Federation of American Hospitals®

Charles N. Kahn III
President and CEO

February 18, 2025

The Honorable Stephanie Carlton
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Information Collection on Review Choice Demonstration for Inpatient Rehabilitation Facility Services (CMS-10765)

Dear Acting Administrator Carlton:

We appreciate the opportunity to provide comments to the Centers for Medicare and Medicaid Services' ("CMS") in response to the intention to collect information regarding the inpatient rehabilitation facility ("IRF") Review Choice Demonstration ("RCD").[1] The FAH is the national representative of nearly 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH has communicated our concerns and objections to the IRF RCD on multiple occasions.[2] We remain concerned with the implementation of the IRF RCD and we urge CMS' new leadership to pause the program and thoroughly review its operations to determine whether the expense to the federal government and the burdens on IRFs and IRF patients outweigh the benefits of this demonstration. With average state-wide affirmation rates above 90%, the RCD in Alabama and Pennsylvania have shown that the expense of reviewing 100% of IRF claims is

[1] Agency Information Collection Activities: Proposed Collection; Comment Request, 89 Fed. Reg. 102,149 (Dec. 17, 2024).
[2] https://assets.fah.org/uploads/2021/04/IRF_RCD_Ltr_2_16_21_Final.pdf and https://assets.fah.org/uploads/2021/10/FAH-Comment-Letter-to-CMS-on-RCD-Round-2-10_08_2021.pdf

not justified. **Therefore, the FAH urges CMS to halt the program and to cancel planned expansion to other states.**

As described in the new information collection, CMS plans to continue the demonstration requiring either 100 percent pre-claim or post-payment review for all IRF admissions in up to 17 states to identify and prevent potential fraud. The demonstration began in Alabama in August 2023 and has since expanded to Pennsylvania with implementation scheduled for Texas and California before eventually expanding further to cover a majority of the IRFs in the country in various Medicare Administrative Contractor ("MAC") jurisdictions. The demonstration subjects IRFs to 100 percent claim review until the IRF reaches a target affirmation or claim approval rate equal to 90 percent, at which time, the IRF could choose to be relieved from the demonstration review (except for a 5 percent spot check of their claims).

The FAH continues to believe that the IRF RCD is a vast overreach that is unwarranted, resulting in the denial of medically necessary IRF care to whole classes of beneficiaries. The FAH acknowledges and continues to support CMS' interest in ensuring program integrity and compliance with payment and coverage regulations under the Medicare IRF benefit, but we continue to have serious concerns regarding the significant burdens on the clinical and administrative staff at IRFs resulting from the IRF RCD implementation. We routinely hear from our members that the RCD is highly burdensome and is increasingly a barrier to timely and efficient care for Medicare beneficiaries requiring the intensive and coordinated rehabilitation and medical management provided in an IRF. We also continue to believe that the IRF RCD exceeds the agency's regulatory authority, undermines the judgement of the treating rehabilitation physicians, and ultimately restricts patients' access to IRF care by redefining IRF coverage criteria through Medicare's administrative contractors rather than through coverage policies issued by CMS.

As discussed further below, we note that CMS has predicated the IRF RCD on the pursuit of identifying fraud in Medicare's IRF benefit, yet has produced no evidence of such fraud in the IRF Prospective Payment System that would justify this overly broad and burdensome RCD. With the stated goal of the program not being met, we urge CMS to suspend the IRF RCD and discontinue the program's planned expansion to other states.

The IRF RCD Imposes Significant Burdens on IRFs

The FAH continues to have significant concerns regarding the amount of administrative burden that is imposed on IRF providers and administrative staff to comply with the IRF RCD. The amount of unnecessary activities and time required to implement a 100 percent review of all Medicare patients admitted to IRFs where this demonstration has been implemented has been massive. The FAH believes that CMS, in expanding the implementation of the IRF RCD, has seriously underestimated both the costs of the original claim documents submission and the iterative nature of communications and resubmissions (in the case of non-affirmations) that are inevitable given the high number of claims being reviewed. The costs alone associated with appealing denials through the first three levels of administrative appeal appear to have been completely omitted from CMS' burden estimates. The FAH believes that the IRF RCD

continues to have the effect of prioritizing regulatory processes and provider burdens over the provision of actual clinical care to patients. Our key concerns with CMS' estimate of burden include:

- Records Submission. Submitting 100 percent of patients' selected case files under the pre-claim review option is extremely difficult, even for providers with the ability to submit documentation electronically. Whether providers submit documents electronically or not, the 30 minutes allocated in CMS' cost estimate remains insufficient to assemble, review for accuracy, and submit a complete and accurate set of selected records in a timely manner. In addition, it is not only clerical staff who compile the patient files for submission to the MACs, despite CMS' assumptions. IRFs that respond to Additional Documentation Requests routinely involve clinical and/or administrative personnel, perhaps even compliance or legal counsel, before submitting anything to a government contractor to ensure accuracy of what is being submitted. These added costs are not accounted for by CMS and the IRFs are forced to shoulder this unwarranted financial burden.

- Communication with the MACs. CMS also fails to consider the ongoing communication between an IRF and the MAC that is often necessary when reviewing a detailed clinical record. The iterative nature of this process often involves clinicians who assisted in determining medical necessity and these activities also carry with them added and unnecessary administrative burden. Worse yet, our members report that the communications between IRF clinicians and MAC staff are often proforma, with the MAC staff offering little more than a recitation of the regulatory coverage requirements and little dialogue or feedback on the reasons for individual non-affirmations and what needs to be done to address deficiencies. This lack of communication only increases the administrative burden on IRFs, which are forced to speculate about how MACs will interpret regulations and guidance.

- Appeals. The costs of unlimited pre-claim document submissions and the increase in appeals being filed resulting from 100 percent IRF claim review are also not considered by CMS. The filing of appeals involves significant time and resources by providers, including collection of supporting evidence, document review, legal fees, and time spent by physicians and other clinicians reviewing file documents and preparing for and appearing before Administrative Law Judges.

The IRF RCD Seeks to Avoid CMS' Regulatory Requirements

The FAH remains concerned that CMS is changing substantive standards of coverage through its RCD audit contractors instead of following, as required by law, the publicly accountable regulatory processes necessary to effectuate such change.[3] One-hundred percent review of IRF claims in the states in which the IRF RCD is implemented will, over time, fundamentally alter coverage standards as IRFs learn which types of patients are likely to lead to high non-affirmation rates despite treating physicians believing those patients qualify for IRF

[3] 42 U.S.C. § 1395hh(a)(2); *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).

care. CMS has a legal obligation to adhere to statutorily- and CMS-established coverage requirements for IRF services and must not delegate to its private contractors the authority to tighten admission criteria through unrelenting audits and no publicly accountable process.

As more data is published on the RCD—which we have repeatedly asked CMS to provide—we will be able to determine the real impact on certain types of patients. Continued expansion of the IRF RCD will likely result in the loss of IRF coverage for certain patient populations, likely clustered around certain diagnostic categories. If this occurs, CMS will have violated the Medicare statute's rulemaking requirement by using its contractors to restrict coverage through case-by-case audits.[4] We encourage CMS to implement proper guardrails to prevent this scenario from occurring if IRF RCD expansion continues in 2025.

Moreover, to justify this demonstration, the agency relies on the statutory authority at 42 U.S.C. § 1395b-1(a)(1)(J), which is explicitly intended for the pursuit of "fraud." The FAH believes that this premise of fraudulent behavior is flawed. The vast majority of IRF claim denials are the result of differences in medical judgment between CMS contractors and the rehabilitation physicians making admission decisions for IRF patients on the front lines of post-acute care. This does not meet the standard for fraud which requires a level of intent to submit false or unnecessary Medicare claims. Indeed, federal courts have explicitly held that clinical judgment disagreements, without evidence of objective falsity, do not rise to the level of being considered "false" under the False Claims Act.[5] CMS has failed to provide any evidence of actual, widespread fraud necessitating the continuation of an unprecedented auditing demonstration of this magnitude.

We note that only 10 out of the 612 inpatient rehabilitation claims (1.6%) used to generate the CMS CERT information were found to be improper payments due to a common cause such as "insufficient documentation" In other words, there is no evidence of actual fraud, but rather an indication of a difference of medical opinion between a patient's attending rehabilitation physician and a Medicare contractor who has never seen the patient. CMS recently ceased the fraud-oriented Hospice Special Focus Program (SFP) despite statistics relating to alleged improper payments that are significantly greater than those being asserted for IRFs. Therefore, we likewise believe it would be reasonable for CMS to suspend the IRF RCD and discontinue the program's planned expansion to other states.

CMS Should Ensure that the Treating Rehabilitation Physician's Judgement is Given Proper Weight

The Medicare statute entitles a beneficiary to coverage of reasonable and necessary inpatient rehabilitative care.[6] Under the regulatory framework, IRF coverage is determined "at the time of the patient's admission."[7] In promulgating these regulations, CMS placed "more

[4] 42 U.S.C. § 1395hh(a)(2).
[5] *See United States v. AseraCare, Inc*., 938 F.3d 1278, 1297 (11th Cir. 2019).
[6] *See* 42 U.S.C. §§ 1395d(a)(1), 1395y(a)(1)(A).
[7] 42 C.F.R. § 412.622(a)(3).

weight on the rehabilitation physician's decision to admit the patient to the IRF."[8] CMS defines a "rehabilitation physician" as "a licensed physician who is determined by the IRF to have specialized training and experience in inpatient rehabilitation."[9]

Despite these requirements on IRFs, CMS has failed to require contractors who are auditing and reviewing IRF claims to also be licensed physicians with specialized training and experience in inpatient rehabilitation. Often, these auditors and reviewers are non-physicians—and, in many instances, non-clinicians—or physicians who lack a sufficient understanding of the IRF coverage requirements and have little or no experience in providing complex inpatient rehabilitation care. Admission decisions that are so complex that they must be made only by physicians with specialized training and experience cannot accurately be reviewed by auditors who lack that specialized training and experience.

The FAH notes the complete lack of consistency when CMS requires IRF admissions to be decided by physicians with training and experience in rehabilitation and then permits those decisions to be overturned by auditors who do not possess that same level of medical training and experience in rehabilitation. In fact, FAH members have repeatedly observed auditors and reviewers improperly interpretating and applying Medicare's IRF coverage regulations in a manner that substitutes their judgement for the rehabilitation physician's judgment at the time of admission. This is evidenced by IRF's widespread experience over the past two decades of Administrative Law Judges ("ALJs") overturning a high rate of IRF claims in favor of the provider. This further imposes unnecessary burdens on healthcare providers and will lead to increases in the backlog of ALJ appeals.

Discontinue the IRF RCD and Planned Expansion

Given the tremendous amount of increased administrative burden placed on both providers and CMS to implement the IRF RCD to date, the lack of outright fraud that has been discovered, the exceedingly high affirmation rates across all providers in both Alabama and Pennsylvania nearly two years into the IRF RCD, and the historically high rate of overturn on appeal at the ALJ level, the FAH questions whether the continuation of the IRF RCD is worthwhile in accomplishing the goals it was intended to address. We continue to agree with the agency's desire to enhance program integrity to protect the Medicare Trust Fund but disagree that further expansion of the IRF RCD is an appropriate way to achieve that goal. We urge CMS to bring the IRF RCD to a close, or at the very least, discontinue the expansion of the program to other states. We encourage CMS to consider alternative oversight approaches that balance program integrity with minimizing undue burdens on IRFs, rehabilitation physicians and their clinical rehabilitation teams, and protecting patient access to IRF care.

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[8] Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010, 74 Fed. Reg. 39,762, 39,791 (Aug. 7, 2009).
[9] 42 C.F.R. § 412.622(c).

The FAH appreciates the opportunity to comment on this IRF RCD information collection. The FAH stands ready to work with CMS on more appropriate ways to balance program integrity, provider burden, and patient access to care. If you have any questions, please contact me or Don May at 202-624-1500 or email at DMay@fah.org.

Sincerely,