Federation of American Hospitals®

Charles N. Kahn III
President and CEO

October 8, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Information Collection on Review Choice Demonstration for Inpatient Rehabilitation Facility Services (CMS-10765*; *OMB Control Number: 0938-NEW)

Dear Administrator Brooks-Lasure and Acting Director Young:

The Federation of American Hospitals (FAH) is the national representative of more than 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, D.C 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 appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") intention to collect information regarding the potential development and implementation of an inpatient rehabilitation facility ("IRF") Review Choice Demonstration ("RCD").[1] The FAH previously submitted comments on February 16, 2021 to CMS strongly opposing the agency's intention to collect information on the demonstration. We restate our strong objection to the proposed IRF RCD and urge CMS to withdraw this proposal. The IRF RCD is poor public policy, based on a faulty premise, that will result in more restrictive IRF coverage standards that bar access to certain Medicare patients.

[1] Agency Information Collection Activities: Submission for OMB Review; Comment Request, 86 Fed. Reg. 50,360 (Sept. 8, 2021).

We believe the IRF RCD is unwarranted, could deny necessary IRF care to whole classes of beneficiaries, and will harm health care during the pandemic. FAH acknowledges and supports CMS's interest in ensuring program integrity and compliance with payment and coverage regulations under the Medicare IRF benefit. While we appreciate the minor substantive changes CMS made to the proposed demonstration, we continue to have serious concerns that the IRF RCD will impose significant burdens on the clinical and administrative staff at IRFs during a nationwide public health emergency ("PHE"), exceed the agency's regulatory authority, undermine the judgement of the treating rehabilitation physician, and ultimately restrict patients' access to IRF care. **We urge the agency to withdraw this ill-conceived, burdensome demonstration in its entirety.**

If CMS chooses to move forward with a demonstration of this nature, we urge the agency to, at the very least, delay further development and implementation until after the COVID-19 PHE is no longer in effect to ensure that the expanded administrative/clinical burdens and patient access challenges created by the demonstration will not impede IRFs' ability to serve their patients and communities during this pandemic. The COVID-19 Delta variant has stretched the clinical and administrative capacity of hospitals across the country. CMS should not impose new documentation and auditing burdens at the same time hospitals and hospital systems are pressed to the brink.

IRFs continue to treat patients with—and recovering from—COVID-19, as well as those transferred from overwhelmed general acute-care hospitals in many areas of the country experiencing surges in hospitalizations. COVID-19 patients can face longer-term and often complex recovery trajectories requiring specialized care to address pulmonary and other complexities and debilities. This is not an appropriate time—nor will it be until well after the PHE ends—to implement a massive new demonstration that will divert clinical staff from patient care to address the IRF RCD's document collection.

Implementing this demonstration during the PHE would also be problematic in light of the current COVID-19 waivers that affect IRF coverage, such as the three hour rule and 60 percent rule. These and related PHE waivers have greatly increased the flexibility of IRFs to collaborate with general acute-care hospital partners as well as to meet the overall health systems' needs as COVID-19 patients continue to flow into hospitals. These waivers have been instrumental in enabling IRFs to help fight against the virus, but the IRF RCD notice does not even recognize the existence of the waivers or how contractors would be expected to audit claims with these waivers in place.

If CMS does decide to eventually implement the IRF RCD, it should wait until at least a year after the COVID-19 PHE is declared over, and contractors should be confined to reviewing only claims with dates of service after such time.

We also urge CMS to confer with IRF stakeholders to pursue more appropriate and far less onerous program integrity efforts in the future. But if CMS eventually moves forward with implementation of the IRF RCD, we request that the agency adopt adequate safeguards to protect

patients' access to the Medicare program's IRF benefit, minimize provider burdens associated with the demonstration, and address longstanding issues in the IRF claims review process.

The IRF RCD Imposes Significant Burdens on IRFs

FAH has significant concerns that the proposed demonstration will impose major new burdens on IRF providers. CMS' estimate of the burden for the demonstration fails to fully capture the activities and time to implement a 100 percent review of all claims in the IRFs where this demonstration will be implemented. CMS' estimates significantly underestimate both the costs of the original submission and the iterative nature of communications and resubmissions that are inevitable given the high number of claims to be reviewed. CMS completely omits any estimate of the costs associated with appealing denials through the first three levels of administrative appeal. Contrary to CMS' recent "Patients over Paperwork" initiative, the IRF RCD will prioritize regulatory processes and provider burdens over the provision of actual clinical care. Our key concerns with CMS' estimate of burden include:

- Records Submission. Submitting 100 percent of patients' case files 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 record in a timely manner. Based on prior IRF review experience, the estimate of time is at least 60 minutes per case (at least double CMS' estimate for all initial submissions). In addition, contrary to CMS' assertion that clerical staff only will compile the patient files for submission to the MACs, 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. CMS' burden estimate does not account for any of these costs. In addition to the time estimate being too low for initial submission, the hourly cost given the use of more than just clerical staff, is much higher than estimated by CMS.

- Communication with the MACs. CMS' burden estimate 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 this process often involves clinicians who assisted in determining medical necessity and these activities must be included in the burden estimate as well.

- Appeals. The estimate completely omits the costs of unlimited pre-claim document submissions and the increase in appeals that will inevitably be filed resulting from 100 percent IRF claim review. 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 preparing for and appearing before Administrative Law Judges.

The IRF RCD Seeks to Avoid CMS' Regulatory Requirements

We are concerned that CMS seeks to change substantive standards of coverage through its RCD audit contractors instead of following, as required, the publicly accountable regulatory processes.[2] One-hundred percent review of IRF claims in the states in which the IRF RCD is implemented will, over time, fundamentally alter coverage standards. IRF physicians will have no choice but to reject admissions of certain patients the MACs refuse to validate as acceptable in an IRF. CMS has an obligation to promulgate coverage requirements for IRF services through notice-and-comment regulations, not by delegating its contractors to tighten admission standards through unrelenting audits. We believe that the IRF RCD could 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.[3]

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 description of the IRF RCD includes a proposal with a flawed premise of fraudulent activity. 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. This does not meet the standard for fraud. 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.[4] CMS has failed to provide any evidence of actual, widespread fraud necessitating an unprecedented auditing demonstration of this magnitude.

In addition, if CMS proceeds with the IRF RCD, the agency must instruct its contractors that IRF denials may only be based upon provisions contained in the Medicare coverage regulation, not the nonbinding Medicare Benefit Policy Manual ("MBPM"), CMS Pub. 100-02, (chapter 1).[5] While the MBPM can certainly continue to serve as guidance for industry best practices, to be referred to by IRFs and CMS alike, the contractors must be bound only by the regulatory requirements and prohibited from using guidance to make binding decisions on payment or coverage of IRF claims.

For example, many IRFs have had claims denied when the MAC determines that the patient's plan of care omits details about the anticipated interventions (including expected intensity, frequency, and duration of therapies required) or anticipated functional outcomes; however, nowhere in the regulation at 42 C.F.R. § 412.622 are any such requirements specified. Instead, the requirements of the regulation establish that the individualized overall plan of care must be developed by a rehabilitation physician with input from the interdisciplinary team within four days of the patient's admission to the IRF.[6] The remaining standards applied by the MACs

[2] 42 U.S.C. § 1395hh(a)(2); *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).
[3] 42 U.S.C. § 1395hh(a)(2).
[4] *See United States v. AseraCare, Inc*., 938 F.3d 1278, 1297 (11th Cir. 2019).
[5] *See Allina Health Servs.*, 139 S. Ct. at 1816, 1823 (Bryer, J., dissenting) (identifying the MBPM as among the manuals subject to the Court's holding).
[6] 42 C.F.R. § 412.622(a)(4)(ii).

exist only in the MBPM and are unenforceable. Denying claims solely for reasons contained in the MBPM that are not otherwise stated in the regulations is contrary to Medicare rulemaking requirements.[7]

Patient Safeguards, Alleviation of Provider Burden, and Improvements in IRF Claim Review

In the event that CMS proceeds with the IRF RCD demonstration, the agency should delay implementation until after the PHE, minimize provider burden, and implement appropriate safeguards to promote transparency and open lines of communication, ensure the proper review of medical records and application of Medicare requirements, and preserve patient access to IRF care.

I. Gain Consensus on the IRF Medical Necessity Standard for Review

We strongly urge CMS to host a series of meetings between senior program integrity officials, CMS contract medical reviewers, and practicing rehabilitation physician leaders to discuss real IRF cases and explore medical necessity of IRF admissions to gain a better understanding of mutual expectations for which patients are appropriate to be treated in the IRF setting. Proceeding with a five-year audit of IRF claims without attempting to first establish a better mutual understanding of IRF medical necessity will create major disruptions in IRF care. It will also fuel a huge increase in IRF cases being added to the administrative appeals backlog.

Although the IRF setting is among the most highly regulated of any post-acute care provider type, clinical judgment continues to play an appropriate key role in admission decisions. Achieving a better consensus on this issue between the IRF field and government auditors before the IRF RCD is implemented could defuse some of the anticipated flashpoints of this demonstration project.

FAH has worked with the American Academy of Physical Medicine and Rehabilitation ("AAPM&R") and the American Medical Rehabilitation Providers Association ("AMRPA") to address the findings of the 2018 Office of Inspector General ("OIG") report No. A-01-15-00500.[8] As a result of discussions with the OIG, these three organizations are now in a position to meet with CMS' and OIG's audit reviewers to have a clinical discussion of real cases included in the OIG report. In fact, the OIG has recently agreed to meet early in 2022 with a panel of seven physicians from the IRF field to discuss seven patient cases from the OIG audit, again, for the purpose of trying to attain a better understanding of factors that favor admission verses non-admission to an IRF setting of care.

We strongly encourage CMS to host a series of similar meetings with these same IRF physicians to discuss these same seven IRF patients. All medical reviewers contracted by CMS with authority to override the decisions of admitting IRF physicians should be required

[7] 42 U.S.C. § 1395hh(a)(2).

[8] OIG, U.S. Dep't of Health & Human Servs., No. A-01-15-00500, Many Rehabilitation Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements (2018) (hereinafter "IRF OIG Report").

to participate in these meetings. This would provide a real-life set of illustrative cases where the merits of each case can be clinically assessed and debated. In fact, participation—or at least observation—of these meetings should be a required component of contract reviewer training prior to the commencement of any IRF audits under the RCD project.

II. CMS Should Limit the Scope of the IRF RCD

The sweeping scope of the proposed demonstration—100% claim review for all IRFs located within the selected MAC's jurisdiction—is unprecedented and unjustified. The FAH considers 100% IRF claim review across 17 states excessive. If CMS decides to move forward with the RCD it must mitigate unnecessary burdens by dramatically lowering this percentage of claim review in the IRF RCD. CMS could clearly achieve its program integrity objectives without taking its expansive proposed approach.

For instance, CMS could require contractors to first examine the pre-admission screening documents only from a sample of patients and enter into a "discussion period"—akin to the RAC discussion period—with providers to explore cases where the MAC would like more information. Another approach might be to audit a sample of cases that are not among the conditions included in the 60% rule and not audit claims for patients who qualify under the 60% rule. However CMS proceeds, the agency should be focused on achieving its objectives in the least restrictive manner so that providers and patients are not unnecessarily burdened by this demonstration.

III. CMS Should Adopt Safeguards to 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.[9] Under the regulatory framework, IRF coverage is determined "at the time of the patient's admission."[10] In promulgating these regulations, CMS placed "more weight on the rehabilitation physician's decision to admit the patient to the IRF."[11] CMS defines a "rehabilitation physician" as "a licensed physician who is determined by the IRF to have specialized training and experience in inpatient rehabilitation."[12]

Despite these requirements on IRFs, CMS has failed to require contractors who are auditing and reviewing IRF claims also be licensed physicians with specialized training and experience in inpatient rehabilitation. Often, these auditors and reviewers are non-physicians or physicians who lack a sufficient understanding of the IRF coverage requirements and have little or no experience in providing complex inpatient rehabilitation care.

CMS is wholly inconsistent when it requires IRF admissions to be decided by physicians with training and experience in rehabilitation and then permits those decisions to be overturned

[9] *See* 42 U.S.C. §§ 1395d(a)(1), 1395y(a)(1)(A).
[10] 42 C.F.R. § 412.622(a)(3).
[11] Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010, 74 Fed. Reg. 39,762, 39,791 (Aug. 7, 2009).
[12] 42 C.F.R. § 412.622(c).

by auditors who are not physicians with the same training and experience in rehabilitation. In fact, FAH members have repeatedly observed auditors and reviewers improperly interpreting 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 Administrative Law Judges ("ALJs") overturning a high rate of IRF claims in favor of the provider.

We are concerned that the contractors' use of non-rehabilitation physicians to deny claims, if permitted under the IRF RCD, will result in a dramatic increase in denials alleging lack of medical necessity. This will further impose unnecessary burdens on health care providers and dramatically increase the backlog of ALJ appeals. More importantly, we are concerned that the demonstration will produce a "gatekeeper" effect on IRF admissions by discouraging the admission of certain categories of patients with conditions that the contractors consider not "typically" in need of IRF care. This may result in patients being inappropriately diverted away from IRFs to settings where intensive, coordinated, interdisciplinary rehabilitation and close medical management are not available to patients.

To address the apparent disconnect between rehabilitation physicians and the Medicare contractors' auditors and reviewers, FAH respectfully requests CMS to incorporate ample safeguards to ensure that patients' access to IRF care will be preserved under the RCD. For instance:

- Only rehabilitation physicians who otherwise meet the regulatory requirements of IRFs should be empowered by CMS to deny claims and must be involved as additional documents are submitted to the MAC for review;

- CMS should establish a Medical Rehabilitation Advisory Board, comprised of CMS personnel, IRF leaders, practicing rehabilitation physicians, beneficiary organizations, and other stakeholders to provide guidance on the interpretation of Medicare's IRF coverage requirements;

- Each MAC that participates in the IRF RCD should be required to establish a similar advisory body to facilitate communication between the MACs and the IRFs under review; and

- CMS and each MAC that participates in the IRF RCD should hold virtual and, eventually, in-person meetings and forums to interact with IRFs and other stakeholders impacted by the program for the purpose of exchanging information, asking questions, addressing concerns, and generally keeping lines of communication open throughout the course of the demonstration.

IV. CMS Should Ensure that the Auditors and Reviewers Are Properly Educated and Trained on Medicare's IRF Coverage Requirements

FAH appreciates the agency's desire to train the MAC reviewers to "ensure consistency prior to beginning the reviews"; however, we have concerns with the agency's assertion that

"[r]eviewers will follow the same review guidelines as they currently do." IRF stakeholders have long expressed frustration regarding the education and training of MAC auditors and reviewers. Over the years, MACs have repeatedly denied claims by making coverage decisions based on non-binding guidance such as the MBPM that are not grounded in Medicare regulations. For example, CMS contractors routinely base IRF denials on statements that assert the patient "could have been treated in a less intensive setting," a standard that does not appear in the IRF coverage regulation and was specifically rejected as a legitimate reason for denial by CMS officials when the 2010 regulations went into effect.

It is critically important that CMS educate and train all audit and medical review personnel to ensure proper evaluation of the medical record and to avoid improper denials that burden the provider, the Medicare appeals process, and especially, the patient. In developing education and training materials/guidelines for the demonstration, CMS and the MACs should use rehabilitation physician trainers and incorporate feedback from the Medical Rehabilitation Advisory Board (recommended above). If CMS proceeds with the IRF RCD, CMS should make publicly available all education and training materials/guidelines, including case examples demonstrating "medically necessary" care. MACs and the Medical Rehabilitation Advisory Board should regularly confer to facilitate discussion regarding the implementation of the demonstration, including how the reviewers are interpreting and applying Medicare's IRF coverage requirements.

V. CMS Should Implement Robust Monitoring of IRF RCD Auditors

FAH appreciates CMS's stated commitment to monitoring the reviewers throughout the demonstration to ensure that the decisions of the MACs are accurate and consistent. In order to avoid improper claim denials, we strongly recommend that CMS provide IRFs subject to the IRF RCD with access to critical data and information derived from monitoring activities conducted within their state and all other states in the demonstration. For example, this data could consist of the number of claims reviewed, denied, and ultimately approved, the reasons for denials, and the types of cases being denied by case mix group and comorbidity tier.

Moreover, CMS should establish a process by which IRFs may engage in a dialogue with CMS and the MACs regarding any concern with the IRF RCD, including the MACs' medical review policies and their application to specific cases. IRFs should be able to request a meeting with their MAC to discuss any concerns with the demonstration throughout the course of the five-year demonstration. We believe that such a process will benefit both the provider and the MAC to resolve outstanding issues and prevent needless denials.

VI. CMS Should Require MACs to Timely Respond

FAH appreciates the agency's acknowledgement that the 10-day response period for pre-claim review was too long. However, in light of the relatively brief length of many IRF stays, the new "5-business days" timeframe still presents a problem for IRFs. This timeframe is particularly problematic when IRFs submit pre-claim reviews while the patient is either in the midst of being treated in the IRF or awaiting discharge to the IRF from the acute care hospital. IRFs operate 24-hours per day, 7-days per week, and patients need to be treated in a timely

manner whenever they arrive on the IRF's doorstep. In light of this reality, the agency should require the MAC reviewers to render a coverage decision within 24 hours of the request. The MAC reviewers should also be available on weekends, holidays, and beyond business hours. We believe this is a reasonable request given that IRFs provide care to patients around the clock.

VII. CMS Should Provide Additional Clarification Regarding the Administration of the IRF RCD

If CMS intends to press forward with the IRF RCD, it should develop and implement the demonstration project with full transparency. FAH seeks clarification regarding how the MACs will receive and respond to electronic submissions. We also urge the agency to confirm that the IRF RCD will apply only to claims with dates of services after the implementation of the demonstration. Lastly, FAH requests confirmation that claims subjected to the IRF RCD will be exempt from additional audit and review activities by all contractors. Exempting claims from subsequent reviews would further alleviate provider burdens.

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FAH appreciates the opportunity to comment on the IRF RCD information collection. As described in detail above, we are concerned that the IRF RCD will adversely impact patient access to IRF care and impose significant burdens on IRFs during the PHE. We respectfully request that CMS withdraw the demonstration or, if the agency insists on moving forward, modify and delay the demonstration as recommended above to ensure beneficiaries have full access to the inpatient rehabilitation that they are entitled to.

FAH stands ready to work with CMS on more appropriate ways to achieve the agency's program integrity goals. 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