit of a hospital (referred to as an inpatient rehabilitation facility (IRF)). Section 1886(d)(1)(B)(ii) of the Act gives the Secretary the discretion to define an IRF. The regulations at 42 CFR §§ 412.25 and 412.29 specify the criteria for a provider to be excluded from the inpatient prospective payment system (IPPS) specified in 42 CFR §412.1(a)(1) and instead be paid under the IRF PPS. 42 CFR 412.29
A facility paid under the IRF PPS is always subject to verification that it continues to meet the criteria for exclusion from the IPPS. The fiscal intermediary (FI) or the Part A/B Medicare Administrative Contractor (MAC) *provides the Regional Office (RO) now referred to as the Office of Program Operations and Local Engagement (OPOLE) with data for determining the classification status of each facility and OPOLE reviews the IRF's classification status each year. Additionally, updates were made to 42 CFR § 412.25(c)(1) to allow a hospital to open a new IRF unit anytime within the cost reporting year, as long as the hospital notifies OPOLE and the MAC in writing of the change at least 30 days before the date of the change for making a determination that a facility either is or is not classified as an IRF. This change applies to the entire cost reporting period. We maintain the current requirements of § 412.25(c)(2), which specify that, if an excluded unit becomes not excluded during a cost reporting year, the hospital must notify the MAC and OPOLE in writing before the change, and this change would remain in effect for the rest of the cost reporting year.*
If a facility fails to meet the criteria necessary to be paid under the IRF PPS, but meets the criteria to be paid under the IPPS, it may be paid under the IPPS.

If a patient is admitted to a facility that is being paid under the IRF PPS, but is discharged from the facility when it is no longer being paid under the IRF PPS, then payment to the facility will be made from the applicable payment system that is in effect for the facility at the time the patient is discharged.

IRFs that are being paid under the IRF PPS need not reapply to be classified for payment under the IRF PPS each year. However, under CMS's new attestation process, an IRF must self-attest to meeting all of the criteria, except for the criteria specified below in §140.1.1B-D, for being excluded from the IPPS and paid under the IRF PPS every 3 years. The A/B MACs (A) are responsible for verifying annually that each IRF meets the criteria specified below in §140.1.1B-D. IRFs are notified in writing by *OPOLE* of the required self-attestation procedures and the time-frames for submitting the required self-attestation forms. The ROs will also notify the IRFs in writing of any other procedures and requirements that apply to them. However, the A/B MACs (A) are not responsible for monitoring or enforcing the IRF self-attestation procedures, which are the responsibility of the State agencies.

All IRFs must notify their A/B MACs (A) and *OPOLE* in writing before making any changes to their operations (i.e. increasing their bed size or square footage, moving to a new location, changing ownership, merging, or other similar changes to the ownership or operations of the facility).

140.1.1 - Criteria That Must Be Met By Inpatient Rehabilitation Facilities

(Rev.12575; Issued:04-11-24; Effective: 07-12-24; Implementation: 07-12-24)

An inpatient rehabilitation hospital or an inpatient rehabilitation unit of a hospital (otherwise referred to as an IRF) is excluded from the IPPS and is eligible for payment under the IRF PPS if it meets all of the criteria listed below. Note that in order for an individual IRF claim to receive Medicare payment under the IRF PPS, it must meet all of the IRF coverage requirements in 42 CFR 412.622(a)(3), (4), and (5), as further clarified in Chapter 1, Section 110 of the Medicare Benefit Policy Manual (Pub. 100-02.

A. - The IRF must have (or be part of a hospital that has) a provider agreement under 42 CFR Part 489 to participate in Medicare as a hospital.

B. - During the most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the A/B MAC (A)) the IRF must have treated an inpatient population that met or exceeded the following percentages:

1. For cost reporting periods beginning on or after July 1, 2004, and ***before July 1, 2005***, the hospital must have served an inpatient population of whom at least 50 percent required intensive rehabilitative services for treatment of one or more of the medical conditions specified below at § 140.1.1C.

2. For cost reporting periods ***beginning on or after July 1, 2005***, the IRF must have served an inpatient population of whom at least 60 percent required intensive rehabilitative services for treatment of one or more of the medical conditions specified below at § 140.1.1C.

C. - List of Medical Conditions:

1. Stroke.

2. Spinal cord injury.

3. Congenital deformity.

4. Amputation.

5. Major multiple trauma.

6. Fracture of femur (hip fracture).

7. Brain injury.

8. Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.

9. Burns.

10. Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other

activities of daily living that have not improved after an appropriate, aggressive, and sustained course (as defined below) of outpatient therapy services or services in other less intensive rehabilitation settings, but have the potential to improve with more intensive rehabilitation.

11. Systemic vasculidites with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course (as defined below) of outpatient therapy services or services in other less intensive rehabilitation settings, but would have the potential to improve with more intensive rehabilitation.

12. Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course (as defined below) of outpatient therapy services or services in other less intensive rehabilitation settings, but would have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

13. Knee or hip joint replacement, or both, during a hospitalization immediately preceding the IRF stay and also meets one or more of the following specific criteria:

a. The patient underwent bilateral knee or bilateral hip joint replacement surgery during the hospital admission immediately preceding the IRF admission.

b. The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

c. The patient is age 85 or older at the time of admission to the IRF.

<u>Definition of "an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings"</u>

For the medical conditions specified above in subsections 10, 11, and 12, an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings must consist of a course of rehabilitation therapy of at least 3 weeks minimum duration with at least two individual (non-group) therapy sessions per week targeting all clinically impaired joints supported by documentation in the medical record of all such services with periodic assessments for clinical functional improvement, within 20 calendar days of an acute hospitalization preceding immediately an IRF stay, or 20 calendar days immediately preceding an IRF admission. However, there may be cases when, in the A/B MAC (A)'s judgment, the preceding interpretation of what is considered an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings should not be used. In these cases, the A/B MAC (A) has the discretion to develop, document, and use another interpretation, which is based upon local practices and more current clinical information, that interprets or defines what the A/B MAC (A) considers is an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings. Regardless of which

interpretation or definition is used by the A/B MAC (A) with respect to what is considered an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings, the course of therapy itself should have the goal of completing the rehabilitation, not preparing a patient for surgery. The outpatient therapy services (or services in other less intensive settings) must immediately precede the IRF admission or result from a systemic disease activation immediately before admission.

The A/B MAC (A) has the discretion to review documentation to assure that the patient has completed an appropriate, aggressive, and sustained course of therapy or services in less intensive rehabilitation settings. CMS expects that the IRF will obtain copies of the therapy notes from the outpatient therapy or from the therapy services provided in another less intensive setting and include these in the patient's medical record at the IRF (in a section for prior records). CMS believes that these prior records will be used by therapists and others caring for the patient in the IRF, and will also be available to the A/B MAC (A) staff who review the medical records for compliance with the requirements specified above in §140.1.1B-D.

D. - Comorbidities.—A comorbidity is a specific patient condition that is secondary to the patient's principal diagnosis. A patient with a comorbidity may be counted as part of the inpatient population that counts towards the required applicable percentage specified above in §140.1.1B-D if:

1. The patient is admitted for inpatient rehabilitation for a medical condition that is not one of the conditions specified above in sub-section 140.1.1C.

2. The patient has a comorbidity that falls in one of the medical conditions specified above in sub-section 140.1.1C; and

3. The comorbidity has caused significant decline in functional ability in the individual such that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under the IRF PPS.

E. - For the first cost reporting period during which a facility first begins being paid under the IRF PPS as a "new" IRF, a facility seeking to be paid under the IRF PPS must provide a written certification to the A/B MAC (A) that the inpatient population it intends to serve meets the requirements specified above in §140.1.1B-D. However, if CMS discovers that the facility did not actually meet the requirements specified above in §140.1.1B-D during any cost reporting period for which the facility provided such written certification of its intent to meet the requirements in §140.1.1B-D, then CMS will adjust the payments associated with that cost reporting period as described below in §140.1.9.

F. - The IRF has in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital rehabilitation program. This procedure must ensure that the preadmission screening is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

G. - The IRF has in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both

medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process. *Beginning with the second week of admission to the IRF, a non-physician practitioner who is determined by the IRF to have specialized training and experience in inpatient rehabilitation may conduct 1 of the 3 required face-to-face visits with the patient per week, provided that such duties are within the non-physician practitioner's scope of practice under applicable state law.*

H. - The IRF furnishes, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.

I. - The IRF has one physician who serves as director of rehabilitation and who—

(1) Provides services to the IRF hospital or its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least 2 years of training or experience in the medical management of inpatients requiring rehabilitation services.

If an IRF serves both inpatients and outpatients, the time spent by the director in performing administrative duties for the entire facility counts toward the direction requirement since it is not feasible to prorate this administrative time between inpatients and outpatients. However, any time spent in furnishing direct patient care can count toward the direction requirement only if the care is furnished to inpatients.

J. - The IRF has a plan of treatment for each inpatient that is established, reviewed, and revised, as needed, by a physician in consultation with other professional personnel who provide services to the patient.

K. - The IRF uses a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans. The IRF must also ensure that team conferences are held at least once per week to determine the appropriateness of treatment.

140.1.2 - Additional Criteria That Must Be Met By Inpatient Rehabilitation Units

(Rev.12575; Issued:04-11-24; Effective: 07-12-24; Implementation: 07-12-24)

In addition to the requirements specified above in §140.1.1, an inpatient rehabilitation unit *shall* meet the additional criteria in paragraphs A through M below in order to be excluded from the IPPS and be paid instead under the IRF PPS.

A. - The inpatient rehabilitation unit must be a part of an institution that has in effect an agreement to participate as a hospital that is not excluded in its entirety from the IPPS.

B. - The inpatient rehabilitation unit must have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.

C. - The inpatient rehabilitation unit must have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily retrievable. The record must indicate the dates of the admission and discharge for patients of the unit. The IRF must also have a process in place to ensure that each patient's medical record at the IRF meets the hospital conditions of participation in 42 CFR Part 482 and all of the documentation requirements specified in 42 CFR §412.622 (a)(3), (4), and (5). Further guidance on the IRF documentation requirements is available in chapter 1, section 110 of the Medicare Benefit Policy Manual (Pub. 100-02). The inpatient rehabilitation unit's policies must provide that necessary clinical information is transferred to the unit when a patient of the hospital is admitted to the inpatient rehabilitation unit, as described further in chapter 1, section 110.1.1 of the Medicare Benefit Policy Manual (Pub. 100-02).

D. - If state law provides special licensing requirements for rehabilitation units, the inpatient rehabilitation unit must be licensed in accordance with the applicable requirements.

E. - The hospital's utilization review plan must include separate standards for the type of care offered by the inpatient rehabilitation unit.

F. - The beds assigned to the inpatient rehabilitation unit must be physically separate from (i.e., not co-mingled with) beds not included in the unit. This means that patients from other parts of the hospital may not be treated in the beds assigned to the inpatient rehabilitation unit.

G. - The hospital must have enough beds not excluded from the IPPS to permit the provision of adequate cost information. The A/B MAC (A) has discretion as to how to apply generally accepted accounting principles when making this analysis.

H. - The inpatient rehabilitation unit and the hospital in which it is located must be serviced by the same A/B MAC (A).

I. - The inpatient rehabilitation unit must be treated as a separate cost center for cost finding and apportionment purposes.

J. - The accounting system of the hospital in which the inpatient rehabilitation unit is located must provide for the proper allocation of costs and maintain statistical data that are adequate to support the basis of allocation.

Compliance with the criteria in items H, I, and J above may be determined based on the hospital's most recently filed cost report or, if necessary, by the hospital's presentation of evidence that shows, to the satisfaction of the A/B MAC (A), that the hospital has the accounting capability to meet these criteria for the cost reporting period for which the exclusion from the IPPS, if approved, applies.

K. - The cost report for the hospital must include the costs of the inpatient rehabilitation unit, covering the same fiscal period as the hospital, and use the same method of cost apportionment as the hospital.

L. - As of the first day of the first cost reporting period for which all other exclusion requirements are met, the inpatient rehabilitation unit must be fully equipped, staffed, and

must be capable of providing hospital inpatient rehabilitation care regardless of whether there are any inpatients in the unit on that date.

M. - Each hospital may have only one unit of each type (psychiatric and rehabilitation) excluded from the IPPS.

The criteria specified in paragraphs A through M above are used to determine whether a part of a hospital qualifies for exclusion from the IPPS. An excluded unit must be established as a separate cost entity for cost reporting purposes.

If a hospital wishes to have *an IRF* unit, it must notify *OPOLE and the A/B MAC in writing of the change at least 30 days before the date of the change currently in regulation at § 412.25(c)(1) to allow a hospital to open a new IRF unit anytime within the cost reporting year. OPOLE will* notify the hospital if they approve of the opening or not of the following: (1) the particular areas that it has designated as the unit, and (2) the square footage and number of beds in the unit. The A/B MAC (A) or *OPOLE* will inform the IRF of the proper procedures. The hospital's notification of its intent to have a unit excluded from the IPPS must be sent to the A/B MAC (A) at the same time that it is sent to *OPOLE*, and it must identify the designated space for the excluded unit through the use of room numbers and/or bed numbers. *OPOLE* will then determine, based on information obtained from the State Survey Agency and the hospital's A/B MAC (A), whether the unit qualifies for exclusion from the IPPS. If *OPOLE* rejects the hospital's request to have the unit excluded from the IPPS, *it will notify the A/B MAC (A), CMS, and the hospital.* If *OPOLE* approves the hospital's request to have the unit excluded from the IPPS, *it will notify the hospital, and will also notify the A/B MAC (A) of the unit's exclusion* from the IPPS and of the new unit's new provider identification number.

The hospital must self-attest that it meets all of the applicable criteria for having a unit that is excluded from the IPPS. This self-attestation is subject to verification by *OPOLE*, the State Agency, and the A/B MAC (A).

After the initial classification as an IRF, changes in the amount of space occupied by the unit, or in the number of beds in the unit, are allowed to be made one time during a cost reporting period if the hospital notifies its Medicare contractor and *OPOLE* in writing of the planned change at least 30 days before the date of the change. A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the remainder of that cost reporting period.

140.1.3 - Verification Process Used To Determine If The Inpatient Rehabilitation Facility Met The Classification Criteria

(Rev.12575; Issued:04-11-24; Effective: 07-12-24; Implementation: 07-12-24)

A. - Determination of the Compliance Review Time Period

This section provides an overview of the guideline to determine the compliance review period. In general, the *OPOLE*, and A/B MAC (A) will use data from the most recent, consecutive, and appropriate 12-month time period (as defined by CMS) that starts on or after July 1, 2004, to determine if a facility is in compliance with all of the criteria used to classify a facility as an IRF. *OPOLE* and A/B MAC (A) will notify the facility of the time

period that will be utilized. *OPOLE* and A/B MAC (A) will begin reviewing data 4 months prior to the start of the facility's next cost reporting period.

For Cost Reporting Periods Starting from ***July 1, 2004 to July 1, 2006 Only***

The compliance review periods are determined based on the following:

1. Guidelines for Determining Compliance Review Periods For IRFs With Cost Reporting Periods That Start Between July 1, 2004 and October 31, 2004.

Data prior to July 1, 2004 will not be used to determine an IRF's compliance with the requirements in §140.1.1B-D. Thus, for IRFs with cost reporting periods beginning on or after July 1, 2004 and before November 1, 2004, less than 12 months of data will be used in their first compliance review period after July 1, 2004. Refer to the first 5 rows of the Table of Compliance Review Periods (below) for an illustration of this.

2. Guidelines for Determining an IRF's Compliance Percentage When the Required Compliance Percentage Threshold Differs Across Two Cost Reporting Periods

When a cost reporting period starts on or after July 1, 2005, but not later than June 30, 2006, and the compliance review period spans two cost reporting periods, the compliance percentage is calculated using either of the following two methods. The IRF must have a patient population in each of the two portions of time in order to use either of the two methods described below.

(A) The IRF must meet the applicable compliance percentage threshold in each of the two portions of the compliance review period separately, as illustrated in the example below.

The following is an example of how this first method would be applied:

The compliance review period for an IRF that has a cost reporting period from July 1, 2005 through June 30, 2006 is March 1, 2005 to February 28, 2006.

The IRF must meet a compliance threshold of 50 percent for the cost reporting period of July 1, 2004 to June 30, 2005.

The IRF must meet a compliance threshold of 60 percent for the cost reporting period of July 1, 2005 to June 30, 2006.

In this example, the first portion of the compliance review period (from March 1, 2005 to June 30, 2005) is part of the IRF's cost reporting period that started on July 1, 2004 and ends on June 30, 2005. The second portion of the compliance review period (from July 1, 2005 to February 28, 2006) is part of the IRF's cost reporting period that starts on July 1, 2005 and ends on June 30, 2006.

Therefore, for the portion of the compliance review period from March 1, 2005 to June 30, 2005, the compliance percentage threshold that the IRF must meet is 50 percent.

For the portion of the compliance review period from July 1, 2005 to February 28, 2006, the compliance percentage threshold that the IRF must meet is 60 percent.

If the IRF does not meet the compliance percentage threshold of 50 percent for the March 1, 2005 to June 30, 2005 portion of the compliance review time period, or the compliance percentage threshold of 60 percent for the July 1, 2005 to February 28, 2006 portion of the compliance review time period, it will be determined that the IRF failed to meet the compliance percentage threshold for the entire compliance review period consisting of March 1, 2005 to February 28, 2006.

(B) The A/B MAC (A) computes one weighted average compliance percentage for the entire 12-month compliance review period. The resulting weighted average compliance percentage will be used to determine if the facility met the compliance threshold requirements in §140.1.1B-D.

The following is an example of how this second method would be applied: The

compliance review period for an IRF that has a cost reporting period from

August 1, 2005 to July 31, 2006 is April 1, 2005 to March 31, 2006. However, the compliance review period is divided into two portions: April 1, 2005 to July 31, 2005 and August 1, 2005 to March 31, 2006.

In the following hypothetical example, 45 percent of the cases met at least one of the medical conditions listed above in §140.1.1C from April 1, 2005 to July 31, 2005, and 80 percent of the cases met at least one of the medical conditions listed in §140.1.1C from August 1, 2005 to March 31, 2006. The weighted average compliance percentage from the two portions of time must be calculated as follows for compliance review periods beginning on or after January 1, 2013.

4/12 = 0.333 which is rounded to 0.33
8/12 = 0.666 which is rounded to 0.67

0.33 X 45% = 0.1485

0.67 X 80% = 0.5360

0.1485 + 0.5360 = 0.6845 which is rounded to 68%

Based on this result of 68 percent from the weighted average calculation, it will be determined that the IRF met the compliance percentage threshold for the compliance review period starting on April 1, 2005.

The table below entitled "Examples of Compliance Review Periods" provides examples of compliance review periods associated with various cost reporting periods.

Examples of Compliance Review Periods. For a facility that has been classified as an IRF, but is not a "new" IRF as defined below in 140.1.4, the following table provides examples of the compliance review periods associated with different cost reporting periods.

Examples of Compliance Review Periods

Start Date of the Cost Reporting Period for Which a Facility Will (or Will Not) be Classified (or Retain Classification) as an IRF	***Compliance Review Period: (Admissions or Discharges During)***	***# of Months in Review Period***	***Compliance Percentage Threshold***
07/01/2005	*07/01/2004 - 02/28/2005*	*8*	*50%*
08/01/2005	*07/01/2004 - 03/31/2005*	*9*	*50%*
09/01/2005	*07/01/2004 - 04/30/2005*	*10*	*50%*
10/01/2005	*07/01/2004 - 05/31/2005*	*11*	*50%*
11/01/2005	*07/01/2004 - 06/30/2005*	*12*	*50%*
07/01/2006	*03/01/2005 - 02/28/2006*	*12*	*03/01/2005 to 06/30/2005: 50 %* *07/01/2005 to 02/28/2006: 60 %*
08/01/2006	*04/01/2005- 03/31/2006*	*12*	*04/01/2005 to 07/31/2005: 50 %* *08/01/2005 to 03/31/2006: 60 %*
09/01/2006	*05/01/2005- 04/30/2006*	*12*	*05/01/2005 to 08/31/2005: 50 %* *09/01/2005 to 04/30/2006: 60 %*
10/01/2006	*06/01/2005- 05/31/2006*	*12*	*06/01/2005 to 09/30/2005: 50 %* *10/01/2005 to 05/31/2006: 60 %*
11/01/2006	*07/01/2005- 06/30/2006*	*12*	*07/01/2005 to 10/31/2005: 50 %* *11/01/2005 to 06/30/2006: 60 %*
12/01/2006	*08/01/2005- 07/31/2006*	*12*	*08/01/2005 to 11/30/2005: 50%* *12/01/2005 to 07/31/2006: 60%*

*For Cost Reporting Periods Starting **After July 1, 2006***

The compliance review periods are determined based on the following:

1. Guidelines for Determining an IRF's Compliance Percentage When the Required Compliance Percentage Threshold Is the Same for the Entire Compliance Review Period

To minimize the level of effort required by Medicare contractors and IRFs, contractors must review one continuous 12-month period if the compliance percentage threshold is the same throughout the entire compliance review period for all compliance review periods beginning on or after January 1, 2013.

2. Guidelines for Determining the Compliance Review Period of a Facility Classified as a New IRF. According to the regulations in §412.25(c), a new IRF can only begin being paid under the IRF PPS at the start of a cost reporting period. If the IRF begins treating patients prior to the start of a cost reporting period, it may receive payment under the IPPS until the start of the next cost reporting period, at which point it can begin receiving payment under the IRF PPS if it meets all of the applicable requirements in §412.25 and §412.29. A new IRF will have a compliance review period that starts immediately when its cost reporting period starts, and ends four months before the start of its next cost reporting period. *For example, if a facility has a cost reporting period that starts on July 1, 2022 and is a new IRF, its compliance review period would start on July 1, 2022 and end on February 28, 2023*. Thus, a facility classified as a new IRF will have an initial compliance review period that is 8 months in length, in order to allow *OPOLE* and A/B MAC (A) a 4-month time period to make and administer a compliance determination.

3. Guidelines for Determining an IRF's Compliance When the IRF Expands its Bed Capacity. Effective October 1, 2011, as long as an IRF meets all of the applicable requirements in §412.25(b) and 412.29(c)(2), it may add new beds one time, at any time, during a cost reporting period. The IRF must provide written certification that the inpatient population it intends to serve (including the patients served in the new beds) meets the requirements in §412.29(b). In addition, the new IRF beds will be included in the compliance review calculations under§412.29(b) from the time that they are added to the IRF.

4. Guidelines for Determining the Compliance Review Period of a Facility That Changes Its Cost Reporting Period. A facility that changes its cost reporting period will have a new compliance review period that is based on its new cost reporting period. For example, if an IRF changes the start of its cost reporting period from July 1, 2011 to October 1, 2011, then the start date of its compliance review period will also change from March 1,2011 to June 1, 2011. Excessive changes to cost reporting periods are not permitted.

NOTE:

For cost reporting periods beginning on or after July 1, *2006*, ***the compliance threshold that must be met is 60 percent as discussed in the FY 2009 IRF PPS proposed rule (73 FR 22674, 22687 through 22688) and finalized in the FY 2009 IRF PPS Final Rule (73 46388).*** Thus, for all compliance review periods beginning on or after January 1, 2013 (except in the case of new IRFs, as described in section 140.3.4 above), the compliance review period will be one continuous 12-month time period beginning 4 months before the start of a cost reporting period and ending 4 months before the beginning of the next cost reporting period.

Patient comorbidities that satisfy the criteria specified in 42 CFR 412.23(b)(2)(i) shall be included in the calculations used to determine whether an IRF meets the 60 percent compliance percentage for cost reporting periods beginning on or after July 1, 2007.

B.- Types of Data Used to Determine Compliance with the Classification Criteria

1. Starting on July 1, 2004, the A/B MAC (A) will use the verification procedures specified below in subsection C which is entitled "Verification of the Medical Condition Criterion Using the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) Data Records" or subsection D which is entitled "Verification of the Medical Condition Criterion Using the Inpatient Rehabilitation Facility's Total Inpatient Population" to verify that an IRF has complied with the requirements specified above in §140.1.1B-D.

2. The verification procedure specified below in subsection C (that is, verification using the IRF-PAI data) will only be used if the A/B MAC (A) has verified that the IRF's Medicare Part A fee-for-service inpatient population is at least 50 percent of the IRF's total inpatient population. Effective for compliance review periods beginning on or after October 1, 2009, A/B MACs (A) must include the IRF's Medicare Part C (Medicare Advantage) inpatient population, along with the IRF's Medicare Part A fee-for-service inpatient population, in determining whether at least 50 percent of the IRF's total inpatient population is made up of Medicare patients.

3. General Guideline Regarding Submission of a List of the Inpatients in Each IRF: In order to verify that an IRF's Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) inpatient populations (combined) reflect the IRF's total inpatient population, the A/B MAC (A) in writing will instruct the IRF to send the A/B MAC (A), by a specific date, a list showing the hospital patient number of each inpatient IRF admission during the IRF's 12-month compliance review period. Note that the term "hospital patient number" used throughout this section refers to a unique patient identifier used internally within the hospital for patient identification and record-keeping purposes. For each inpatient on the list, the IRF must include the payer the IRF can bill, or has billed, for treatment and services furnished to the inpatient. If an inpatient on the list has multiple payers that the IRF can bill, or has billed, the IRF must include and specify each type of payer. In addition, for each inpatient on the list, the IRF must include the IRF admission and discharge dates.

Exception to the General Guideline: The Secretary of Health and Human Services can declare a Public Health Emergency under section 319 of the Public Health Service Act or another appropriate statute, and the President can declare either a National Emergency under the National Emergencies Act or a Major Disaster under the RobertT. Stafford Disaster Relief and Emergency Assistance Act, or other appropriate law. In accordance with such declarations, certain regulations or operational policies may be waived in specific geographic areas for limited and defined periods of time. If applicable, in accordance with the waiver provisions, the IRF may be permitted to admit patients (referred to in this section as national emergency or disaster inpatients) who otherwise would be admitted to another inpatient setting. The national emergency or disaster inpatients will not be included as part of the IRF's total inpatient population when the IRF's compliance with the requirements specified in§140.1.1B-D is determined by the A/B MAC (A) reading a sample of medical records. Therefore, when the IRF submits the list of hospital patient numbers stipulated above in section 140.1.3B3, the IRF will identify each national emergency or disaster inpatient by placing either the capital letter "E" or "D" after the patient's unique internal hospital identification number. The A/B MAC (A) will verify the information and, if appropriate, exclude these patients from the list of inpatients used to select a sample of medical records. The IRF should appropriately document in the medical record sufficient information to identify an inpatient as a national emergency or disaster inpatient.

4. *The A/B MAC (A) will use the list of hospital patient numbers to determine the IRF's total inpatient population during the IRF's compliance review period. In addition to the above processes, the A/B MAC (A) has the discretion to sample and compare other parameters (that is, diagnoses, procedures, length-of-stay, or any other relevant parameter) to determine that the Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) population (beginning on or after October 1, 2009) is representative of the IRF's total inpatient population.*

   A determination by the A/B MAC (A), in accordance with the preceding methodologies, that the IRF's inpatient population for the compliance review period consisted of at least 50 percent Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) patients (beginning on or after October 1, 2009) means that the A/B MAC (A) can use the procedure stipulated below in subsection C to presumptively determine if the IRF met the compliance threshold as specified above in §140.1.1B-D.

5. The A/B MAC (A) will inform *OPOLE* if an IRF fails to send the list showing the hospital patient number associated with each inpatient IRF admission during the most recent, consecutive, and appropriate 12-month period, as defined by CMS. Further, the A/B MAC (A) will inform *OPOLE* if the list of hospital patient numbers does not show the payer or payers or the admission and discharge dates for each hospital patient number on the list. *OPOLE* will notify the IRF that failure to send the A/B MAC (A) the list within an additional 10 calendar days will result in a determination by *OPOLE* that the IRF has not met the requirements specified above in §140.1.1B-D and the facility will no longer be eligible for payment under the IRF PPS.

C. - Verification of the Medical Condition Criteria Using the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) Data Records (The Presumptive Methodology)

1. To determine if a facility has presumptively complied with the criteria specified above in §140.1.1B-D, the CMS will enable the A/B MAC (A) to access the CMS' IRF-PAI data records. Specifically, each A/B MAC (A) will be allowed to access only the

IRF-PAI information submitted by IRFs that submit claims to that A/B MAC (A).

In order to ensure that the software that matches each IRF to a particular A/B MAC (A) is constantly updated, the A/B MAC (A) must electronically send *OPOLE* a table that has at least the following title and column headings:

A/B MAC (A) List Of IRF Provider Numbers (Specify The A/B MAC (A)'s Name)

The Name of Each IRF That Submits Claims To This A/B MAC (A)	IRF Provider Number	IRF Cost Reporting Period

After checking the A/B MAC (A)'s list of IRFs for completeness and, as necessary, communicating with the A/B MAC (A) to ensure the accuracy of the information, *OPOLE* will forward the A/B MAC (A)'s list of IRFs to the CMS designated mailbox IRFACTIVEPROVIDER@cms.hhs.gov. The CMS contractor that maintains the IRF-PAI database will then, if necessary, update the IRF-PAI database software used to presumptively verify compliance with the requirements specified in §140.1.1B-D. The A/B MAC (A) must coordinate with their CMS *OPOLE* to obtain access to the software system.

The A/B MAC (A) will provide *OPOLE* with user information from all A/B MAC (A) staff that are required to access the IRF-PAI data records.

When the A/B MAC (A) accesses the IRF-PAI data records, the A/B MAC (A) will be able to generate an IRF compliance review report using the IRF-PAI information from the IRFs on the A/B MAC (A)'s list. The *Internet Quality Improvement and Evaluation System (iQIES) system* software used to generate the IRF compliance review report will automatically use the specific diagnosis codes from the appropriate files listed in "*Presumptive Compliance*" *relative to the appropriate fiscal year regulation which are available for download from the IRF PPS website at* : *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/rules-related-files* to determine if a particular IRF is presumptively in compliance with the requirements specified in §140.1.1B-D. Prior to generating the IRF compliance review report, the A/B MAC (A) must allow the IRF to decide whether the IRF compliance review report will be generated using the IRF- PAI data records of patients who were admitted during the IRF's compliance review period (even if they were discharged outside of the compliance review period), or the IRF-PAI data records of patients who were discharged during the IRF's compliance review period (even if they were admitted outside of the compliance review period).

Below are the sections of the IRF compliance review report with example data required for submission:

IRF Compliance Review Report

State	Provider Number	Provider Name	Cost Report Start Date	Compliance Review Period
Any State	IRF Number	Best Rehab	08/01/20*23*	04/01/20*22* To 03/31/20*23*

Submitted Assessments	Eligible Assessments	Percent
100	60	60%

The submitted assessments section identifies all the IRF-PAI data records that the IRF submitted to the IRF-PAI database during the compliance review period. The eligible assessments are the assessments submitted during the compliance review period that match one of the codes in the associated files described as "*Presumptive Compliance*" relative to the appropriate fiscal year regulation, which can be downloaded from the IRF PPS website at ***https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient rehabilitation/rules-related-files***. *The cost report start date shown is the start of the facility's next cost reporting period*.

2. If an IRF's inpatient Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) populations (combined) (beginning on or after October 1, 2009) are at least 50 percent of its total inpatient population and the presumptive methodology (described above) indicates that the IRF met or exceeded the requirements specified in §140.1.1B-D, then the IRF is presumed to have met the requirements specified above in §140.1.1B-D. However, even when an IRF is presumed to have met the requirements specified above in §140.1.1B-D, *OPOLE* and A/B MAC (A) still have the discretion to instruct the IRF to send to *OPOLE* or A/B MAC (A) specific sections of the medical records of a random sample of inpatients, or specific sections of the

medical records of inpatients identified by other means by the CMS or the A/B MAC (A).

3. Each A/B MAC (A) must submit a report to the appropriate CMS *OPOLE* (with a copy to the CMS Central Office) on at least a quarterly basis that shows each IRF's status with respect to compliance with the requirements specified above in §140.1.1B-D.

The associated files described as "Presumptive Compliance" relative to the appropriate fiscal year regulation, which can be downloaded from the IRF PPS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/rules-related-files will be used to determine presumptive compliance with the requirements specified above in §140.1.1B-D.

The files listed in "Presumptive Methodology Files – Implementation of Changes" that is attached to the IRF Compliance Rule Specification Files, which can be downloaded from the IRF PPS website at http://www.cms.gov/Medicare/Medicare-Fee-for- Service-Payment/InpatientRehabFacPPS/Criteria.html, will be used to determine presumptive compliance with the requirements specified above in §140.1.1B-D.

D.– Additional Verification of Arthritis Condition Criteria

Compliance with the regulatory requirements for the arthritis conditions specified above in§140.1.1 B-D cannot be determined by the presence of an impairment group code or diagnosis code alone, but can only be verified through review of the IRF medical record. For this reason, we removed arthritis impairment group codes and diagnosis codes from the list of codes used to determine presumptive compliance for compliance review periods beginning on or after October 1, 2015

However, beginning on or after October 1, 2015, we also provided for an additional item on the IRF-PAI (item #24A) to enable IRFs to indicate whether the patient's arthritis condition(s) meets all of the relevant regulatory requirements specified in §140.1.1 B-D. Using the process described below, the A/B MAC (A) must verify through medical review whether the IRF cases that would not otherwise meet the compliance criteria, and that have a "1 – Yes" marked in item #24A, meet the severity and prior treatment requirements in §140.1.1B-D. If so, then the A/B MAC (A) must add the appropriate number of these cases to the cases that meet the presumptive compliance criteria.

The A/B MAC (A) shall use the following process for compliance review periods beginning on or after October 1, 2015:

1. If the A/B MAC (A) has determined, using the process outlined in subsection C above, that the IRF does not presumptively meet the requirements specified above in §140.1.1B-D, then the A/B MAC (A) must access an IRF-PAI data report called the IRF Arthritis Verification Report through the *iQIES system* .

Below are the sections of the IRF Arthritis Verification Report with example data:

IRF Arthritis Verification Report

Provider Number	Provider Name	Patient Name	Patient ID	IRF-PAI ID	Admission Date	Discharge Date
	Best Rehab	A. Smith B. Jones Z. Honey	12345678A 22345678A 32345678A	987654321 987654322 987654323	10/1/*22* 10/2/*22* 10/3/*22*	10/15/*22* 10/14/*22* 10/13/*22*

2. The A/B MAC (A) must determine whether or not adding all of the cases listed on the IRF Arthritis Verification Report for that IRF would be enough to increase the IRF's compliance percentage to equal or exceed 60 percent.

3. If adding all of the cases listed on the IRF Arthritis Verification Report for that IRF would be enough to increase the IRF's compliance percentage to equal or exceed 60 percent, then the A/B MAC (A) must use generally accepted statistical sampling techniques to obtain a statistically valid random sample of those patients listed for the IRF on the IRF Arthritis Verification Report. If the total number of patients listed for the IRF on the IRF Arthritis Verification Report is less than 10, then the A/B MAC (A) will review all patients listed for the IRF on the IRF Arthritis Verification Report. (Note that if adding all the cases listed in the IRF Arthritis Verification Report for that IRF would not be enough to increase the IRF's compliance percentage to equal or exceed 60 percent, then the A/B MAC (A) will not proceed further with the IRF arthritis verification process and will use the presumptive compliance percentage generated from section C above.)

4. The A/B MAC (A) will obtain and examine the medical record sections and any other pertinent information submitted by the IRF to determine if the patients from the random sample obtained in step 2 meet all of the severity and prior treatment requirements specified in §140.1.1B-D.

5. The percentage of patients from the list that the A/B MAC (A) determines to have met the severity and prior treatment requirements specified in §140.1.1B-D will be extrapolated to the complete list of patients for the IRF on the IRF Arthritis Verification Report.

6. The A/B MAC (A) shall then add the appropriate number of cases (based on the percentage in step 4) from the IRF Arthritis Verification Report to the cases that meet the presumptive compliance criteria, and re-calculate the IRF's presumptive compliance percentage.

For example:

- IRF A submitted 545 IRF-PAIs in the compliance review period.

- IRF A's presumptive compliance percentage (determined by the A/B MAC (A) using the steps outlined in subsection C above) **was less than** 60 percent.

- In this case, the A/B MAC (A) must access the IRF Arthritis Verification Report.

- The IRF Arthritis Verification Report shows 100 patients listed for IRF A.

- The A/B MAC (A) determines that inclusion of all 100 patients listed for IRF A would increase IRF A's presumptive compliance percentage enough to meet or exceed the 60 percent threshold.

- The A/B MAC (A) uses generally accepted statistical sampling techniques to randomly select 10 patients from that list for medical review, and based on the medical review determines that 7 of the 10 patients meet all of the requirements specified in §140.1.1B-D.

- The A/B MAC (A) will then extrapolate this percentage (7/10 = 70 percent) to the full list of patients shown on the IRF Eligibility Arthritis Verification Report for IRF A. Thus, the A/B MAC (A) will add 70 patients (70 percent of 100) listed for IRF A on the IRF Arthritis Verification Report to the total number of IRF A's patients that meet the presumptive compliance criteria.

- The A/B MAC (A) will then recalculate IRF A's presumptive compliance percentage with the addition of the 70 cases.

- The A/B MAC (A) will base the determination of the IRF's presumptive compliance with the requirements specified in §140.1.1B-D on the updated calculation of the IRF's presumptive compliance percentage.

- The A/B/ MAC (A) will report this updated presumptive compliance percentage, instead of the presumptive compliance percentage from subsection C above, on the quarterly report that the A/B MAC (A) sends to the appropriate CMS *OPOLE* (with a copy to the CMS Central Office).

NOTE: Even when an IRF is presumed to have met the requirements specified above in§140.1.1B-D using the updated presumptive methodology calculation, *OPOLE* and A/BMAC (A) still have the discretion to use the medical review methodology described in subsection E below to verify the IRF's compliance with the requirements in §140.1.1B-D.

E. - Verification of the Medical Condition Criteria Using the Inpatient Rehabilitation Facility's Total Inpatient Population (Medical Review Methodology)

1. The A/B MAC (A) must use the IRF's total inpatient population to verify that the IRF has met the requirements specified above in §140.1.1B-D if:

(i) the IRF's Medicare population (including Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) patients, effective October 1, 2009) is not at least 50 percent of its total inpatient population; or

(ii) the A/B MAC (A) is unable to generate a valid IRF compliance review report using the IRF-PAI database methodology specified previously; or

(iii) the A/B MAC (A) generates an IRF compliance review report, based on the use of the presumptive methodology, which demonstrates that the IRF has not met the requirements specified above in §140.1.1B-D.

If the IRF's Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) populations (combined, effective October 1, 2009) comprise less than 50 percent of the IRF's total inpatient population, or the A/B MAC (A) otherwise determines that the Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) populations (combined, effective October 1, 2009) are not representative of the overall IRF inpatient population, or the A/B MAC (A) is unable to generate a valid report using the presumptive methodology, the presumptive determination is that the IRF did not meet the requirements specified above in §140.1.1B-D.

2. As previously stated above, the A/B MAC (A) will instruct the IRF to send the A/B MAC (A) a list showing the hospital patient number of each inpatient that the IRF admitted during the most recent, consecutive, and appropriate 12-month period, as defined by CMS. The list of hospital patient numbers must include the payer(s) and admission and discharge dates that correspond with the inpatients whose hospital patient numbers are shown on the list. The A/B MAC (A) will then use generally accepted statistical sampling techniques to obtain a random sample of inpatients from the list. The random sample of inpatients drawn from the list must be sufficiently large to ensure that the A/B MAC (A) can determine, with at least 95 percent confidence,

whether the IRF's compliance percentage is below the required compliance threshold (i.e., not in compliance) or at or above the required compliance threshold (i.e., in compliance).

For example, suppose that the required compliance threshold for an IRF to be in compliance with the requirements specified above in §140.1.1B-D is 60 percent. The A/B MAC (A) reviews a random sample of claims from IRF A and estimates that IRF A's compliance percentage is 58 percent. Suppose that the standard deviation that the A/B MAC (A) calculates for IRF A's random sample of IRF claims is plus or minus 4 percentage points, so that the 95 percent confidence interval in this particular example is between 54 percent and 62 percent (with 58 percent as the midpoint). In this case, the IRF is considered to be in compliance with the 60 percent rule, since 60 percent is within the 95 percent confidence interval. To verify whether the IRF is in fact in compliance with the requirements specified above in §140.1.1B-D, the A/B MAC (A) may need to draw a larger random sample of the IRF's inpatients. For example, a larger random sample of IRF A's inpatients might have reduced the standard deviation to plus or minus 1 percentage point, which would have led the 95 percent confidence interval to be between 57 percent and 59 percent. This would have demonstrated with 95 percent confidence that the IRF was not in compliance with the requirements specified above in §140.1.1B-D (because the entire 95 percent confidence interval was below the required compliance threshold of 60 percent).

If the compliance percentage threshold differs within the compliance review period (i.e., is 50 percent for a portion of the compliance review period and 60 percent for the other portion of the period), then a random sample of inpatients will be drawn from each of the two time periods separately.

The use of generally recognized statistical sampling principles may result in a determination that it would be inappropriate to use a sample to determine the facility's compliance percentage. If a random sample is not appropriate in a particular case, then the A/B MAC (A) will use the IRF's entire inpatient population to determine the IRF's compliance percentage. In addition, if the IRF had 100 or fewer inpatients during the compliance review period, then the A/B MAC (A) must use the IRF's total inpatient population (consisting of both Medicare and non- Medicare inpatients) to determine the IRF's compliance percentage.

Prior to selecting the random sample of inpatients, the A/B MAC (A) must allow the IRF to decide if the IRF wants the sample to contain either the patients who were admitted during the IRF's compliance review period (even if some of those patients were discharged outside of the compliance review period) or the patients discharged during the IRF's compliance review period (even if some of those patients were admitted outside of the compliance review period).

If the A/B MAC (A) uses a random sample of the IRF's inpatient population (rather than the IRF's total inpatient population) to determine the IRF's compliance percentage, then the A/B MAC (A) must ensure that an adequate sample size is used to determine (with at least a 95 percent statistical level of confidence) whether or not the IRF has met the requirements in §140.1.1B-D. In some cases, this will require the A/B MAC (A) to expand the size of the random sample of inpatients selected from a particular IRF.

The A/B MAC (A) will instruct the IRF to send it copies of specific sections of the medical records for all of the inpatients to be used in the compliance review. The A/B MAC (A) has the discretion to decide which specific sections of the medical records to obtain, provided that the requested medical record sections contain enough information to allow the A/B MAC (A)'s reviewers to determine the medical condition(s) for which each inpatient received treatment in the IRF. In addition to submitting the requested sections of the medical records, the IRF has the discretion to send the A/B MAC (A) other clinical information regarding these same inpatients.

3. The A/B MAC (A) will examine the medical record sections and any other information submitted by the IRF to determine if the IRF meets the requirements specified above in §140.1.1B-D. To determine if a specific inpatient matches one of the medical conditions specified in §140.1.1C, the A/B MAC (A) may use the diagnosis and impairment group codes specified in the appropriate files listed in "Presumptive Methodology Files – Implementation of Changes" that is attached to the IRF Compliance Rule Specification Files, which can be downloaded from the IRF PPS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/rules-related-files* for general guidance. The A/B MAC (A) is not permitted to use these codes to make a final determination as to whether or not the specific inpatient required intensive rehabilitation services for treatment of one or more of the medical conditions specified in §140.1.1C. The determination of whether a specific inpatient required intensive rehabilitation services for treatment of a condition can only be

determined through careful review of that inpatient's unique clinical characteristics and circumstances, as reflected in the inpatient's medical record.

4. In general, when the A/B MAC (A) is using a sample of medical records to determine compliance with the requirements in §140.1.1B-D, the A/B MAC (A) always has the discretion to determine if a patient meets or does not meet any of the medical conditions listed in §140.1.1C based upon a review of the clinical record, regardless of the results of the presumptive methodology described previously. In other words, the compliance percentage that is determined using the medical review methodology described in this section will supersede the compliance percentage that was determined for the same compliance review period using the presumptive methodology. To ensure that the compliance review process is similar for all IRFs, the A/B MAC (A) must have written policies that describe the reasons for using a random sample of medical records to determine an IRF's compliance percentage when the presumptive methodology has shown that the IRF met the compliance threshold.

5. The A/B MAC (A) will inform *OPOLE* if an IRF fails to provide information in accordance with the requirements specified above in subsection D2. *OPOLE* will notify the IRF that failure to provide the A/B MAC (A) with the information in accordance with the requirements specified above in subsection D2 will result in a determination by *OPOLE* that the IRF has not met the requirements specified above in §140.1.1B-D.

F. – ***Submission of Compliance Data Requirements***

By the 15th day of each month, the A/B MAC (A) responsible for determining the compliance percentage for each IRF using either of the methods specified above in §§140.1.3C or 140.1.3D *shall submit a report to CMS via e- mail to cmscompliancedata@cms.hhs.gov.* Instructions regarding the format of the report, how to complete the report, and where to send it are specified on the IRF PPS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/rules-related-files.

The submitted report should indicate the IRF data for the specific month and year, as well as the MAC name. The data elements for the report must include the following:

- *MAC Number,*
- *Name of Provider,*
- *City,*
- *State,*
- *Zip Code,*
- *Provider Number,*
- *Cost Report Begin Date (mm/dd/y*
- *Review Period From and To Dates (mm/dd/yyy),*
- *Percent of the Medicare Population,*
- *Percent of Compliance using the Presumptive Method (if the presumptive method is used),*

- *Percent of Compliance using Medical Review Sample (if the medical review method is used following a failed presumptive method or at the discretion of the MAC), and*
- *Comments (indicating any additional relevant information).*

The following demonstrates how a typical report should look. All data provided in the example report below are fictitious.

IRF Data for the month and year of: *May 2022*
MAC Name: *BCBS of Healthy OH*

MAC Number	***Name of Provider***	***City***	***State***	***Zip***	***Provider Number***
01234	*Acme Rehabilitation Unit*	*Healthy*	*OH*	*12345*	*04T123*
01234	*Zenith Rehabilitation Unit*	*Healthy*	*OH*	*12345*	*04T321*

Cost Report Begin Date *(mm/dd/yyyy)*	***Review Period From and To Dates*** *(mm/dd/yyyy - mm/dd/yyyy)*	*Percent of the* ***Medicare Population***	*Percent of Compliance using the* ***Presumptive Method***	*Percent of Compliance using* ***Medical Review Sample***	***Comments***
07/01/2022	***01/01/2021 – 02/29/2022***	*50.00%*	*60.00%*		
10/01/2022	***06/01/2021 – 05/31/2022***	*20.00%*	*NA*	*65.00%*	

1. *The A/B MAC (A) must verify that the requirements specified above in*

§140.1.1B-E and §140.1.2 G-K were met.

2. The State Agency will determine whether the criteria specified above in §140.1.1F-K and §140.1.2 Q were met.

140.1.5 - Changes in the Status of an IRF Unit

(Rev.12575; Issued:04-11-24; Effective: 07-12-24; Implementation: 07-12-24)

For purposes of payment under the IRF PPS, the status of an IRF unit may be changed from not excluded from the IPPS to excluded from the IPPS *at any time within a cost reporting period as noted in 42 CFR §412.29.* The hospital must notify the A/B MAC (A) and *OPOLE* in writing of the change at least 30 days before the date of the change. In addition, the hospital must maintain the information needed to accurately determine which costs are and are not attributable to the IRF unit. *A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the remainder of that cost reporting period.*

140.2.5.1 - Area Wage Adjustments

(Rev.12575; Issued:04-11-24; Effective: 07-12-24; Implementation: 07-12-24)

To adjust payments for area wage differences, CMS first identifies the labor-related portion of the prospective payment rates which is published annually in the Federal Register. The labor-related unadjusted Federal payment is multiplied by a wage index value to account for area wage differences. CMS uses the inpatient acute care hospital wage data to compute the wage indices on the basis of the labor market area in which the acute care hospital is located, but without taking into account geographic reclassification under §§1886(d)(8) or (d)(10) of the Act and without applying the "rural floor" under §4410 of the BBA. The wage data excludes the wages for services provided by teaching physicians, interns and residents, and nonphysician anesthetists under Medicare part B, because these services are not covered under the IRF PPS. For IRF PPS discharges occurring before October 1, 2005, the IRF PPS *utilizes* labor market area definitions based upon new statistical area definitions issued by the Office of Management and Budget (OMB). *The new labor market area definitions include* new definitions of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, more commonly referred to as Core-Based Statistical Areas (CBSAs). CBSA-based designations reflect the most recent available geographic classifications and more accurately reflect current labor markets. The OMB also established New England City and Town Areas, which are similar to the previous New England MSAs. CMS uses the county-based areas for all MSAs in the Nation, including those in New England. Adopting county-based labor market areas for the entire country creates consistency and stability in the Medicare payment program because all of the labor market areas, including New England, are defined using the same system (that is, counties), rather than different systems in different areas of the country, and minimizes program complexity. CMS uses the Metropolitan Divisions where applicable under the new CBSA-based labor market area definitions to determine urban areas. Micropolitan Areas are treated as rural labor market areas under the IRF PPS. To calculate the statewide rural wage index for each State, CMS combines all of the counties in a State outside of designated urban areas along with all Micropolitan Areas.

Beginning in FY 2023 a five percent cap will be applied on any decrease to a provider's wage index from that provider's final wage index in the prior fiscal year. For subsequent years, a provider's wage index would not be less than 95 percent of its wage index calculated in the prior FY. A new IRF will be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied, because a new IRF will not have a wage index in the prior FY.