

February 18, 2025

William N. Parham, III, Director Centers for Medicare and Medicaid Services Office of Strategic Operations and Regulatory Affairs Paperwork Reduction Staff Attention: CMS-10765

## **SUBMITTED VIA REGULATIONS.GOV**

Re: Encompass Health Comments on the Notice of Collection of Information for a Review Choice Demonstration for Inpatient Rehabilitation Facility (IRF) Services (CMS-10765)

Dear Director Parham:

Encompass Health submits the following comments on the Notice of Data Collection for the Review Choice Demonstration for Inpatient Rehabilitation Facility Services (IRF RCD), published in the Federal Register on December 17, 2024 (CMS-10765, 89 FR 102149) ("the Notice"). Encompass Health is headquartered in Birmingham, Alabama, with 7 hospitals subject to the IRF RCD in Alabama and a total of 166 inpatient rehabilitation facilities (IRFs) in 38 states and Puerto Rico. In 2024, Encompass Health hospitals had over 245,000 inpatient discharges, more than 80% of whom were Medicare beneficiaries.

In this Notice, CMS announced its intention to continue data collection for the IRF RCD, citing the Agency's authority to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the heath programs established by the Social Security Act." We continue to firmly reiterate that this demonstration has not produced any evidence of fraud under the IRF Prospective Payment System (IRF PPS). Fraud is an intentional act of deceit or misrepresentation in order to induce another party to part with something of value. While other payment systems in the Medicare program may be subject to "fraudsters," inpatient rehabilitation hospitals are legitimate and sophisticated medical operations that are built around a unique combination of several types of clinical professionals, including independent physicians. While the RCD may highlight the struggles that third-party contractor reviewers experience in correctly applying the nuance of Medicare's traditional IRF coverage criteria, a mere difference of medical judgment – which, in the case of such RCD contractor reviewers, is based solely on chart review and often results in impermissible or unjustified denials – does **not** amount to fraud. As has been articulated in previous court rulings, claims that are denied on the basis of disagreements in clinical or medical judgment do not rise to the level of being "false" under the False Claims Act, so long as no objective falsity is present. In other words, medical judgment disagreements do not unilaterally indicate fraud.

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<sup>&</sup>lt;sup>1</sup> See, <u>United States v. AseraCare, Inc.</u>, 938 F.3d 1278, 1297 (11th Cir. 2019) ("[A] reasonable difference of opinion among physicians reviewing medical documentation ex post is not sufficient on its own to suggest that those judgments—or any claims based on them—are false under the FCA.").

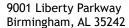


Accordingly, continuing to justify the time and expense of the IRF RCD on the prospect of fraud in the IRF Prospective Payment System is wrong. To make matters worse, any continued misapplication of IRF review standards under this flawed premise stands to prevent legitimate, qualified patients from accessing necessary IRF care. Without any indication of fraud in the IRF payment system, the RCD program represents a waste of time and resources for providers, patients, and the federal government.

Prior to the beginning of the demonstration, we raised concerns to CMS about the potential for the reviewers at the assigned Medicare Administrative Contractor (MAC) to misinterpret IRF coverage criteria or use "ad hoc" criteria when reviewing IRF RCD claims. This concern has now repeatedly occurred over the course of the demonstration in Alabama, which is currently in cycle three. We have experienced alarming misapplications of the IRF coverage criteria and instances of reviewers utilizing criteria from other unrelated review demonstration programs, such as those used in the prior authorization program for certain hospital outpatient department services. Such instances indicate a clear and concerning lack of understanding of IRF coverage criteria, and calls into question how these contractor reviewers were trained.

One of the top concerns raised to CMS prior to the start of the demonstration was the lack of transparency in the number of contractor reviewers who would review RCD claims, their clinical backgrounds and familiarity with IRF coverage, and how they would be trained on the IRF coverage criteria. The ongoing and increasing variation in affirmation rates from month-tomonth in Alabama indicate that various review standards are being applied. Such volatile affirmation rate swings cannot be explained by underlying patient clinical dynamics or hospital operations: indeed, comparing Encompass Health's RCD patient population through the first two full cycles of the demonstration in Alabama, there is no difference in the mix of patient rehabilitation impairment categories (RIC), patients' lengths of stay, or patients' time in therapy. Yet there are significant differences in the affirmation rates. As was predicted, the inconsistent and misapplication of IRF coverage criteria has led to an increasing number of "non-affirmed" decisions in Alabama, increasing the number of claims which then go through the appeals process. Claims going through the appeals process are not included in providers target affirmation rates, even when those non-affirmations are overturned in their favor, resulting in artificially low affirmation rates and less transparency into how both the contractor and IRF providers are performing under the demonstration.

The government's burden and cost estimates published with the Notice also do not reflect the actual time and cost required to successfully navigate the RCD process. For example, the efforts necessary to appeal erroneous non-affirmations is not included, yet takes a substantial amount of time and resources. The Notice and additional documents provided detail that it should take one administrative employee about 30 minutes to compile and submit each claim for affirmation. This does not account for the significant time taken to find additional materials as needed during the contractor's review, or the time it takes for a hospital's clinical team to prepare for and participate in appeals of non-affirmed cases.





While we have opportunities to highlight these concerns to CMS as well as the MAC in Alabama, these ongoing issues have yet to be addressed and corrected in the IRF RCD demonstration. Therefore, we request that CMS pause or suspend the demonstration in Alabama until further oversight and education can occur in order to ensure the proper application of IRF coverage criteria by the contractor reviewers there. Without this pause and evaluation step, the demonstration risks setting up disparate coverage of IRF care for Medicare beneficiaries and divergent review standards across the IRF sector based solely on if a case is reviewed in one state versus another. We note that CMS recently decided to cease the Hospice Special Focus Program, another CMS fraud-oriented program, in order to evaluate its operations among concerns of improper implementation. We request the same action for the IRF RCD.

For questions about the contents of this comment letter, please reach out to me at Andrew.Baird@encompasshealth.com or 202-734-8312.

Sincerely,

Andrew Baird

SVP, Public Policy, Legislation & Regulation

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**Encompass Health** 



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"). 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.<sup>2</sup> 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

<sup>&</sup>lt;sup>1</sup> Agency Information Collection Activities: Proposed Collection; Comment Request, 89 Fed. Reg. 102,149 (Dec. 17, 2024).

<sup>&</sup>lt;sup>2</sup> 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.<sup>3</sup> 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

<sup>&</sup>lt;sup>3</sup> 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.<sup>4</sup> 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. 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. Under the regulatory framework, IRF coverage is determined "at the time of the patient's admission." In promulgating these regulations, CMS placed "more

y + 12.022(a)(3).

<sup>&</sup>lt;sup>4</sup> 42 U.S.C. § 1395hh(a)(2).

<sup>&</sup>lt;sup>5</sup> See United States v. AseraCare, Inc., 938 F.3d 1278, 1297 (11th Cir. 2019).

<sup>&</sup>lt;sup>6</sup> See 42 U.S.C. §§ 1395d(a)(1), 1395y(a)(1)(A).

<sup>&</sup>lt;sup>7</sup> 42 C.F.R. § 412.622(a)(3).

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

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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<sup>&</sup>lt;sup>8</sup> Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010, 74 Fed. Reg. 39,762, 39,791 (Aug. 7, 2009).

<sup>&</sup>lt;sup>9</sup> 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,



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February 18, 2025

#### SUBMITTED ELECTRONICALLY

The Honorable Jeff Wu **Acting Administrator** Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244-1850

#### RE: AAPM&R Comments on the Review Choice Demonstration for Inpatient Rehabilitation Facility ("IRF") Services (CMS-10765)

Dear Acting Administrator Wu:

On behalf of the American Academy of Physical Medicine & Rehabilitation (AAPM&R), we are pleased to submit these comments in response to the Centers for Medicare and Medicaid Services' (CMS') intention to collect information regarding the Review Choice Demonstration (RCD) for inpatient rehabilitation facility (IRF) services. AAPM&R commends CMS for their commitment to ensuring proper Medicare payments while protecting beneficiaries from receiving unnecessary services. However, we have ongoing concerns about the impact of the RCD on patient access to IRF care, the administrative burden created by 100% claim review, and the resulting pressure this places on the ability of IRFs to deliver timely, highquality rehabilitative care. A summary of our concerns is provided below.

AAPM&R is the national medical specialty organization representing more than 10,000 physicians who are specialists in physical medicine and rehabilitation (PM&R). PM&R physicians, also known as "physiatrists," are medical experts in treating a wide variety of conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disabilities, and are experts in designing comprehensive, patient-centered treatment plans. Physiatrists utilize cutting edge as well as time-tested treatments to maximize function and quality of life. Due to their training and expertise, PM&R physicians are uniquely qualified to help guide the multidisciplinary planning effort needed to address the rehabilitation and medical needs of this rapidly growing patient population.

Since being implemented in Alabama in August 2023, the IRF RCD has expanded to Pennsylvania with implementation scheduled for Texas and California next before eventually expanding further to cover approximately half of all IRFs across the country. In just these two states alone, the IRF RCD has impacted thousands of Medicare claims for admission to IRFs.







Under the IRF RCD, facilities in target states are subject to 100% pre-claim or post-payment review for all Medicare beneficiaries who are admitted to IRF care. Claims for these services must meet a "target affirmation rate" of 90%, meaning there must be no documentation errors in the file documents and the Medicare Administrative Contractor (MAC) must determine, in its view, whether an IRF admission is medically necessary. If this standard is met, facilities may forgo 100% pre- or post-payment review but are still subject to "spot checks" on 5% of their claims.

RCD Increases Physician Documentation Burdens: The immense provider burden associated with 100% pre- or post-payment claim review under the IRF RCD remains an ongoing concern for AAPM&R and our physician members. PM&R physicians provide specialized, intensive rehabilitation to vulnerable Medicare beneficiaries who qualify for and are entitled to hospital-level rehabilitation care that is intensive, coordinated, and interdisciplinary, coupled with rehabilitation physician management and supervision. Medicare beneficiaries with significant disabling conditions such as stroke, brain injury, spinal cord injuries, and complex orthopedic and neuro-muscular conditions are treated by AAPM&R member physicians in IRFs across the country, which are also already subject to rigorous documentation and regulatory requirements outside of the RCD.

We believe that diverting important physician time and resources away from direct patient care to comply with these increased documentation requirements is not only burdensome, but it impacts quality and could increase risks for patients. Our members have reported that delays associated with securing pre-claim review approvals has also resulted in treatment delays that could compromise patient outcomes. AAPM&R urges CMS to ensure that the review process under the IRF RCD remains transparent, efficient, and does not inadvertently limit beneficiary access to necessary and important IRF care to improve their health status and ability to function and live as independently as possible.

Greater Commitment Needed from CMS to Public Report RCD Data: Additionally, AAPM&R continues to have concerns about the lack of public reporting data that has been released thus far on the results of the program. Despite the fact that the RCD was initiated in August 2023, CMS took more than a year and a half, aside from verbal reports, to issue any publicly reported written data on the status of the program despite consistent pleas from stakeholders to disclose more about its impact on patients and providers. We believe that more regular public reporting on IRF RCD outcomes, including non-affirmation rates, reasons for denials, number of non-affirmations ultimately reversed on appeal, and the impact on access to IRF care, will be critical in assessing the trends, effectiveness, efficiency, and unintended consequences of the program.

While we commend CMS and the Center for Program Integrity ("CPI") for recently releasing a limited data set on the results of the IRF RCD program, we feel that CMS can and should do better with regards to informing impacted stakeholders on the status of the program. Given the Trump Administration's stated commitment to greater transparency and accountability in health care programs, AAPM&R urges CMS to commit to regular, timely, and meaningful publication of RCD results. We believe that CMS must demonstrate a deeper commitment to data reporting



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and transparency on a more timely basis before it further expands the program to both Texas and California and eventually over half of the country. By doing so, AAPM&R strongly believes that the program will be enhanced going forward by reducing non-affirmation rates and by ensuring that Medicare beneficiaries who need IRF services are able to access the care they need—both of which being the stated and intended goals of the IRF RCD.

AAPM&R believes that publishing IRF RCD data in a more predictable and timely manner and with sufficient specificity is critical for impacted stakeholders to understand the program and how it may impact their patients and their operations. Additionally, this data is critical for both CMS officials and policymakers to better judge the effectiveness of the RCD as a whole and whether its findings and/or savings justify the financial and administrative burden on IRF providers and on the federal government to operate the program. We note that the limited data released thus far indicates exceedingly high affirmation rates across all providers in Alabama and Pennsylvania. Given the strikingly high affirmation rates being reported to date, AAPM&R encourages CMS to consider whether the significant and mutual burden associated with compliance with the RCD requirements warrants the continued expansion to Texas and California, which have significantly higher patient populations than Alabama and Pennsylvania.

RCD Cannot Subvert the Regulatory Process for Changing Coverage Criteria: The Medicare statute requires CMS to determine coverage by regulation or national coverage determination ("NCD").¹ In interpreting the language of the Medicare statute, the U.S. Supreme Court held in 2019 the statute means that CMS cannot establish or change substantive legal standards for coverage or payment unless it promulgates a regulation or NCD.² According to the Supreme Court's holding in this particular case, the Medicare statute imposes even greater procedural requirements on CMS than the Administrative Procedures Act—meaning that CMS cannot use its contractors to restrict coverage criteria. It must follow public notice and comment requirements through a formal regulation or coverage determination.

As the IRF RCD expands to new states, AAPM&R is committed to ensuring that CMS is not deferring to one or two RCD MACs (e.g., Palmetto GBA in Alabama and Novitas Solutions in Pennsylvania) to interpret federal statutes and regulations on IRF coverage in a manner that imposes these MAC interpretations, *de facto*, on all Medicare beneficiaries throughout the country. This is a trend that AAPM&R members have perceived since the RCD was implemented in 2023 and has only become more problematic as the RCD expands to new target states. We encourage CMS to implement proper guardrails to prevent this scenario from occurring as IRF RCD expansion continues in 2025.

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AAPM&R appreciates CMS's commitment to safeguarding the integrity of Medicare payments while ensuring that beneficiaries receive medically necessary rehabilitation services. We urge

<sup>&</sup>lt;sup>1</sup> 42 U.S.C. § 1395hh(a)(2).

<sup>&</sup>lt;sup>2</sup> Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019).



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CMS to consider alternative oversight approaches that balance program integrity with minimizing undue burdens on PM&R physicians and IRFs while protecting patient access to care. We welcome further opportunities to engage with CMS on this issue and provide additional input, as needed. Should you have any questions about these comments or if you would like more information, please contact Chris Stewart, Director of Advocacy and Government Affairs at AAPM&R, via email at <a href="mailto:cstewart@aapmr.org">cstewart@aapmr.org</a> or by calling 847-737-6030.

Sincerely,

Prakash Jayabalan, MD PhD

Chair, Health Policy & Legislation Committee

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February 18, 2025

## **ELCTRONIC SUBMISSION**

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

> RE: <u>FAIR Fund Comments to CMS Information Collection Regarding Review</u> Choice Demonstration for Inpatient Rehabilitation Facilities (CMS-10765)

Dear Acting Administrator Carlton:

The Fund for Access to Inpatient Rehabilitation ("FAIR") appreciates this third opportunity to comment on the proposed information collection activity by the Centers for Medicare and Medicaid Services ("CMS") regarding the inpatient rehabilitation facility ("IRF") Review Choice Demonstration ("RCD"). FAIR submitted comments to CMS dated February 16, 2021, in strong opposition to the agency's intention to proceed with the proposed demonstration. We again restated our opposition to the proposed IRF RCD and urged CMS to withdraw this proposal on October 8, 2021, in response to another Request for Information. We now take this opportunity to restate our continued concerns regarding the ongoing IRF RCD and its planned expansion. The RCD has been an expensive failure—rather than rooting out fraud and abuse, it has instead shown that the vast majority of IRF admissions meet coverage requirements. The RCD increases costs to the Medicare program and IRF providers while imperiling patient access to care. Rather than continuing this wasteful spending on expensive audit contractors, CMS should halt the RCD and put its funds to more productive uses for the American taxpayers.

FAIR is a non-profit organization of inpatient rehabilitation hospitals and units that is devoted to ensuring patient access to inpatient hospital rehabilitation under the Medicare program. Medicare beneficiaries with significant disabling conditions, such as strokes, brain injuries, multiple sclerosis, spinal cord injuries, amputations, and many neuromuscular and musculoskeletal conditions, rely on IRFs to provide critically important intensive rehabilitative therapy coupled with close medical supervision directed by a rehabilitation physician. This IRF care is necessary to improve beneficiaries' health status and ability to function.

<sup>&</sup>lt;sup>1</sup> 89 Fed. Reg. 103,149 (December 17, 2024)

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 seventeen states to identify and prevent potential fraud. This extremely expensive program is not worth its cost. The demonstration began in Alabama in August 2023 and has since expanded to Pennsylvania with implementation next scheduled for Texas and California before eventually expanding further to cover a majority of IRFs in the country across several Medicare Administrative Contractor ("MAC") jurisdictions. The demonstration subjects IRFs to 100 percent case 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 demonstration in Alabama and Pennsylvania has demonstrated that no widespread fraud exists among IRFs, and this lack of fraud fatally undercuts CMS's rationale for expanding the RCD. The IRF RCD affirmation rates in Alabama and Pennsylvania are consistently high, between approximately 80% and 100%, with the fourth quarter of 2024 bearing a 91% affirmation rate. The expense to CMS to administer this program is significant and far exceeds the utility of this demonstration project as a tool to weed out fraud and abuse. Simply put, the RCD is a waste of taxpayer funds.

CMS apparently initiated the RCD due to a mistaken belief that IRFs improperly admit many patients. But previous finding of high error rates resulted from unqualified auditors, not improper admission decisions. These prior, unqualified audit contractors resulted in unrealistically high error rates that CMS cites as justification for the RCD.<sup>2</sup> But the RCD in Alabama and Pennsylvania have shown that those previous high error rates were vastly overstated and wrong.

IRF audits can only be successful when overseen by qualified rehabilitation physicians who actually review medical charts. IRF admission decisions are complex medical judgments. The admitting physician must weigh both the patient's need for intensive rehabilitation and rehabilitation physician oversight and supervision while the patient undergoes a rigorous therapy program. The rehabilitation physician manages not just the patient's primary diagnosis, but in many instances, multiple, comorbid conditions. It is the rehabilitation physician's role to lead the rehabilitation team to ensure that the patient can complete the IRF program with a reasonable expectation of improvement. CMS requires IRF admissions to be decided by physicians with training *and* experience in rehabilitation.<sup>3</sup> Yet, CMS requires nothing of the sort from most of its audit contractors, which typically employ nurses, therapists, and sometimes, non-clinical personnel to second-guess the admission decisions of the rehabilitation physicians who actually treat Medicare patients.

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<sup>&</sup>lt;sup>2</sup> CMS cites high error rates by its Comprehensive Error Rate Testing (CERT) contractors to justify the RCD. CMS, Supporting Statement Part A, Pre-Claim Review Demonstration for Inpatient Rehabilitation Facility Services, (citing CERT reports), available at <a href="https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10765">https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10765</a>.

<sup>&</sup>lt;sup>3</sup> 42 C.F.R. § 412.622(a)(3)(iv), (a)(4)(i)(A), (c).

CMS asserts that reduction of fraud is the primary reason for the IRF RCD, yet the very high affirmation rates in Alabama and Pennsylvania fatally undermine CMS's rationale for the RCD. Furthermore, CMS has shown no evidence that the pre-RCD error rates were anything more than good faith disagreements between treating physicians and non-physician auditors. CMS has not shown any intent to file false or unnecessary claims, the very definition of fraud. Yet, CMS has embarked on a nationwide 100% case review of every single Medicare beneficiary admitted to an IRF in selected states. Without a showing of actual fraud, FAIR restates our concerns that CMS does not have the authority to implement this expansive demonstration project, and it should be either discontinued in the near term or, at the very least, not expanded to additional states.

We are very concerned that expansion of the IRF RCD will lack the relatively high quality oversight that we have seen in Alabama and Pennsylvania. If the expanded RCD employs the types of reviewers that audited IRFs prior to the RCD, patients will likely lose IRF coverage for certain conditions and diagnostic categories. This would have a significant negative impact on patients, their families, and the providers who treat them in IRFs. If the RCD results in the loss of IRF coverage for certain classes of patients, CMS will have violated its rulemaking responsibilities under the Medicare statute. For this reason alone, we urge CMS to refrain from expanding this program to other states and seriously consider discontinuing the demonstration project altogether.

By targeting certain types of patients, the RCD may result in widespread denial of IRF coverage for whole classes of conditions. We are very concerned that the end result of CMS's restrictive audits under the IRF RCD will be to inappropriately take patients out of IRF care and instead treat them in non-hospital settings where they will receive inadequate rehabilitation therapy and no meaningful rehabilitation physician management. If this occurs, CMS will have violated the Medicare statute's rulemaking requirement and will be using contractors' audits to modify coverage criteria, rather than evidence-based processes, in place for decades at CMS.<sup>4</sup>

The Medicare statute requires CMS to determine coverage by regulation or national coverage determination ("NCD"):

No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation . . . . <sup>5</sup>

The U.S. Supreme Court has affirmed that this law means what is says: CMS cannot establish or change substantive legal standards for coverage or payment unless it promulgates a regulation or

<sup>&</sup>lt;sup>4</sup> 42 U.S.C. § 1395hh(a)(2).

<sup>5</sup>Id.

NCD.<sup>6</sup> The Medicare statute thus imposes even greater procedural requirements on CMS than the Administrative Procedure Act.<sup>7</sup>

The stakes are high with the continuation of the IRF RCD. Treatment in an IRF has been demonstrated to increase longevity. IRF care also greatly increases a patient's chances of continuing to live at home following illness or injury. IRFs accomplish this with a wholistic approach to care that is provided by an interdisciplinary team of rehabilitation professionals. Not everyone needs the intensive of rehabilitation that IRF's provide, but the decision about who gets access to IRF care should be left to qualified rehabilitation physicians, rather than non-physician, often non-clinical, auditors who have little training in the field of medical rehabilitation or clinical experience in caring for IRF patients.

Given the lack of outright fraud that has been demonstrated to date, the significant expense for CMS to administer this time-intensive and burdensome program, and the exceedingly high affirmation rates across IRF providers in both Alabama and Pennsylvania nearly two years into the IRF RCD, FAIR believes that the continuation of the IRF RCD is not worthwhile and will not accomplish 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 consider alternative, less costly oversight approaches that balance program integrity with minimizing undue burdens on IRFs and protecting patient access.

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FAIR appreciates the opportunity to comment on this IRF RCD information collection. We have attached our prior comments on the RCD, which CMS did not adequately address and request that you do so at this time. If you have any questions or would like to contact FAIR, please call or email FAIR's counsel, Ron Connelly, at (202) 466-6550 or Ron.Connelly@PowersLaw.com.

Sincerely,

Ronald S. Connelly, J.D.

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FAIR Counsel

Attachment

<sup>&</sup>lt;sup>6</sup> Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019).

<sup>&</sup>lt;sup>7</sup> *Id*.

<sup>&</sup>lt;sup>8</sup> Dobson DaVanzo & Assocs., LLC, Assessment of Patient Outcomes of Rehabilitative Care Provided in Inpatient Rehabilitation Facilities (IRFs) and After Discharge, E-3 (2014), <a href="https://www.sutterhealth.org/pdf/services/physical-therapy-rehabilitation/patient-outcomes-of-irf-vs-snf.pdf">https://www.sutterhealth.org/pdf/services/physical-therapy-rehabilitation/patient-outcomes-of-irf-vs-snf.pdf</a>.

<sup>9</sup> Id.