

Appendix 1 – Response to 60-day comments (2/18/25)

CMS Responses to Public Comments Received for CMS-10765: Review Choice Demonstration (RCD) for Inpatient Rehabilitation Facility (IRF) Services. CMS received 4 responses with the following 6 comments. A summary of those comments and our responses are below.

- 1. Commenters stated that the IRF RCD diverts physician time and resources away from direct patient care due to increased documentation requirements. One commenter expressed concerns that these requirements may lead to delays in securing pre-claim review approvals, potentially postponing necessary treatment. Also, many commentors expressed concerns about the administrative burden the IRF RCD places on clinical and administrative staff. Commentors stated that requiring 100 percent review of all Medicare patients admitted to an IRF adds to an already complex process, increasing time spent on records submission, communication with Medicare Administrative Contractors (MACs), and appeals. Lastly, others commented that the IRF RCD increases costs for Medicare and IRF providers, which could create barriers to timely and efficient patient care.**

Response:

CMS acknowledges the concerns raised regarding documentation requirements and their potential impact on physician time and patient care. However, the IRF RCD does not impose new documentation requirements; rather, it validates documentation that should already be part of the standard clinical and billing processes used to support Medicare claims. These requirements reflect long-standing Medicare policies that govern IRF admissions and reimbursement criteria.

It is critically important to clarify that no medically necessary treatment should be postponed or delayed while awaiting a pre-claim review decision. The RCD process is not intended to create barriers to timely care, hence why providers can resubmit as many times as needed to obtain a provisional affirmation while services are being rendered. If a provider receives a non-affirmation, they can request a discussion with the MAC Chief Medical Director (CMD) to review the case in greater detail. This process allows providers to better understand what documentation or clinical elements may be needed to support an affirmation.

The purpose of the CMD discussion is to support informed decision-making, not to delay treatment or access to services, which in turn should decrease appeals and lessen that burden. To address administrative burden concerns, CMS has implemented flexibilities for IRFs that balances oversight with operational efficiency. Initially, providers submit all IRF admissions for review. After 6 months, IRFs who meet the required pre-claim review affirmation rate or postpayment review approval rate may choose subsequent options with fewer claims subject to review. Providers who continue to demonstrate compliance with Medicare coverage and documentation requirements may remain in these less intense review options for the duration of the demonstration.

Regarding concerns about increased costs, the demonstration is intended to prevent, detect, and combat fraud, waste, and abuse. As an example, the demonstration reduces improper

payments, a significant source of waste for the Medicare program, by identifying and addressing billing or documentation issues earlier in the process. This proactive approach helps minimize costly appeals, denials, and overpayments, ultimately reducing administrative burden and financial impact for both Medicare and providers over time.

2. **Some commenters alleged that misapplication of IRF review standards could prevent qualified patients from accessing care. Another commentor stated that the IRF RCD represents an unnecessary overreach, resulting in the denial of medically necessary services. Commenters suggested that these factors could negatively impact patient outcomes. Some commentors were concerned that CMS has not required auditors and reviewers to be licensed physicians with specialized training and experience in inpatient rehabilitation, raising concerns about their ability to accurately assess complex admissions. Additionally, commenters raised concerns about a lack of transparency regarding the contractor reviewers responsible for evaluating RCD claims. They questioned the reviewers' clinical backgrounds, their familiarity with IRF coverage criteria and the training the reviewers received. Lastly, some commenters stated that reviewers have misapplied IRF coverage criteria and have inappropriately used standards from unrelated demonstrations, such as those used in prior authorization program for hospital outpatient services. A commentor noted inconsistencies in affirmation rates, suggesting that varying review standards are being applied.**

Response:

CMS does not believe this demonstration could prevent qualified patients from accessing care. An IRF may begin providing inpatient rehabilitation therapy services prior to submitting the pre-claim review request and may continue to do so while waiting for a decision. In that way, beneficiary access to treatment is not delayed. There is no requirement to discharge patients when a non-affirmation is received. If a provider receives a non-affirmation, they may resubmit their request and include any additional documentation to the MAC, to support that the IRF stay is reasonable and necessary.

CMS requires the MACs to use registered nurses, therapists, or physicians to perform coverage determinations. The MACs have established a training process approved by CMS to ensure that the reviewers are consistent. To ensure fair and accurate medical reviews, each MAC is required to appoint a CMD who must be a board-certified Doctor of Medicine with expertise in a rehabilitation specialty recognized by the American Board of Medical Specialties. The CMD reviews all medical necessity denials to ensure that determinations align with Medicare guidelines and that appropriate clinical judgement is applied. This ensures that clinical review decisions are guided by experienced medical leadership and consistent interpretation of policy. Furthermore, the use of a CMD provides a direct channel for collaborative dialogue between clinical experts and providers, helping to resolve documentation concerns efficiently. CMS strongly encourages providers to take advantage of this opportunity to promote clarity and alignment with Medicare coverage criteria.

CMS ensures ongoing oversight of MAC activities, working closely with the MACs to refine guidance and confirm that reviews are being applied appropriately. CMS has also published

extensive educational materials for IRFs and Medicare reviewers, clarifying policies and documentation requirements to ensure alignment across contractors.

If IRFs identify concerns about misapplication of coverage criteria or the use of unrelated standards, it is critical that these concerns be reported to the MAC and CMS. In the beginning of the demonstration, some decision letters were sent to Alabama providers that contained unrelated language about a different prior authorization program in error. When CMS was made aware of the issue, we intervened to correct it immediately. While CMS has received additional concerns and has investigated them, no consistent or systemic misapplication of coverage criteria has been substantiated to date through formal review. CMS remains committed to reviewing any future concerns and will continue to provide education and training as needed to ensure alignment with Medicare requirements.

Affirmation rates may vary across MAC jurisdictions due to differences in the documentation submitted and how well that documentation aligns with Medicare's medical necessity requirements. Each MAC region is unique, and variation in affirmation rates is expected. These differences do not necessarily reflect inconsistency in the application of standards but rather the variability in case-specific documentation.

CMS has implemented safeguards to ensure consistency and fairness in the demonstration and has initiated numerous guardrails to ensure continued support and collaboration through the demonstration. These initiatives have included a series of education opportunities, independent clinical reviews, and internal and external workgroups to reinforce a standardized demonstration.

When potential subjectivity or inconsistency in MAC reviews are identified, CMS provides additional education and training to ensure proper standards are applied. CMS also conducts oversight of all MAC activities, collaborating closely with them to refine review processes and maintain alignment with Medicare policy. CMS believes that with continuous oversight and continued provider education, the IRF demonstration supports consistent application of coverage standards without restricting access to necessary care.

- 3. One commenter stated that CMS does not account for added costs related to additional documentation, compliance or legal counsel, and the commentor noted that IRFs are responsible for the additional financial burden. Additionally, some commentors also stated that the government's published burden and cost estimates do not accurately reflect the actual time and resources needed to comply with the RCD process. Others noted that CMS underestimated the costs associated with appealing denials.**

Response:

CMS reiterates that the IRF RCD does not impose new documentation requirements. The documentation required under the demonstration aligns with existing Medicare requirements; IRFs are already expected to maintain this documentation regardless of the demonstration. Under the RCD, providers submit existing documentation for review, and as such, no additional documentation burden is being introduced.

To create a process that balances provider burden while continuing our fiduciary responsibility to lower the IRF improper payment rate and prevent fraud, waste, and abuse, CMS structured the demonstration to offer increased flexibility, provider choice, as well as risk-based incentives to maintain compliance with Medicare requirements. Providers who meet the affirmation rate threshold within a six-month cycle have the option to select a review choice that requires fewer submissions, thereby reducing the frequency of reviews.

CMS acknowledges commenters' concerns that the published burden and cost estimates may not fully reflect the resources required to participate in the demonstration. However, we did not receive specific suggestions or data regarding how those estimates should be calculated differently. CMS conducted a thorough analysis to calculate the costs related to the demonstration and believes that the published burden costs include a reasonable cost estimate associated with submitting the necessary documentation. Moreover, it is important to clarify that the current burden and cost estimates apply to the pre-claim review process only. Appeals are considered a post-claim process and are therefore outside the scope of this information collection estimate. CMS remains committed to monitoring the demonstration and considering feedback to ensure it continues to balance program integrity with provider burden.

4. **Commenters expressed concerns about the lack of publicly reported data on the IRF RCD, noting that CMS took more than a year and a half to issue any public reports on the program status, aside from verbal updates. Some commenters believes that more frequent public reporting on key outcomes, such as non-affirmation rates, reasons for denial, appeal reversals, and impact on access to IRF care is necessary to assess the programs' effectiveness and potential unintended consequences.**

Response:

CMS has addressed transparency concerns regarding the IRF RCD by publishing the FY 2024 Quarterly Updates¹. In response to stakeholder feedback, CMS recognizes the need to present demonstration data in a more detailed and useful format. Rather than aggregating data by fiscal year, stakeholders have requested state-specific and cycle-level breakdowns. To meet this need, CMS is developing new web postings that will include both state and cycle-level data, providing more granular insights and information on the demonstration's outcomes. These modifications will be implemented in future releases.

5. **One commentor noted that instead of addressing fraud and abuse, the IRF RCD has primarily demonstrated that most IRF admissions meet coverage requirements. Some commenters questioned CMS' justification for the IRF RCD, stating that high affirmation rates in Alabama and Pennsylvania contradict the program's rationale for the RCD. Commenters stated and questioned that CMS has not provided evidence that pre-RCD error rates reflected anything more than good faith disagreements between treating physicians and non-physician auditors rather than fraudulent claims. One commenter cited CMS' authority to develop demonstrations for investigating fraud and stated that the IRF RCD has not produced any evidence of fraudulent activity under the IRF Prospective Payment System (IRF PPS).**

¹ <https://www.cms.gov/files/document/irf-rcd-stats-fy-2024.pdf>

Response:

CMS' mission is to prevent, detect, and combat fraud, waste, and abuse in the Medicare programs and address these vulnerabilities. It's important to be aware that CMS will not publicly share metrics related to potential fraud, so as not to interfere with law enforcement or other sensitive program integrity efforts, there have been documented cases of fraud related to IRF services in the past.^{2,3} In addition to deterring potential fraud, reviews of medical documentation under this demonstration allow CMS to better understand the scope and causes of improper payments and work with IRFs to reduce documentation errors and inappropriate admissions. CMS' data demonstrates over the past several years an increase in the Comprehensive Error Rate Testing (CERT) improper payment rate for IRF services.⁴

Year	Average CERT Rate	Medical Necessity Errors	Projected Dollars in Error
2021	17.25%	65.95%	1.13 billion
2022	19.2%	71.75%	1.28 billion
2023	27.25%	92.9%	1.86 billion
2024	26.5%	89.9%	2.03 billion

The IRF demonstration allows CMS to focus on the prevention of improper or fraudulent claims, which reduces Medicare's current reliance on the practice of "pay and chase" for inappropriate billing, which occurs when the service is paid and CMS relies on postpayment review and recoupment of improper payments. There are various aspects of fraud, waste, and abuse and in this instance it is important to note that the improper payment rate is not a measure of fraud. They are payments that did not meet statutory, regulatory, administrative, or other legally applicable requirements, which may include fraudulent occurrences.

It is important to note that most improper payments occur due to IRFs admitting patients who are unable to participate in and benefit from an intensive rehabilitation therapy program. For example, patients who require only individual therapy interventions (e.g., speech therapy or occupational therapy), rather than an intense interdisciplinary program, or patients whose injuries are too severe to participate would not qualify for an IRF admission. Aside from medical necessity errors, high rates of improper payments are due primarily to insufficient documentation errors, such as an incomplete pre-admission screening by a physician within the 48 hours immediately preceding IRF admission. This demonstration is not intended to change any of the payment requirements or structures in Medicare or to test new value-based purchasing options to improve and reduce costs. Rather this demonstration tests if implementing a review choice for IRFs that includes pre-claim review, will improve the detection and prosecution of fraud, while reducing improper payments.

² <https://www.justice.gov/archives/opa/pr/encompass-health-agrees-pay-48-million-resolve-false-claims-act-allegations-relating-its>

³ <https://www.justice.gov/archives/opa/pr/vibra-healthcare-pay-327-million-resolve-claims-medically-unnecessary-services>

⁴ <https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/comprehensive-error-rate-testing-cert/cert-reports>

In this demonstration, Alabama and Pennsylvania have demonstrated relatively high affirmation rates because of CMS' guidance and MAC education and outreach to the provider community that helps to meet coverage requirements. The purpose of the demonstration is to improve compliance with Medicare program requirements to ensure that the right payments are made at the right time for IRF services and to test improved methods for the identification, investigation, and prosecution of potential Medicare fraud, waste, and abuse, an important mission of CMS.

6. **Commenters requested that CMS pause or suspend the IRF RCD to allow for further oversight and education to ensure contractor reviewers correctly apply IRF coverage criteria. One commenter specifically suggested pausing the demonstration in Alabama until these issues are addressed. Others stated that CMS and the MACs have not resolved ongoing concerns with the IRF RCD, warranting a temporary suspension. Additionally, one commentor stated that CMS conducts a thorough review of the program's operations to assess whether the cost to the federal government and the burdens on IRFs and patients outweigh the benefits.**

Response:

CMS maintains that the IRF RCD plays a vital role in promoting accurate application of coverage criteria and protecting the Medicare Trust Fund. To ensure consistency and fairness, CMS works in real time with its contractors to provide education on review standards. Monthly Inter-Rater Reliability (IRR) calls are conducted with all contractors to promote alignment across reviews, and CMS also conducts internal sample reviews in collaboration with policy experts.

CMS remains dedicated to fostering meaningful partnerships with the provider community. CMS is committed to working collaboratively to address provider concerns and welcome open communication. Providers are encouraged to bring forward any specific issues or questions so we can work together toward effective solutions. In response to stakeholder concerns, CMS has held both virtual and in-person meetings to listen and gather feedback. All input is carefully evaluated, and appropriate steps are taken to address any issues identified.

Due to persistently high improper payment rate among IRFs, CMS believes the continuation of this demonstration is warranted on the basis of program integrity and fiscal responsibility. CMS believes that this demonstration protects our programs' sustainability for future generations by serving as a responsible steward of public funds.