June 23, 2023

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Re: CPR Comments on Review Choice Demonstration for Inpatient Rehabilitation Hospital Services

Dear Directors Leonard and Cinquegrani:

The undersigned members of the Steering Committee of the Coalition to Preserve Rehabilitation ("CPR") write to express concerns and offer recommendations regarding the Inpatient Rehabilitation Facility ("IRF") Review Choice Demonstration ("RCD"), which is scheduled to be implemented in Alabama on August 21, 2023, before expanding to Pennsylvania, Texas, and California and eventually other states in several Medicare Administrative Contractor ("MAC") jurisdictions. We also appreciate the opportunity to review and provide comments on the RCD guidance documents that the Centers for Medicare and Medicaid Services ("CMS") released on May 25, 2023, and in subsequent days. CPR is a coalition of 57 national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities, and chronic conditions may regain and/or maintain the maximum level of health and independent function.

As our comments to the Office of Management and Budget reflected in 2021 in response to the IRF RCD proposal, we continue to have serious concerns about the design of the demonstration and the consequences it could have on patient access to care in IRFs. Specifically, we are concerned that this demonstration will:

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- Undermine the medical judgment of trained rehabilitation physicians
- Disrupt the course of IRF treatment due to pre-claim denials
- Place a significant administrative burden on inpatient rehabilitation hospitals, and
- Construct barriers to medically necessary rehabilitation care both immediately and over time by creating a "gatekeeper" effect on IRF admissions.

Without appropriate changes to the demonstration, Medicare beneficiaries may be inappropriately diverted away from the IRF setting to which they are entitled to less intense settings of post-acute care, resulting in the risk of lesser outcomes. The gatekeeper effect could result in a de facto rewriting of the Medicare IRF coverage policies without going through the regulatory process to restrict coverage.

We are also concerned that the RCD guidance documents do not accurately reflect the current Medicare coverage requirements for inpatient rehabilitation services. ***Attached to these comments are redlined versions of the three RCD guidance documents*** that explain in detail why these documents do not comport with the binding Medicare regulations. CPR aligns itself with these redlined documents, submitted jointly for CMS's consideration by multiple rehabilitation stakeholder organizations.

We respectfully urge CMS to establish adequate safeguards to protect patient access to this important Medicare benefit, minimize provider burdens associated with the demonstration, and address longstanding concerns with the IRF claims review process. We also request that the agency address the issues identified in the attached redline version of the RCD guidance documents to ensure that the MAC reviewers appropriately review claims for IRF services.

Brief Background

Under the IRF RCD, facilities will be subject to 100% pre-claim or post-payment review for their Medicare claims until they meet the "target affirmation rate." At that point, they may forgo 100% pre- or post-payment review but would still be subject to selective review or so-called "spot checks" on 5% of their claims. Although the demonstration will begin with most IRFs located in the State of Alabama, it will be expanded to several other states, eventually encompassing 17 states, three U.S. territories, and the District of Columbia. When fully implemented, CMS estimates that the IRF RCD will apply to 526 freestanding rehabilitation hospitals and hospital-based inpatient rehabilitation units across the United States. Considering the large numbers of IRFs that will be impacted by this demonstration, it is critically important that CMS ensure that the IRF RCD does not adversely impact Medicare beneficiaries.

The Demonstration Will Limit Patient Access to IRF Care

CPR has repeatedly expressed concerns about the demonstration's potential to limit access to inpatient rehabilitation hospital care for patients in need of the high level of medical management and intensive rehabilitation therapy provided in IRFs. CPR is a strong proponent of physician-led care in IRFs, and decisions regarding which patients are appropriate for admission to an inpatient

rehabilitation hospital should be left to qualified treating rehabilitation physicians in consultation with the rehabilitation team.

We are concerned that this demonstration will significantly increase the percentage of denied IRF cases, even when the rehabilitation physician has made a considered medical judgment that a given patient is in need of this level of care. CPR believes that this demonstration will empower non-physician MAC reviewers to supersede the judgment of a treating physician with specialized training and experience in inpatient hospital rehabilitation. Under the RCD demonstration, the documentation submitted by IRFs for pre-claim or post-payment review will be reviewed by "trained nurse reviewers." However, the extensive regulatory criteria defining the requirement for IRF care clearly provide that a rehabilitation physician—a licensed physician who is determined by the IRF to have specialized training and experience in inpatient rehabilitation—must determine whether the patient meets the requirements for an IRF admission. Although nursing, and rehabilitation nursing in particular, is a critical function in IRFs, we believe that trained nurses should not be empowered to overturn physician judgment. We question the decision for the demonstration reviews to be conducted by nurses who are not allowed to make admission decisions in an IRF.

We are also concerned that MAC reviewers may be empowered under the demonstration to utilize so-called "rules of thumb" when reviewing claims for IRF services. If MAC reviewers begin to improperly deny claims for patients whose conditions may be atypical of the need for IRF care (but are determined to nonetheless qualify for IRF admission), we are concerned that this will lead to *de facto* categorical denials that are a "rule of thumb." As the agency is aware, *Hooper v. Sullivan*[1] requires an individual assessment of what services are required by each patient and makes it clear that a hard and fast numerical rule can *only* be used to screen for coverage, not to grant or deny Medicare coverage. The *Hooper* court clearly prohibited the use of rules of thumb to deny IRF admissions, which raises serious questions about the potential impact of this demonstration.

Placing the Patient and Family in an Untenable Position

In the case of pre-claim review, a denial would place the rehabilitation physician in the position of either discontinuing the course of treatment for a patient that they believe requires IRF-level care or continuing to treat the patient and placing the IRF at risk of nonpayment and being subjected to the administrative appeals process if subsequent pre-claim submissions are not approved. This places the patient and the family in the untenable position of either accepting a discharge to a less appropriate setting of care or having to challenge the treating physician and IRF administrative staff to continue to provide services that the IRF knows may never be reimbursed. This adds a financial crisis to the patient and family when they are focused on a medical crisis. CPR strongly urges CMS to clarify explicitly how these situations should be handled and how they intend to ensure that the IRF RCD is not implemented at the expense of patients and their families.

[1] *Hooper v. Sullivan*, No. H-80-99 (PCD), 1989 WL 107497 (D. Conn. July 20, 1989).

Appeal Delays Will Exacerbate the Gatekeeper Effect

Providers who disagree with denials during the pre-claim or post-payment review would still be able to appeal the denials of claims. However, the Medicare appeals process has been plagued with a backlog of cases, forcing providers to wait years before they can appear before an Administrative Law Judge. Because CMS is not implementing any expedited or separate appeals process to accommodate timely appeals under the RCD, we expect initial denials to have outsized influence on the decision by the IRF to submit additional pre-claim review requests. It will not take long for IRFs and admitting rehabilitation physicians to identify which types of patients their contractor questions and many IRFs will have no choice but to stop admitting those patients against their medical judgment. In this manner, we believe the gatekeeper effect will be exacerbated as initial denials essentially function as the final word on IRF admission decisions for an extended period of time under the demonstration.

For these reasons, we strongly believe that the medical decisions regarding the appropriate setting for complex patients with serious illnesses, injuries, disabilities, or chronic conditions should be made between the patient and qualified rehabilitation physician and the rehabilitation team.

The RCD Will Increase Provider Burden and Decrease Time Spent with Patients

CPR also has concerns that the RCD will divert clinical time away from treating patients due to the extensive documentation requirements under the RCD and the clinical time necessary to contest claim denials through the pre-claim and post-payment review system. We fear that the demonstration will contribute to physician and other practitioner burnout at a time when IRFs are dealing with significant staffing shortages.

Safeguards Needed to Protect Patients Under the RCD

CPR offers the following recommendations to minimize (to the extent possible under the RCD structure) the negative impact of the demonstration on Medicare beneficiaries. We have limited these recommendations to only the most essential changes necessary to protect patients, though we note that there is a myriad of other revisions we would support in order to decrease the risk of patient harm under the demonstration. As stated above, we also urge CMS to address the issues identified in the attached redline version of the RCD guidance documents to ensure that the MAC reviewers appropriately review claims for IRF services.

Robust Audit Process for Contract Reviewers

We appreciate the agency's stated recognition for the need to conduct oversight over the MACs carrying out the demonstration. CPR encourages CMS to implement significant training and regular continued education for reviewers on the IRF coverage criteria, including the role of the rehabilitation physician and care team in conducting clinical evaluations and making medical decisions around the need for a patient's admission to the IRF setting. We continue to urge the agency to ensure that its review of auditors focus on denials based on medical necessity, as we believe that such criteria may be more susceptible to improper evaluation by the MACs.

Public Data Reporting to Identify Impact on Access

It is critical that CMS collect and publicly report data on IRF admissions, discharges, and denials as soon as possible after the implementation of RCD and on a regular basis throughout the five-year duration of the demonstration. Given the significant change in access to IRF care that we expect, CMS should report a broad range of data to ensure that stakeholders and patient advocates are sufficiently able to understand the potential barriers to accessing care under the new program. Additionally, transparent and detailed data will allow stakeholders to identify types of patients and diagnoses that are most at risk for inappropriate and/or disproportionate denials under the RCD and work to ensure that the MACs do not employ "rules of thumb" to deny access to certain patients based largely on diagnosis.

Conclusion

We appreciate your attention to our serious concerns involving this demonstration project. Should you have any additional questions regarding these comments, please contact Peter Thomas, CPR Coordinator, by email at Peter.Thomas@PowersLaw.com, or by calling 202-607-5780.

Sincerely,

Members of the Coalition to Preserve Rehabilitation Steering Committee:

Center for Medicare Advocacy
Christopher & Dana Reeve Foundation
Falling Forward Foundation
United Spinal Association

Attachment: Legal Redline of Program Documents

Attachment

Legal Redline of Program Documents

Review Choice Demonstration for Inpatient Rehabilitation Facility Services

Operational Guide

May 25, 2023

Table of Contents

Purpose

Previous CMS experience, Office of Inspector General reports, Government Accountability Office reports, and Medicare Payment Advisory Commission reports indicate questionable billing practices, inappropriate Medicare payments, and questionable utilization of Inpatient Rehabilitation Facility (IRF) services. The Review Choice Demonstration establishes a review choice process for IRF services to test whether such a process improves methods for the investigation and prosecution of fraud.

The purpose of this Operational Guide is to interpret and clarify the review process for Medicare participating IRFs when rendering services for Medicare beneficiaries during the Review Choice Demonstration. This guide will advise IRFs on the process for submitting documents in support of the services as well as the final claim.

Chapter 1: Inpatient Rehabilitation Benefit

For any service to be covered by Medicare it must:

1. Be eligible for a defined Medicare benefit category;
2. Be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; and
3. Meet all other applicable Medicare statutory and regulatory requirements.

In accordance with 42 CFR § 412.622(a)(3)[1], in order for an IRF claim to be considered reasonable and necessary under section 1862(a)(1) of the Act, there must be a reasonable expectation that the patient meets all of the following requirements at the time of the patient's admission to the IRF:

1. Requires the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy), one of which must be physical or occupational therapy.
2. Generally require and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least three hours of therapy per day and at least five days per week. In certain well-documented cases, this intensive rehabilitation therapy program may consist of at least 15 hours of intensive rehabilitation therapy per week. Benefit from this intensive rehabilitation therapy program is demonstrated by measurable improvement that will be of practical value to the patient in improving the patient's functional capacity or adaptation to impairments. The required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.
3. Is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation therapy program that is described in paragraph (a)(3)(ii) of this section.
4. Require supervision by a rehabilitation physician. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least three days per week throughout the patient's stay in the IRF 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. [This section omits the flexibility to have a non-physician practitioner with specialized training and experience in inpatient rehabilitation conduct one of the three required face-to-face visits with the patient per week, beginning with the second week of admission to the IRF, provided that such duties are within the non-physician practitioner's scope of practice under applicable state law. See 42 C.F.R. 412.622(a)(3)(iv).]

For additional information on the requirements for the Medicare IRF Benefit, see 42 CFR

[1] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.622#p-412.622(a)(3).

412.622(a)(4)[2] and (5)[3]. See Chapter 1 of the Medicare Benefit Policy[4] [The MBPM cannot add substantive payment standards following *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019) ("*Allina*")] for more information on the coverage criteria for IRF services.

[2] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.622#p-412.622(a)(3).
[3] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.622#p-412.622(a)(4).
[4] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.622#p-412.622(a)(5).

Chapter 2: Overview of the Review Choice Demonstration for IRF Services

This demonstration will include IRFs that: provide IRF services and are enrolled in the Medicare FFS program; and beneficiaries. The term submitter will be used throughout this document to describe the person or entity that submits the claims, documentation and/or pre-claim review request under the different choices.

The Review Choice Demonstration will apply to IRFs that bill to Medicare Administrative Contractor (MAC) jurisdictions JJ, JL, JH, and JE; regardless of where services are rendered.

The demonstration will apply to IRF services with a *from* date on or after:

- **08/21/2023 for IRFs located in Alabama**
- **TBD for IRFs located in Pennsylvania, Texas, and California**
- **TBD for IRFs that bill to MAC jurisdictions JJ, JL, JH, and JE.**

IRFs will have the option to initially select between two review choices:

- Choice 1: Pre-Claim Review,
- Choice 2: Postpayment Review, or

An IRF's compliance determines their next step. Every 6 months, the IRFs pre-claim review affirmation rate or postpayment review approval rate will be calculated. If the IRF meets the target affirmation rate or greater (based on a 10 request/claim minimum), the IRF may select from one of the three subsequent review choices:

- Choice 1: Pre-Claim Review,
- Choice 3: Selective Postpayment Review, or
- Choice 4: Spot Check Review.

If the IRF's rate is less than the target affirmation rate or they have not submitted at least 10 requests/claims, the IRF must again select from one of the initial three choices.

An IRF's target affirmation rate is based on the following sliding scale from the time an IRF starts the demonstration:

- First review cycle: 80% affirmation rate
- Second review cycle: 85% affirmation rate
- Third review cycle: 90% affirmation rate

Any new IRFs will be subject to the target affirmation rate review cycle that their state has in process at that time.

An IRF under Unified Program Integrity Contractor (UPIC) review is not eligible for participation in this demonstration. However, all IRFs are encouraged to make a choice selection. Questions regarding UPIC review should be directed to the UPIC.

IRF Telephone Inquiries:
IRFs who have questions about the demonstration review process should call their billing MAC:
Palmetto GBA Jurisdiction J at 855- 696-0705.
Novitas Jurisdiction H at TBD
Novitas Jurisdiction L at TBD
Noridian Jurisdiction E at TBD

See Appendix A: Review Choice Demonstration Flowchart

Chapter 3: IRF Program Criteria Subject to the Demonstration

The following revenue code, type of bill, provider type, and CMG codes are subject to complex medical review for the demonstration:

- Revenue code
  - 0024
- Type of bill
  - 11X
- CMG codes
  - A0101, A0102, A0103, A0104, A0105, A0106, A0201, A0202, A0203, A0204, A0205, A0301, A0302, A0303, A0304, A0305, A0401, A0402, A0403, A0404, A0405, A0406, A0407, A0501, A0502, A0503, A0504, A0505, A0601, A0602, A0603, A0604, A0701, A0702, A0703, A0704, A0801, A0802, A0803, A0804, A0805, A0901, A0902, A0903, A0904, A1001, A1002, A1003, A1004, A1101, A1102, A1103, A1201, A1202, A1203, A1204, A1301, A1302, A1303, A1304, A1305, A1401, A1402, A1403, A1404, A1501, A1502, A1503, A1504, A1601, A1602, A1603, A1604, A1701, A1702, A1703, A1704, A1705, A1801, A1802, A1803, A1804, A1805, A1806, A1901, A1902, A1903, A1904, A2001, A2002, A2003, A2004, A2005, A2101, A2102, B0101, B0102, B0103, B0104, B0105, B0106, B0201, B0202, B0203, B0204, B0205, B0301, B0302, B0303, B0304, B0305, B0401, B0402, B0403, B0404, B0405, B0406, B0407, B0501, B0502, B0503, B0504, B0505, B0601, B0602, B0603, B0604, B0701, B0702, B0703, B0704, B0801, B0802, B0803, B0804, B0805, B0901, B0902, B0903, B0904, B1001, B1002, B1003, B1004, B1101, B1102, B1103, B1201, B1202, B1203, B1204, B1301, B1302, B1303, B1304, B1305, B1401, B1402, B1403, B1404, B1501, B1502, B1503, B1504, B1601, B1602, B1603, B1604, B1701, B1702, B1703, B1704, B1705, B1801, B1802, B1803, B1804, B1805, B1806, B1901, B1902, B1903, B1904, B2001, B2002, B2003, B2004, B2005, B2101, B2102, C0101, C0102, C0103, C0104, C0105, C0106, C0201, C0202, C0203, C0204, C0205, C0301, C0302, C0303, C0304, C0305, C0401, C0402, C0403, C0404, C0405, C0406, C0407, C0501, C0502, C0503, C0504, C0505, C0601, C0602, C0603, C0604, C0701, C0702, C0703, C0704, C0801, C0802, C0803, C0804, C0805, C0901, C0902, C0903, C0904, C1001, C1002, C1003, C1004, C1101, C1102, C1103, C1201, C1202, C1203, C1204, C1301, C1302, C1303, C1304, C1305, C1401, C1402, C1403, C1404, C1501, C1502, C1503, C1504, C1601, C1602, C1603, C1604, C1701, C1702, C1703, C1704, C1705, C1801, C1802, C1803, C1804, C1805, C1806, C1901, C1902, C1903, C1904, C2001, C2002, C2003, C2004, C2005, C2101, C2102, D0101, D0102, D0103, D0104, D0105, D0106, D0201, D0202, D0203, D0204, D0205, D0301, D0302, D0303, D0304, D0305, D0401, D0402, D0403, D0404, D0405, D0406, D0407, D0501, D0502, D0503, D0504, D0505, D0601, D0602, D0603, D0604, D0701, D0702, D0703, D0704, D0801, D0802, D0803, D0804, D0805, D0901, D0902, D0903, D0904, D1001, D1002, D1003, D1004, D1101, D1102, D1103, D1201, D1202, D1203, D1204, D1301, D1302, D1303, D1304, D1305, D1401, D1402, D1403, D1404, D1501, D1502, D1503, D1504, D1601, D1602, D1603, D1604, D1701, D1702, D1703, D1704, D1705, D1801, D1802, D1803, D1804, D1805, D1806, D1901, D1902, D1903, D1904, D2001, D2002, D2003, D2004, D2005, D2101, D2102

Important: IRF claims for Veteran Affairs, Indian Health Services, Part A/B rebilling, demand bills submitted with condition code 20, no-pay bills submitted with condition code 21, and all Part A and Part B demonstrations are not part of this demonstration.

Note: Above codes are subject to change.

Chapter 4: Overview of Choices

IRFs will initially select between two review choices:

- Choice 1: Pre-Claim Review,
- Choice 2: Postpayment Review

IRFs who do not actively select one of the initial two review choices will be automatically assigned to participate in Choice 2: Postpayment Review.

IRFs will have until two weeks prior to the start of the demonstration in their state to make their choice selection. IRFs can make their selection by utilizing the specific MAC online provider portal. IRFs may select from one of the two review choices available to them. IRFs should be sure to read each choice thoroughly prior to making a selection.

IRFs will be evaluated for 6 months. If the full affirmation rate or claim approval for those 6 months meets the target affirmation rate/claim approval rate (based on a minimum of 10 submitted pre-claim review requests or claims) in the first year, the IRF may select one of the three subsequent review choices:

- Choice 1: Pre-Claim Review,
- Choice 3: Selective Postpayment Review, or
- Choice 4: Spot Check Review.

IRFs that do not actively choose one of the subsequent review options will automatically be assigned to participate in Choice 3: Selective Postpayment Review.

If the IRF's rate is less than the target affirmation rate or they have not submitted at least 10 requests/claims, the IRF must again choose from one of the initial two options.

An IRF's target affirmation rate is based on the following sliding scale from the time an IRF starts the demonstration:

- First review cycle: 80% affirmation rate
- Second review cycle: 85% affirmation rate
- Third review cycle: 90% affirmation rate

Any new IRFs will be subject to the target affirmation rate review cycle that their state has in process at that time.

An IRF's choice selection is made at the PTAN level.

Chapter 5: Pre-Claim Review; Submitting a Pre-Claim Review Request (Choice 1)

Submitters may submit a pre-claim review request at any time prior to the submission of the final claim. IRFs have an unlimited number of resubmissions of the pre-claim review request prior to the final claim being submitted for payment.

Submitters should include, at a minimum, the following data elements in an IRF pre-claim review request:

Beneficiary Information

- Beneficiary's Name;
- Beneficiary's Medicare Number (also known as MBI); and
- Beneficiary's Date of Birth.

Physician/Practitioner Information

- Physician/Practitioner's Name;
- Physician/Practitioner's National Provider Identifier (NPI);
- Physician/Practitioner PTAN (optional); and
- Physician/Practitioner's Address.

Inpatient Rehabilitation Facility Information

- IRF Name;
- CMS Certification Number;
- PTAN (optional); and
- IRF Address.

Submitter Information

- Contact Name; and
- Telephone Number.

Other Information

- Submission Date;
- Indicate if the request is an initial or resubmission review; and
- If resubmission, the UTN must be included.

Additional Required Documentation

Each beneficiary's medical record at the IRF must contain the following documentation:

- Pre-admission screening
  - A comprehensive evaluation:
    - Serves as the primary documentation of the patient's status prior to admission and documents the specific reasons [The regulation doesn't use the terms "specific reasons." This should be revised, consistent with the regulation, so that MACs do not use this to impose a subjective standard and deny claims that, in the reviewer's opinion, are not specific enough.] that led the IRF clinical staff to conclude that the IRF admission was reasonable and necessary.
  - Must include:
    - Prior level of function
    - Expected level of improvement
    - Expected length of time to achieve that level of improvement
    - Risk for clinical complications (detailed description)[Same comment as above. The regulation doesn't state "detailed description," which can be used by MACs to impose subjective standards.]
    - Conditions/comorbidities that caused the need for rehabilitation and why these require physician monitoring (detailed description) [This phrase is not in the regulatory requirements for the PAS. The regulation does require that the patient need physician supervision, but this need is not specifically tied to "conditions/comorbidities." This terminology could improperly discount the physician's role as leader of the interdisciplinary team]
    - Combinations of treatments needed
    - Anticipated discharge destination
  - Licensed or certified clinicians conducting the preadmission screening must write out the detailed reasoning/justification for the IRF admission. [This requirement is not in the regulation. MACs might reject phrasing that is standardized though accurate. This appears to come from the MBPM, which, as noted above, cannot impose substantive payment standards. The MBPM states: "IRFs must make this documentation detailed and comprehensive." And "each IRF may determine its own processes for collecting and compiling the preadmission screening information. The focus of the review of the preadmission screening information will be on its completeness, accuracy, and the extent to which it supports the appropriateness of the IRF admission decision, not on how the process is organized."]
- Individualized overall plan of care [Under pre-claim review, a claim could be submitted before the IPOC has been completed. Therefore, the IPOC should not be required for a pre-claim review.]
  - The purpose of the overall plan of care is for the rehabilitation physician to gather pertinent information that has been collected regarding the patient's medical and functional treatment needs and goals since the beginning of admission and to synthesize this information into an overall plan of care that will guide the patient's

treatment during the IRF stay.

- A non-physician practitioner can fulfill the IRF services and documentation requirements currently required to be performed by the rehabilitation physician in 42 CFR § 412.622(a)(3), (4), and (5). Therefore, of a non-physician practitioner with the current definition of a rehabilitation physician in that we expect the IRF to determine if the non-physician practitioner has specialized training and experience in inpatient rehabilitation and may perform any of the duties that are required to be performed by a rehabilitation physician, provided that the duties are within the non-physician practitioner's scope of practice under applicable state law. [In both the regulations and MBPM, the only discussion of NPPs is regarding the flexibility to conduct 1of 3 face-to-face visits beginning with the second week. Is CMS indicating that other coverage and documentation requirements are being revised under the RCD? Some of the IRF documentation requirements cited in § 412.622(a)(4) can be completed by a "licensed or certified clinician(s)"; the regulations do **not** require that this clinician have the same "specialized training and experience in inpatient rehabilitation" that is required of the NPP that conducts 1/3 face-to-face visits. Furthermore, the second sentence of this bullet point appears to be mistyped and it is not clear what was intended.]

- Documentation from the medical record the supports the beneficiary's need for active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy), one of which must be physical or occupational therapy.
- Documentation from the medical record that supports the required therapy services begin within 36 hours from midnight of the day of admission to the IRF.

[The above two bullets suggest that MACs could demand documentation beyond the required PAS and IPOC. Therefore, these bullets should either be removed or revised to clarify that only the PAS and IPOC are required (and as noted above, the IPOC should be removed as a requirement for the pre-claim review).

Also, the 36-hour requirement in the second bullet comes from the regulation but ignores the statement in the regulation that "there must be a reasonable expectation that the patient meets all of the following requirements at the time of the patient's admission to the IRF," one of which is that the patient needs required therapy services. If an IRF reasonably believed at admission that the patient "generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program," but unforeseen circumstances prevent therapy from starting within 36 hours, the regulation does not foreclose payment.]

- Documentation from the medical record that supports the rehabilitation physician began the three times per week face-to-face visits with the beneficiary.
- Documentation from the medical record that supports the intensive and coordinated interdisciplinary approach to providing rehabilitative services began, as documented by the weekly interdisciplinary team conference notes. [A pre-claim review could be submitted prior to the first team conference. The claim should not be denied if it is missing team conference notes, and the claim is submitted before the first team meeting.]
- Resubmissions will require additional documentation, when available
    - If the provider receives a non-affirmed decision, the submitter should review the decision letter that was provided, and make whatever modifications are needed to the pre-claim review package and resubmit the request. This includes indicating the request is a resubmission of a non-affirmed decision and providing the non-affirmed UTN on the request form.

Please note the response will be sent to the submitters using the same method as the request was sent if available. However, if the submission is via fax, a response is only sent via fax if a valid return fax number is included in the request. Otherwise the response will be sent via mail.

Cases Where Services are Not Covered Under the Medicare Benefit, Medicare is Primary, and Another Insurance Company is Secondary:

IRFs or beneficiaries may submit the claim without a pre-claim review decision if the claim is non-covered (GY modifier).

If an IRF or beneficiary chooses to use the pre-claim review for a denial then the following process is to be followed:

- The submitter may submit the pre-claim review request with complete documentation as appropriate. If all relevant Medicare coverage requirements are **not** met for the IRF stay, then a non-affirmed pre-claim review decision will be sent to the IRF and to the beneficiary advising them that Medicare will not pay for the service.
- A claim with a non-affirmed decision submitted to the MAC for payment will be denied. The claim must include the Unique Tracking Number (UTN) provided in the decision letter.
- The submitter may forward the denied claim to his/her secondary insurance payee as appropriate to determine payment for the IRF benefit period.

Cases Where Another Insurance Company is Primary and Medicare is Secondary:

If an IRF plans to bill another insurance first and bill Medicare second, the submitter and beneficiary have two options:

1. **Seek Pre-Claim Review:**
    - The submitter submits the pre-claim review request with complete documentation as appropriate. If all relevant Medicare coverage requirements are met for the IRF stay, then a provisional affirmative pre-claim review decision will be sent to the IRF and to the

beneficiary advising them that Medicare will pay for the IRF benefit period as long as all other requirements are met.

- The IRF renders the service and submits a claim to the other insurance company.
- If the other insurance company denies payment on the claim, the IRF or beneficiary can submit a claim in accordance with Medicare Secondary Payer (MSP) provisions, to the MAC (listing the pre-claim review UTN on the claim). The MAC will process the claim according to the MSP provisions.

2. Skip Pre-Claim Review:

- The IRF renders the service and submits a claim to the other insurance company.
- If the other insurance company denies payment on the claim, the IRF or beneficiary can submit a claim in accordance with Medicare Secondary Payer (MSP) provisions, to the MAC (listing the pre-claim review UTN on the claim). The MAC will process the claim according to the MSP provisions.

3. Timeframe for Decisions:

- The MAC will send notification of the decision to the submitter and the beneficiary within 2 business days (excluding federal holidays) for an initial request.
- A resubmitted request is a request submitted with additional documentation after the initial pre-claim review request receives a non-affirmed decision. The MAC will send notification of the decision of these requests to the IRF and the beneficiary within 2 business days (excluding federal holidays).

Chapter 6: Pre-Claim Review: A Provisional Affirmative Decision

A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the service likely meets Medicare's coverage, coding, and payment requirements.

Decision Letter(s):
The MAC will make and communicate a decision to provisionally affirm or non-affirm the request for approval for the services via telephone within two (2) business days. Additionally, the MAC will send a decision letter to the submitter within 10 business days via the MAC provider portal, mail, or fax for initial requests and for resubmitted requests. IRFs submitting via esMD will receive their decision letter via the MAC provider portal, if enrolled to receive greenmail, as decision letters sent via esMD are not available at this time. Decision letters will be mailed to IRFs that do not receive mail via the MAC provider portal. A copy of the decision letter(s) will also be mailed to the beneficiary.

Non-Transferability of a Provisional Affirmative Pre-Claim Request Decision:

- A provisional affirmative pre-claim review decision does not follow the beneficiary if they change IRFs.
- Only one IRF is allowed to request pre-claim review per beneficiary per IRF stay. Ina situation where a patient is discharged and readmitted to the same IRF on the same day, a new pre-claim review request is not needed unless a separate claim will be filed.
    - See 42 CFR Part 412[5], for further information on what constitutes discharge for billing and payment purposes.
- A subsequent IRF may submit a pre-claim review request to provide IRF services for the same beneficiary, and must include the required documentation in the submission. A new pre-claim review request must be provided regardless if an affirmed decision was made for the previous IRF.

IRF's Actions:

- Render services
- Submit pre-claim review request for an eligible service
- Submit the claim with the unique tracking number (UTN) on the claim.
    - See Chapter 9 for details
    - Should be submitted to the applicable MAC for adjudication.

(Positions 1-18) in positions 19 through 32 of loop 2300 REF02 (REF01=G1) on type of bill 11x.

- If all requirements are met the claim will be paid and absent evidence of possible fraud or gaming, will be excluded from future medical review by the MAC or Recovery Audit Contractor.
- Claims falling under this option may be subject to UPIC review if fraud is suspected. Claims may also be selected as part of the CERT sample.

[5] https://www.govinfo.gov/content/pkg/FR-2019-08-08/pdf/2019-16603.pdf

Chapter 7: Pre-Claim Review: A Non-Affirmed Decision

Incomplete Requests:
An incomplete request will result in the pre-claim review request being sent back to the submitter for resubmission, and the IRF and the Medicare beneficiary being notified.

When an incomplete request is submitted:

- The MAC will communicate and provide notification of what is missing with the pre- claim review request to the submitter within two (2) business days via telephone. Additionally, the MAC will send a detailed decision letter to the submitter within 10 business days via the MAC provider portal, mail, or fax for initial requests and for resubmitted requests.
- The submitter may resubmit another complete package with all documentation required as noted in the decision letter. See Chapter 8 for instructions on resubmitting a pre-claim review request.
- If the claim is submitted to the MAC for payment with a non-affirmed pre-claim review decision, it will be denied.
    - All ordinary claim appeal rights will then apply.
    - The claim could then be submitted to secondary insurance.

Non-Affirmed Decisions Following Review:
The pre-claim review package does not show requirements for coverage under the Medicare IRF benefit were met.

When a review results in a non-affirmed decision:

- The MAC will send a decision letter to the IRF that includes all of the reasons a non-affirmed decision was determined. The beneficiary will also receive a copy of the decision letter.
- For non-affirmed decisions due to documentation errors where the beneficiary seems to have otherwise met Medicare coverage criteria, the MAC will also reach out to the IRF via phone to provide individualized education on the reasons for the non-affirmed decision and encourage the IRF to resubmit the request as soon as possible.

IRF's Actions for All Non-Affirmed Decisions:

- Resubmit a pre-claim review request with additional documentation, if appropriate.
- Use the IRF pre-claim review request checklist/tool to ensure that the request package complies with all requirements.

Chapter 8: Pre-Claim Review: Resubmitting a Pre-Claim Review Request

- The submitter should review the decision letter that was provided.
- The submitter should make whatever modifications are needed to the pre-claim review package and follow the resubmission procedures.
- The MAC will provide notification of the decision through a decision letter sent within 2 business days of the review to the IRF and the beneficiary.

Chapter 9: Pre-Claim Review: Claim Submission Where Pre-Claim Review was Requested

Cases Where a Pre-Claim Review Request was Submitted and Received a Provisional Affirmative Decision:

- The submission of the IRF claim is to have the UTN that is located on the decision letter. For submission of electronic claims, the UTN must be in positions 1 through 18. When the claim enters the Fiscal Intermediary Shared System (FISS), the UTN will move to positions 19 through 32, and zeros will autofill the first field. For providers submitting electronic claims, the Medicare Treatment Authorization field must contain blanks or valid Medicare data in the first 14 bytes of the treatment authorization field at the loop 2300 REF02 (REF01=G1) segment for the ASC X12 837 claim.
- For all other submissions, the provider must TAB to the second field of the treatment authorization field (positions 19–32) and key the UTN. If information is entered into the first field (positions 1 through 18), it will come into FISS as zeros. If the Treatment Authorization Code is entered into the first field, FISS changes the Treatment Authorization code to zeros, and the claim will not be accepted. If the UTN is entered into the first Treatment Authorization field, FISS will change the UTN to all zeros. The claim is accepted into FISS with the zeros and without the UTN. The claim will process without the UTN but will edit for the IRF UTN.
- Should be submitted to the applicable MAC for adjudication.
- Final Claim:
    - Should be submitted with the pre-claim review UTN on the claim.
    - Should include the NPI of the rendering provider on the claim.
    - Should be submitted to the applicable MAC for adjudication.
    - If the IRF changes during the IRF benefit period, and the receiving IRF did not submit a pre-claim review request, the claim will undergo a complex medical review. The new IRF is required to submit all medical documentation to support the services billed.
- Each IRF stay will receive a unique UTN.

Cases Where a Pre-Claim Review Request was Submitted and Received a Non-Affirmed Decision:

- The submission of the IRF claim must include the non-affirmed UTN that is located on the decision letter. For submission of electronic claims, the UTN must be in positions 1 through 18. When the claim enters the Fiscal Intermediary Shared System (FISS), the UTN will move to positions 19 through 32, and zeros will autofill the first field. For providers submitting electronic claims, the Medicare Treatment Authorization field must contain blanks or valid Medicare data in the first 14 bytes of the treatment authorization field at the loop 2300 REF02 (REF01=G1) segment for the ASC X12 837 claim.
- For all other submissions, the provider must TAB to the second field of the treatment authorization field (positions 19–32) and key the UTN. If information is entered into the first field (positions 1 through 18), it will come into FISS as zeros. If the Treatment Authorization

Code is entered into the first field, FISS changes the Treatment Authorization code to zeros, and the claim will not be accepted. If the UTN is entered into the first Treatment Authorization field, FISS will change the UTN to all zeros. The claim is accepted into FISS with the zeros and without the UTN. The claim will process without the UTN but will edit for the IRF UTN.

- Should be submitted to the applicable MAC for adjudication.
- Final Claim:
  - Should be submitted with the pre-claim review UTN on the claim.
  - Should include the NPI of the rendering provider on the claim.
  - Should be submitted to the applicable MAC for adjudication.
- If the claim is submitted to the MAC for payment with a non-affirmed pre-claim review decision, it will be denied.
  - The standard claims appeals process will apply.
  - This claim could then be submitted to secondary insurance.

Chapter 10: Pre-Claim Review: Claim Submission Where Pre-Claim Review was NOT Requested

If an applicable claim is submitted without a pre-claim review request being submitted, and the provider has selected Choice 1 – Pre-Claim Review, it will be stopped for prepayment review.

Prior to the start of the demonstration, IRFs do not need to do anything differently when submitting a claim without a UTN. They do not need to put any information in the remarks field. They do not need to submit any unsolicited documentation. They should include the NPI for the rendering provider on the claim.

Once the demonstration is live in a state, final claims submitted under the pre-claim review choice without a pre-claim review request decision on file will be stopped for prepayment review.

Stopping a Claim for Prepayment Review:

- The MAC will stop the claim and send an ADR through the US Postal Service or Online Provider Portal.
- The IRF will have 45 days to respond to the ADR with all requested documentation.
- The IRF can send the documentation via:
  - Palmetto GBA Online Portal (www.onlineproviderservices.com)
  - Fax (803-419-3263)
  - Mail (PO Box 100131 Columbia, SC, 29202-3131)
  - esMD (if available, for more information see: www.cms.gov/esMD)

Note: Additional MAC information will be added at a later date.

Chapter 11: Postpayment Review (Choice 2 - Default Choice)

Under this choice all claims submitted during the cycle will be pulled for postpayment review. The postpayment review process will follow the procedures and rules in place under the IRF benefit. If an IRF doesn't make an initial choice selection, choice 2 will be automatically selected.

Claim Submission

- IRF collects all necessary paperwork such as the Plan of Care
- IRF provides inpatient rehabilitation services
- IRF submits the claim to the MAC

Additional Documentation Request

Once the claim is received the MAC will process for payment and send the IRF an ADR. The IRF will submit all medical documentation and other documents that are necessary in order to conduct a review and reach a conclusion about the eligibility of the beneficiary and medical necessity.

Records may include documents such as:

- Plan of Care
- Inpatient Rehabilitation Facility Records
- Progress Notes
- Nursing Visit Notes

Timing

The IRF will have 45 days to respond to the ADR. The MAC will then have 60-days to review the documentation and communicate a decision. If no response is received, an overpayment will be initiated.

Review

Reviewers shall consider documentation in accordance with Medicare coverage rules and conditions. The postpayment review under this choice will follow the same review standards as are in place absent the demonstration.

Decision

The MAC will communicate the claim review decision to the IRF. If a claim is denied, the MAC will follow the standard payment recoupment procedures already in place. The IRF retains all appeal rights for denied claims.

Chapter 12: Review Cycle and Compliance Threshold

IRFs who select either Choice 1 or Choice 2 will be evaluated over a 6-month review cycle. Within 30 days of the end of the cycle, the MAC will communicate to the IRF their pre-claim review affirmation or postpayment claim approval rate, and if they have met the review threshold.

If the IRF's full affirmation rate or claim approval for those 6 months meets the target affirmation rate (based on a minimum of 10 submitted pre-claim review requests or claims), the IRF may select one of the three subsequent review choices:

- Choice 1: Pre-Claim Review,
- Choice 3: Selective Postpayment Review, or
- Choice 4: Spot Check Review.

If the IRF's affirmation or claim approval rate is less than the target affirmation rate or they have not submitted at least 10 requests/claims, the IRF must again choose from one of the initial three options. In Choice 1: Pre-Claim Review, only fully affirmed decisions will be factored into an IRF's affirmation rate.

An IRF's target affirmation rate is based on the following sliding scale from the time an IRF starts the demonstration:

- First review cycle: 80% affirmation rate
- Second review cycle: 85% affirmation rate
- Third review cycle: 90% affirmation rate

Any new IRFs will be subject to the target affirmation rate review cycle that their state has in process at that time.

Chapter 13: Subsequent Review Choices (Choices 1, 3, and 4)

Once an IRF reaches the target affirmation rate, they may choose one of three subsequent review choices:

- Choice 1: Pre-Claim Review: The IRF may begin or continue participating in pre-claim review for a 6-month period.
- Choice 3: Selective Postpayment Review: Under this choice the IRF will render services and submit claims according to their normal process. Every 6 months the MAC will select for postpayment review a statistically valid random sample of claims, based on the previous six month's claim volume.
- Choice 4: Spot Check Prepayment Review: Under this choice, the MAC will select a random sample of 5% of an IRF's submitted claims, based on their previous six month's claim volume, for pre-payment review, to ensure continued compliance. [If these choices are based on a random sample, will the results be extrapolated? We believe that extrapolation is inappropriate as part of the subsequent review choices.]

If the IRF's provisional full affirmation/approval rate remains at or above the target threshold rate, the IRF may choose to continue to participate in a subsequent review choice. If the IRF falls below the target threshold rate, the IRF must select from one of the initial review choices.

IRFs with a full target affirmation rate or greater that do not actively select one of the subsequent review choices by their selection deadline (typically 2 weeks prior to the start of the new 6-month review cycle) will automatically be assigned to participate in Choice 3: Selective Postpayment Review.

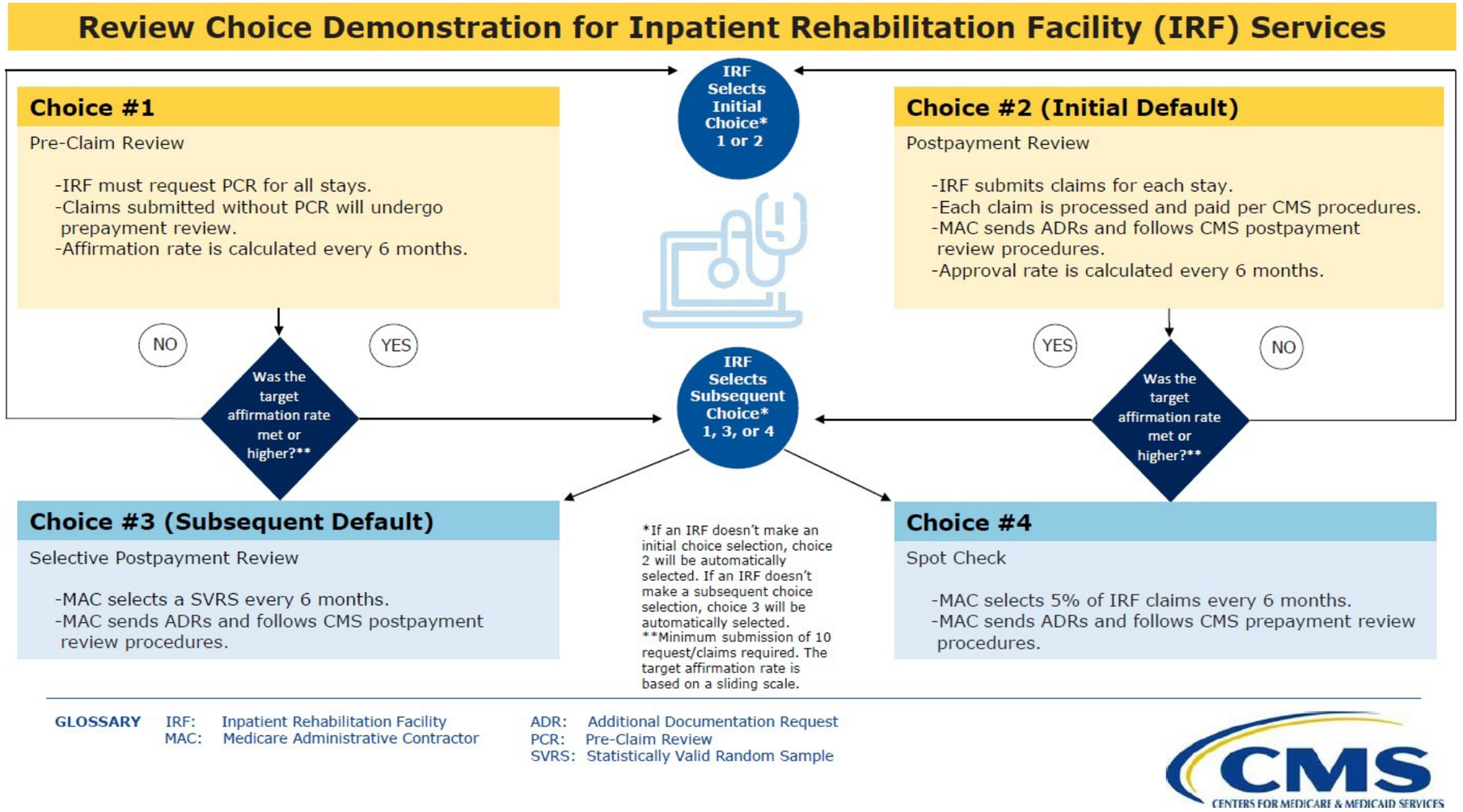
Chapter 14: Claim Appeals

The Review Choice Demonstration does not include a separate appeal process for a non-affirmed pre-claim review decision. However, a non-affirmed pre-claim review decision does not prevent the IRF from submitting a final claim. A submission of a final claim with a non-affirmed UTN and resulting denial by the MAC would constitute an initial determination on the claim that would make the appeals process available for beneficiaries and IRFs.

Appeals will follow all current procedures no matter which choice an IRF selects. For further information consult the CMS Pub. 100-04, Chapter 29[6], Appeals of Claims Decision.

[6] https://www.cms.gov/RegulationsandGuidance/Guidance/Manuals/downloads/clm104c29.pdf

Appendix A: Review Choice Demonstration Flowchart



Inpatient Rehabilitation Facility (IRF) Review Choice Demonstration (RCD) Review Guidelines

[This whole background section is taken from the MBPM and should be deleted because reviewers will use it as a substantive standard to deny claims. The MBPM cannot add substantive payment standards following *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019) ("*Allina*"). Currently, MACs and other CMS contractors routinely deny claims by asserting that the patient didn't have "complex" nursing needs, etc., which is not a standard in the coverage regulations. If CMS keeps this paragraph, it should clarify that the "background" is not a coverage or payment standard that may be applied by MACs.]

Medical Necessity: 42 CFR §§412.622(a)(3), (4), and (5)

The documentation in the patient's IRF medical record must demonstrate a reasonable expectation that the criteria for medical necessity were met at the time of admission to the IRF under 1862(a)(1)(A)(i) of the Social Security Act if the patient meets all of the following requirements:

- Active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy), one of which must be physical or occupational therapy.
- Generally, requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy per week. [Added from the regulation]
- Patients must be able to fully participate in and benefit from [This language is inconsistent with the regulation, which requires only a "reasonable expectation" at admission that the patient will meet the coverage requirements. The terms "must" and "fully" improperly establish standards that are stricter than the regulation.] the intensive rehabilitation therapy program prior to transfer from the referring hospital [This text is not in the regulation. In particular, there is no requirement that the patient be able to participate "prior to transfer." To the contrary, for all requirements, there must be a reasonable expectation "at the time of admission to the IRF" as stated in the opening paragraph. This entire bullet should be deleted because it either restates requirements stated in other bullets or misstates regulatory requirements.] at the time of admission to the IRF.
- Benefit from this intensive rehabilitation therapy program is demonstrated by measurable improvement that will be of practical value to the patient in improving the patient's functional capacity or adaptation to impairments.
- Required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.

Requires physician supervision by a rehabilitation physician, defined as a licensed physician who is determined by the IRF to have [Added text from the regulatory definition] specialized training and experience in inpatient rehabilitation.

The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient [This is not stated in the regulation and will create confusion. Furthermore, CMS should insert the current regulatory definition of a week into the Review Guidelines to ensure that contractors apply the appropriate definition when assessing compliance for this requirement.] at least 3 days per week throughout the patient's stay in the IRF 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.
Note: 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 [Added from the regulation] *may conduct 1 of the 3 required face-to-face visits per week.*

Preadmission Screening: 42 CFR § 412.622(a)(4)(i)

An evaluation of the patient's condition and need for rehabilitation therapy and medical treatment

- Is there documentation of a preadmission screening (or evaluation of the patient's condition and need for rehabilitation therapy and medical treatment)? [This should be changed to "or equivalent documentation."]
- Did it ([“and” suggests that an update is required in all cases. An update within 48 hours is only required if the initial PAS was completed more than 48 hours before admission.] or an update) occur within the 48 hours immediately preceding the IRF Admission?
- Required Elements-
    - Prior level of function (prior to the event or condition that led to the patient's need for intensive rehabilitation therapy),
    - Expected level of improvement,
    - Expected length of time necessary to achieve that level of improvement, [Length of time necessary to achieve the level of improvement. Because this estimate of time may not necessarily equal the length of stay, we are concerned that this language (without further elaboration) could improperly lead to denials where the length of stay exceeds the expected time to achieve the improvements.]
    - Evaluation of the patient's risk for clinical complications,
    - Conditions/comorbidities that caused the need for rehabilitation, [This language differs from the regulation and could be used to improperly limit the physician's role to managing conditions/comorbidities rather than the cause for the patient's need for rehabilitation. It ignores the physician's role in managing the rehabilitation team.]
    - Treatments needed (that is, physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), and
    - Anticipated discharge destination.
- The rehabilitation physician must also review and document concurrence with the findings and results of [Added language from the regulation. These terms suggest that what is important is not concurrence with the PAS itself but concurrence with the content of the PAS.] the pre-admission screening before the patient is admitted to the IRF.

Note: If the patient is being transferred from a referring hospital, the preadmission screening could either be done in person or through a review of the patient's medical records from the referring hospital (either paper or electronic format), as long as those medical records contain the necessary assessments to make a reasonable determination. However, a preadmission screening conducted entirely by telephone should generally include transmission of the patient's medical records from the referring hospital to the IRF and a review of those records by licensed or certified clinical staff member in the IRF to ensure it includes a detailed and comprehensive review of the patient's condition and medical history in accordance with 42 CFR § 412.622(a)(4)(i)(B).[This comes from the MBPM. However, it is quoted out of context and could be interpreted to preclude an IRF unit from conducting a PAS based on the records (i.e., not in person). This passage in the MBPM is contrasted with admissions from the home or community where acute medical records might not be available. Thus, it is meant to distinguish admissions from hospitals with admissions from the community.]

Overall Plan of Care: 42 CFR § 412.622(a)(4)(ii) (This documentation may not be available for submission of pre-claim reviews.)

- [This should be deleted because it is a substantive payment standard that is solely in the MBPM and not the regulation.]The rehab physician is responsible for developing the overall plan of care with input from the interdisciplinary team.
- The overall plan of care must be completed within the first 4 days of the IRF admission.
- [Same comment as above. This is from the MBPM only and should be deleted.] It should generally include:
    - The expected intensity (meaning number of hours per day),
    - Frequency (meaning number of days per week),
    - Duration (meaning the total number of days during the IRF stay) of physical, occupational, speech-language pathology, and prosthetic/orthotic therapies required by the patient during the IRF stay.

Required Admission Orders: 42 CFR § 482.12(c)(2), § 482.24(c), and § 412.3

A physician must generate admission orders for the patient's care. These admission orders should generally be retained in the patient's medical record at the IRF.

- The inpatient rehabilitation admission order is a condition of participation, and not something review contractors assess on a claim-by-claim basis to determine appropriateness of payment.
- Medical reviewers shouldn't review for, or deny, based on the lack of an admission order.

Note: In rare circumstances the order to admit is missing or defective, yet the intent, decision, and recommendation of the ordering physician or other qualified practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record. An example, a signed pre-admission screening can satisfy this admission order requirement*. Medical review contractors have the discretion to determine that this information constructively satisfies the requirement that a written hospital inpatient admission order be present in the medical record per* § 482.24(c).

[The entire preceding passage should be deleted. As the passage acknowledges, the admission order is not a condition of coverage or payment. Therefore, it should not be part of the RCD, which is intended to assess compliance with coverage and payment rules, not conditions of participation.]

Interdisciplinary team approach to care [Replaced with language from the regulation**]:** 42 CFR 412.622(a)(5)

The information in the patient's IRF medical record must document a reasonable expectation that, at the time of admission to the IRF, the patient required the patient must require an interdisciplinary team approach to care [As written, this confuses/conflates two requirements: 1) multidisciplinary therapy; and 2) interdisciplinary team approach. The multidisciplinary therapy requirement was addressed on page 1. Section 412.622(a)(5) addresses interdisciplinary approach, which is broader than therapy]. The documentation supports the following:

- Interdisciplinary team meetings held a **minimum of once per week**
- **Must include the following persons**: a rehabilitation physician; registered nurse; social worker or a case manager (or both); and licensed or certified therapist from each therapy discipline involved in treating the patient.
- Must be **led by a rehabilitation physician** either in person or remotely **who documents concurrence** with all decisions made at each meeting. [The reference to "all decisions made at each meeting" is an overstatement pulled from the MBPM and should be omitted or changed to reflect the regulation. In addition, we suggest inserting "such as video or teleconferencing" after "in person or remotely." This language is now directly in the regulation and some IRFs have reported contractors disputing whether a physician appropriately participated in the meeting when they just called in rather than Zoom or other videoconference.]
- **Interdisciplinary team meeting to focus on:**
    - **Reviewing the individual's progress** towards the stated [Changed to match the regulation] rehabilitation goals;
    - **Identify [**Changed to match the regulation] **any problems** that could impede progress towards the goals;
    - **Where necessary, reassessing the validity of the rehabilitation goals** previously established; and [Changed to match the regulation]
    - **Monitoring and revising the treatment plan**, as needed.

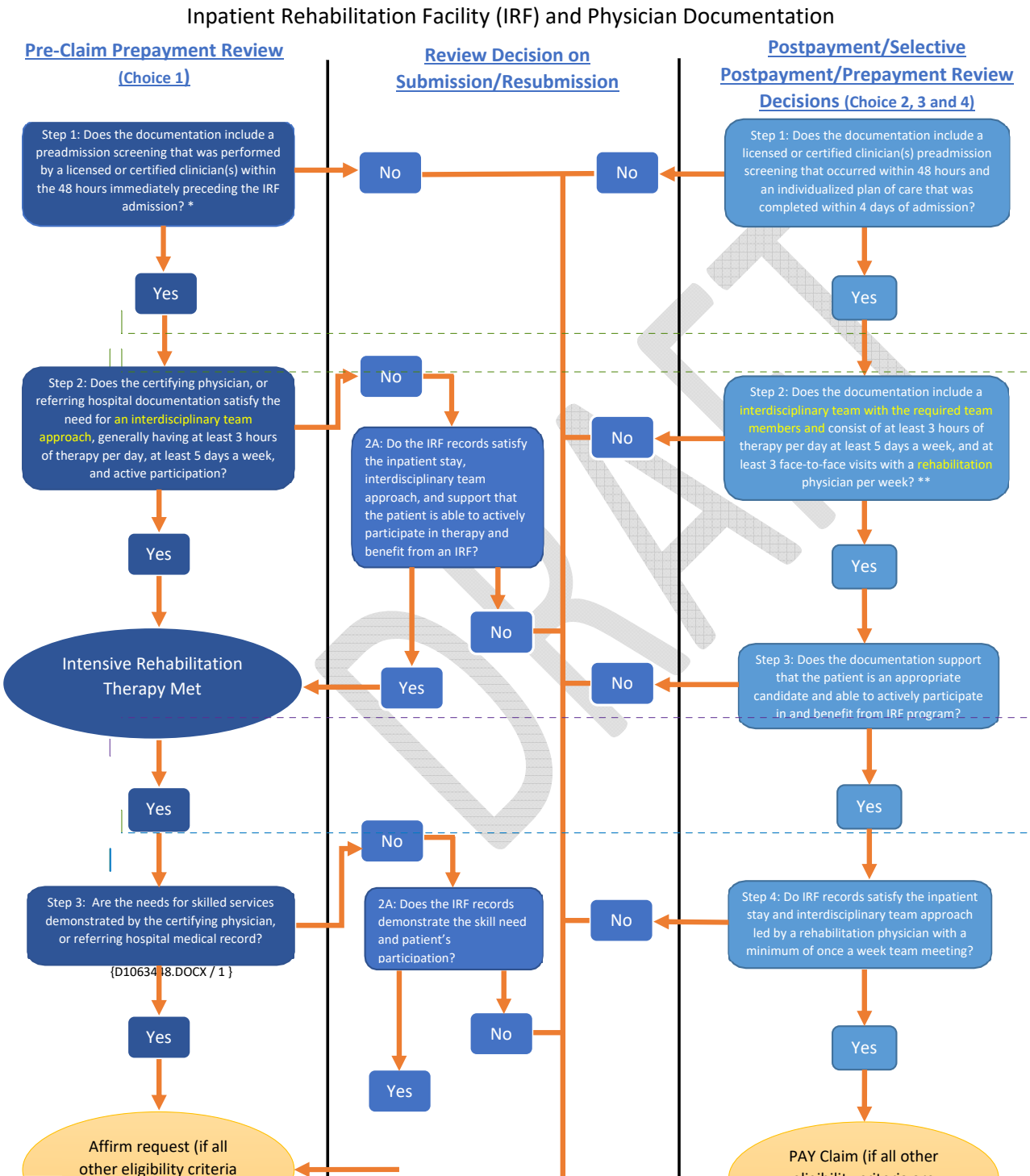
Intensive Level of Rehabilitation Services:

The information in the patient's IRF medical record must document a reasonable expectation that at the time of admission to the IRF the patient generally required intensive rehabilitation therapy services. [This is not in the regulation. Other settings could conceivably provide therapy of 3 hours per day/five days per week. What makes the IRF setting unique is not just intensive therapy; it is the combination of intensive therapy, physician supervision, and interdisciplinary care. Our concern with the term "unique" is that it could be used as a variation of the subjective "less intensive setting" standard from the rescinded HCFA Ruling 85-2, which was used a subjective, catch-all rationale for denying claims.]

- Generally-accepted standard by which the intensity of these services is typically demonstrated in IRFs is by the provision of intensive therapies at least 3 hours per day at least 5 days per week, or at least 15 hours per week[1] However, this is not the only way that such intensity of services can be demonstrated.
- In accordance with 42 CFR § 412.622(a)(3)(ii), the required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.

Note: While patients requiring an IRF stay are expected to need and receive an intensive rehabilitation therapy program, as described above, this may not be true for a limited number of days during a patient's IRF stay because patients' needs vary over time. The Brief Exceptions Policy is for unexpected clinical events occurring during the course of a patient's IRF stay that limits the patient's ability to participate in the intensive therapy program for a brief period not to exceed 3 consecutive days (e.g., extensive diagnostic tests off premises, prolonged intravenous infusion of chemotherapy or blood products, bed rest due to signs of deep vein thrombosis, exhaustion due to recent ambulance transportation, surgical procedure, etc.). If these reasons are appropriately documented in the patient's IRF medical record, such a break in service (of limited duration) should generally not affect the determination of the medical necessity of the IRF admission.

[1] A "week" is defined as a 7 consecutive calendar day period, starting with the date of admission.



Commented [JN1]: Pre-Claim Review, Step 2: The regulatory language in 42 CFR 412.622(a)(3) requires a "reasonable expectation" that the patient (1) require active and ongoing therapeutic intervention of multiple therapy disciplines, (2) can participate in/benefit from an intensive rehabilitation therapy program, (3) is sufficiently stable to participate in the program, and (4) requires rehabilitation physician supervision. Is the standard of "satisfy the need" stated here different from the regulatory standard that the documentation demonstrate a "reasonable expectation" that the patient meets these criteria?

Why does the Flow Chart only reference the interidsiciplinary team approach component of the IRF coverage criteria and not the multiple therapy disciplines, stability, and physician supervision requirements?

Commented [JN2]: Review Decision, Step 2A: What does it mean when this step asks "Do the IRF records satisfy the inpatient stay"?

Why is CMS not assessing other components of the IRF coverage criteria, such as the physician supervision requirement?

Commented [Comments3]: Step 3 under post-payment review asks if the patient is an appropriate candidate for the IRF program, while step 2 asks if the patient participates in intensive therapy. If the step 2 is answered "yes" then the patient satisfied the 3-hour rule and was able to actively participate in the rehab program under step 3.

Commented [JN4]: Review Decision Step 2A (second bubble).

(It appears this bubble is intended to be labeled Step 3A, not a second Step 2A bubble).

The term "skill need" is not found in the IRF coverage regulations or the MBPM. What is this intended to mean?

Commented [HC5R4]: Also, this step refers to the "patient's participation," which would not be applicable to pre-claim reviews submitted at admission.

Option to Resubmit non-affirm pre-claim

Review Decision Flowchart

*Per IRF regulation, a pre-admission screening serves as the primary documentation of the patient's status prior to admission and demonstrates the need for rehabilitation therapy and medical treatment that must be conducted by licensed or certified clinician(s) within the 48 hours immediately preceding the IRF admission. The individualized plan of care must be completed within the first 4 days of the IRF admission, therefore it is submitted for pre-claim resubmissions or postpayment reviews. **The 2nd week of the IRF stay, a non-physician practitioner can perform one of the weekly face-to-face.

Commented [Comments6]: Step 3 under pre-claim review. Why is the "need for skilled services" a separate step from the "need for an interdisciplinary team approach" above. If a patient needs an interdisciplinary team, then by definition, they need the skilled services that are part of that team.

Commented [JN7R6]: The term "skilled services" is not found in the IRF coverage criteria nor the MBPM for IRF services. We believe this is a reference to the SNF coverage criteria (as defined in the MBPM Chapter 8, 30.2.1.