Federation of American Hospitals®

Charles N. Kahn III
President and CEO

February 16, 2021

Elizabeth Richter, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

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

Dear Acting Administrator Richter:

The Federation of American Hospitals (FAH) is the national representative for over 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 America. Our members include teaching and non-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 appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) information collection to support the potential implementation of an inpatient rehabilitation facility (IRF) Review Choice Demonstration (RCD) to enhance program integrity under the Medicare IRF benefit. While the FAH supports efforts to ensure integrity and compliance of Medicare payment and coverage regulations for IRFs and all care settings, we have serious concerns with the RCD as described in the information collection. We urge CMS to withdraw this ill-conceived demonstration approach as part of the Administration's regulatory review activity.

As described in the information collection, CMS is proposing a demonstration that would require either 100 percent pre-claim review or 100 percent post-payment review for all IRF patients to prevent and identify potential fraud. The demonstration would begin in IRFs in

Alabama; then be expanded to Pennsylvania, Texas and California; and then further expanded to IRFs covered by a select group of Medicare Administrative Contractor (MAC) jurisdictions. The demonstration would require that IRFs be subject to 100 percent case review until the IRF reaches a target affirmation or claim approval rate equal to 90 percent approved reviews. Once an IRF reaches the target pre-claim review affirmation or post-payment review approval rate, it may choose to be relieved from the demonstration review, except for a 5 percent spot check of their claims to ensure compliance.

The FAH strongly opposes the demonstration as currently described and urges CMS and the Administration to withdraw this demonstration from development in its current form. The description of the RCD includes a proposal with a flawed premise of fraudulent activity, a reliance on failed approaches for reviewing medical necessity of inpatient rehabilitation, and an excessive level of regulatory burden that will divert resources from patient care to paper pushing.

If CMS chooses to move forward with a demonstration, we urge CMS to delay further development until after the COVID-19 public health emergency (PHE) to ensure that the new reporting burden and access challenges created by the program will not impede IRFs' expanded role and efforts serving patients and communities during this national crisis. IRFs are treating patients with and recovering from COVID-19, as well as those transferred from overwhelmed general acute-care hospitals. COVID-19 patients can face longer-term and often complex recovery trajectories requiring specialized care to address pulmonary and other complexities and debilities.

The PHE waivers for IRFs greatly increased the flexibility to collaborate with general acute-care hospital partners as well as to meet the overall health systems needs as other providers such as SNFs and home health agencies felt overwhelming pressures. These waivers have been instrumental in enabling IRFs to help fight against the virus, but they have not been addressed by the described RCD and we urge CMS to ensure that the PHE has ended and that local health systems have recovered from the long-term effects before implementing any new type of RCD program.

KEY CONCERNS WITH REVIEW CHOICE DEMONSTRATION

RCD Rationale Based on Identification and Prevention of Potential "Fraud" is Misplaced

The Agency's justification for advancing this demonstration focuses on the existence of "fraud" in the IRF sector, however, there is no evidence cited in the notice or in any published audits or reports that support this identified problem. The majority of IRF claims denials are the result of differences in medical judgment between CMS contractors and the rehabilitation physicians making admission decisions for IRF patients.

Based on the material provided with the Federal Register notice and supporting documentation, this demonstration is being proposed based on the underlying assumption that IRFs' payment error rates, as identified by the Comprehensive Error Rate Testing Contractor

(CERT) program, and IRFs' Medicare margins as identified by MedPAC, are somehow indicative of broad fraudulent activity occurring in the IRF sector. However, we note that the overwhelming majority of the 2020 CERT payment error rate for freestanding IRFs was attributed to "medical necessity" errors (80%), while the other 20% was attributed to "insufficient documentation." For hospital-based IRF units, "medical necessity" errors were nearly 60% of the errors, with the other nearly 40% attributable to "insufficient documentation." In these cases, Medicare beneficiaries were provided specialized rehabilitation care, usually following an acute hospital discharge for a serious illness or injury.

However, in Medicare coverage and medical necessity determinations, medical judgment disagreements do not necessarily indicate fraud. Disagreements between experienced rehabilitation physicians and nurse reviewers, in the form of "medical necessity" denials, are not indicative of fraud. Indeed, federal courts have explicitly held that clinical judgment disagreements, without evidence of objective falsity, do not rise to the level of "false" under the False Claims Act.[1] They do, though, highlight a major disconnect between the parties charged with carrying out Medicare's IRF patient admission policies – highly trained medical rehabilitation physicians – and the personnel (many of whom are non-physicians or are not highly trained medical rehabilitation physicians) who are evaluating those rehabilitation physicians' admission decisions. Evidence of this disconnect can be found in the high rate of overturn of these denials on appeal. It is not clear whether, and if so how, an IRF RCD program will address this disconnect, though framing it as one that is intended to reduce "fraud" conveys a complete lack of understanding of the IRF sector.

CMS has cited the improper payment rate for IRF claims as an indicator of fraud without producing any evidence of actual fraud and in direct conflict with statements tied to its own reviews. Even the Office of Inspector General (OIG), in its 2018 report IRF coverage and documentation, does not use the term fraud in its review of IRF claims. Until CMS provides legitimate evidence of fraud in IRFs, the Agency should not rely on the statutory authority at 42 U.S.C. 1395b-1(a)(1)(J) – which is explicitly intended for the pursuit of "fraud" – in order to justify this IRF RCD. Relying upon this statute as the basis for this demonstration has no legal rationale and the demonstration – established and designed to identify fraud – is not an appropriate model for reviewing IRF care and should be withdrawn.

The RCD Claims Review is Based on Poor History of CMS Medical Review of IRF Care

Based on historical experience with IRF claims reviews by MACs, recovery audit contractors (RACs), the Supplemental Medical Review Contractor (SMRC), and CERT, as well as the OIG, we are seriously concerned that the IRF RCD reviews will result in many inappropriate denials of IRF claims. Appeals of IRF claims denials stemming from reviews of these various programs have historically had a high rate of success and the majority of denied claims are ultimately found to have been improperly denied.

While the national IRF error rate, as estimated annually by the CERT, has dropped significantly since 2016 to the current rate of 30.8 percent for both IRF hospitals and units, it is still likely overstated due to common and pervasive problems with IRF reviews. As detailed by

[1] *See* United States v. AseraCare, Inc., 938 F.3d 1278, 1297 (11th Cir. 2019).

Uniform Data System for Medical Rehabilitation (UDSMR) in their January 28, 2021 comment letter to CMS on this RCD, there are a number of reasons for these problems, including:

1. Contractors use nonspecific findings for meeting reasonable and necessary admission criteria, even though claim denials require an explicit rationale that describes exactly why the items and services at issue do not meet Medicare guidelines.
2. Many denial rationales fall outside of IRF regulations. The IRF medical necessity requirements are complex and established at 42 CFR §412.622 and in the *Medicare Benefit Policy Manual.* Reviewers frequently misinterpret the regulations by inaccurately using these criteria related to:
    a. whether beneficiaries meet clinical conditions for acute care;
    b. patient ability to sustain intensive rehabilitation;
    c. reviewer opinion that a patient could have been treated in a lesser level of care; and
    d. denial statements that represent reviewer opinion and are not based on the IRF regulations or guidance.
3. Reviewers often provide conflicting denial rationales. For example, implying that a beneficiary was too ill or that the beneficiary's functional level was too low to allow the patient to participate in intensive rehab, but at the same time stating that the patient's functional or medical complexity did not warrant IRF care.
4. Establishing inconsistent and arbitrary thresholds for medical and functional acuity. CMS has established various payment levels to address patient acuity and function and those same variances should not be used for determining medical necessity.

Fundamentally, the lack of "medical necessity" as a basis for many claim payment denials among IRFs are rooted in a process that involves the substantial discounting of the judgment and experience of medical rehabilitation physicians who are charged with individually evaluating each Medicare beneficiary who is presented to an IRF for potential admission. Medicare requires these specialized physicians – and only these physicians – to exercise their medical and professional judgment and experience to determine whether Medicare beneficiaries can be admitted to an IRF, through applying specific rules and standards to each unique patient case. Because of the special needs of these patients and the applicable medical necessity requirements, poorly crafted review programs lead to large number of denials that are ultimately overturned upon appeal.

In the Fiscal Year 2021 IRF Prospective Payment System Final Rule,[2] CMS affirmed the physician role in deciding not to finalize a policy it initially proposed that would have delegated certain physician care planning and IRF admissions functions to non-physician practitioners. In the Final Rule, CMS said its decision to modify its proposal would "…maintain the central role and judgment of the rehabilitation physician in the patient's plan of care" and "…preserve the rehabilitation physician's training and judgment at the center of the patient's care plan in the IRF." With this recent action, CMS thus reaffirmed its long-held view that IRF admission decisions should be determined by the clinical judgment of a rehabilitation physician – not of a non-physician practitioner, such as a nurse reviewer. The fact that IRF claims in the IRF RCD

[2] 85 Fed. Reg. 48424, 48452 (August 10, 2020).

program would be reviewed and subject to denial by MACs' nurse reviewers is inconsistent with CMS' overarching policy that rehabilitation physicians must approve all Medicare admissions into an IRF.

It is a notable inconsistency, therefore, that CMS' own rules place such a high value on the judgement, experience, and training of rehabilitation physicians but CMS' oversight process easily disregards it based on a review by contractor staff at the MAC and CERT that lack such training and experience. This, in turn, leads to inappropriate denials that must be appealed.

The demonstration with its 100 percent claims review will only act to magnify the impact of this existing disconnect and result in increased claims denials, difficulty for providers to achieve the 90 percent affirmation rate, and increased filing of appeals. And the risks of this program could be significant: misapplied, or even improper or inapplicable, coverage criteria in the RCD can alter an IRF's (or multiple IRFs') admission practices by discouraging the treatment of patients with particular clinical, functional, or medical conditions identified by RCD auditors as ineligible for an IRF and thus consistently denied. IRFs that are unable to vigorously and consistently defend their admissions through a cumbersome and expensive appeals process may ultimately reduce or cease admitting these patients, thereby reducing patients' access to IRF care. Given the record that MACs have with denying claims (many of which are overturned later on appeal), it is not appropriate to pursue the IRF RCD under these circumstances.

The Burden of the IRF RCD is Significantly Underestimated

The IRF Review Choice Demonstration will significantly add operational burden and costs to IRF providers. It is the opposite of CMS' recent "Patients over Paperwork" initiative and values regulatory process and burden over actual clinical care. If CMS moves forward with the demonstration, the Agency should make every attempt to minimize that burden and delay the RCD until well after the PHE so resources are not diverted away from patient care during this critical time. CMS' estimate of the burden for the demonstration fails to fully capture the activities and time to implement a 100 percent review of claims. The estimates fail to capture both the costs of the original submission and also the iterative nature of communications and resubmissions that are inevitable given the high number of inappropriate denials discussed previously. Key concerns with CMS' estimate of burden include:

- Records Submission. Submitting 100 percent of cases will be extremely difficult, even for providers with the ability to submit documentation electronically. For providers without an ability to submit all documentation materials electronically, the 30 minutes allocated in the cost estimate will be insufficient to assemble and submit a complete and accurate package.
- Communication with the MAC. The estimate of burden focuses mainly on the development and submission of the initial review package but fails to capture the ongoing communication over a case that often exists when reviewing a detailed clinical record. The iterative nature of the process, which often involves clinical staff, is common in other auditing programs and estimates for this activity must be enhanced.

- Appeals. The estimate fails to reflect the increase in appeals that will be filed resulting from 100 percent claims review, particularly with the concerns noted previously with MAC review procedures. The filing of appeals involves significant time and resources by providers, including collection of supporting evidence, legal fees, and time before the appeals body.

Given the false premise for the RCD, the complexity of reviewing IRF cases and the high rate of erroneous review denials, the significant burden of a program requiring 100 percent of cases being reviewed, and the insufficient impact analysis for this program, we urge CMS and the Administration to withdraw from the development of this program and to focus future efforts on training and education programs that would improve both IRF and contractor understanding of the appropriate admission criteria for beneficiaries to IRFs – as well as implementation of fair and appropriate program integrity efforts.

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The FAH appreciates the opportunity to comment on the Proposed Rule. If you have any questions, please contact me or a member of my staff at 202-624-1534.

Sincerely,

cc:
Carol Blackford
Connie Leonard
Ing-Jye Cheng
William N. Parham, III