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February 16, 2021

Liz Richter, Acting Administrator Centers for Medicare and Medicaid Services Office of Strategic Operations and Regulatory Affairs Division of Regulations Development

Attention: CMS-10765 Room C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

Submitted electronically via www.regulations.gov

Re: <u>Proposed Review Choice Demonstration for Inpatient</u> Rehabilitation Facility Services (CMS-10765)

Dear Acting Administrator Richter:

The American Academy of Physical Medicine & Rehabilitation (AAPM&R) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed information collection on a Review Choice Demonstration for Inpatient Rehabilitation Facility (IRF) Services (CMS-10765). AAPM&R has major concerns with this proposal and its potential impact on rehabilitation physicians and the Medicare patients our members serve in inpatient rehabilitation hospitals and units. As such, we urge you to withdraw this proposal and work to develop a less onerous alternative that meets CMS legitimate need to only pay for medically necessary care while preserving patient access to vital inpatient rehabilitation hospital services. If CMS decides to proceed with this demonstration, we urge the agency to significantly restructure the demonstration program in a manner that reduces physician burden and maximizes patient access.

AAPM&R is the national medical specialty organization representing more than 9,000 physicians who are specialists in physical medicine and rehabilitation (PM&R). PM&R physicians, also known as "physiatrists," are medical experts in a wide variety of conditions that affect nearly every organ system including, but not limited to, the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disability, and are experts in designing comprehensive, interdisciplinary, patient-centered treatment plans. Physiatrists utilize cutting-edge as well as time-tested treatments to maximize recovery, functional status, and quality of life.



Maintaining high quality care in inpatient rehabilitation hospitals is a significant priority to AAPM&R members. Rehabilitation physicians are equipped with the medical expertise required to lead the interdisciplinary care team in the comprehensive medical management and rehabilitation care of the vulnerable patients with highly complex needs who comprise the typical patient population in IRFs. Physiatrists have a well-established clinical and leadership role in rehabilitation units in acute care hospitals and free-standing inpatient rehabilitation hospitals (collectively referred to as inpatient rehabilitation facilities, or IRFs). By virtue of their extensive training and expertise in medicine, rehabilitation, impairment and function, physiatrists commonly serve as IRF medical directors and as the primary admitting physicians in these facilities. Appropriately, physiatrists are also typically the designated leader of the patient's interdisciplinary rehabilitation care team in this setting. As such, physiatrists direct and supervise intensive rehabilitation programs, while exercising their medical expertise in the comprehensive medical management of comorbid conditions and rehabilitative care of these vulnerable and complex patient population suffering from injuries, illnesses, disabilities, and chronic conditions, including most recently, the ongoing effects of COVID-19 and its treatment in intensive care units (ICU).

I. Overview

CMS proposes to implement a "Review Choice Demonstration" (RCD) for IRFs, which would subject selected IRFs to 100% pre-claim or post-claim review of their Medicare claims. While this demonstration would begin with all IRFs in Alabama, CMS proposes to expand the RCD to all providers in four Medicare Administrative Contract (MAC) jurisdictions, covering 17 states, three U.S. territories, and the District of Columbia. AAPM&R has significant concerns with this proposal, which would dramatically increase physician burden in a field already subject to onerous documentation requirements. It would also serve as an unprecedented intrusion by CMS contractors in the exercise of independent physician judgment.

As CMS continues its court-ordered efforts to reduce the 200,000-case backlog of Medicare appeals, this demonstration project also stands to directly restrict the types of patients that rehabilitation physicians routinely admit to the IRF level of care. Without a functioning appeals process, timely decisions by third-party, independent Administrative Law Judges (ALJs) are not possible, placing rehabilitation physicians in the unenviable position of either denying IRF admission to patients they believe meet the medical



necessity criteria or continuing to accept such patients and placing their IRFs at serious financial risk if the stay is denied.

This demonstration, therefore, is very likely to produce a gatekeeping effect that will result in inappropriate denials of IRF admission for potentially thousands of Medicare beneficiaries who are entitled to this level of rehabilitation care. Instead, these Medicare beneficiaries will wind up in other, less appropriate settings where their conditions could be inadequately treated, their long-term outcomes compromised, and their likelihood of readmission increased. For an example of an IRF patient, someone with brain injury may need drugs, therapies, exams, diagnoses, and rehabilitation. For people with spasticity, seizures, or sleep disorders, physiatrists and other rehabilitation physicians' purpose is to manage these concurrent issues. Rehabilitation medicine is the only way to stop, slow, or reverse the diseases processes caused by brain injury.

AAPM&R urges CMS not to move forward with this proposal. Below, we provide detailed responses to problematic aspects of the proposed demonstration and, if CMS decides to proceed with this demonstration, alternatives that will lessen physician burden while preserving patient access. CMS should work with stakeholders in the rehabilitation system to ensure that any demonstration is implemented with minimal impacts on rehabilitation physicians practicing in IRFs, without creating undue barriers for patients in need of inpatient hospital rehabilitation care, and without sacrificing IRF level care.

II. Background of Medical Rehabilitation Provided by Physicians in IRFs

Perhaps no other area of Medicare is more regulated than IRFs. At the center of the IRF-level of care is the rehabilitation physician, whose experience, skills, and judgment in rehabilitation medicine help patients overcome physical deficits and return to independent living. When a person is injured, becomes seriously ill, or requires surgery, acute hospital care is often just the first step toward recovery and returning to a normal life. Patients frequently require a course of post-acute, hospital-based rehabilitation, where a physician with specialized training and experience in rehabilitation strategically plans, coordinates, and oversees the patient's medical and rehabilitative care during an intensive rehabilitation program.

IRFs strive to improve the functional status and quality of life of patients recovering from surgical procedures, strokes, spinal cord injuries, brain injuries, amputations, hip fractures, and many other conditions. Intensive



inpatient hospital rehabilitation optimizes a person's health, functional skills, and ability to live independently and perform common daily activities, such as walking, using a wheelchair, bathing, or eating.

IRFs provide medical management and physician-supervised intensive rehabilitation therapy programs that consist of physical and occupational therapy, speech language pathology, prosthetic/orthotic services, rehabilitation nursing, and a wide variety of related services designed to improve function.

IRF care is highly effective. Outcomes for certain conditions in IRFs are significantly better than in lower-intensity levels of care, such as skilled nursing facilities (SNFs). Evidence-based guidelines categorically recommend that certain patients with particular critical diagnoses receive immediate IRF care. For example, the American Heart Association and the American Stroke Association recommend IRF care for all stroke patients.¹

Prior to 2010, the determination of Medicare coverage for IRF services focused on whether the services and location were reasonable and necessary and listed eight criteria that IRFs and CMS auditors could use as guideposts when assessing Medicare coverage. Medicare auditors frequently second-guessed physician judgments under the pre-2010 standards. Recovery Audit Contractors (RACs) used the coverage criteria to override significant numbers of physician decisions to admit patients to IRFs. Using non-physician clerical staff, RACs routinely asserted that patients "could have been treated in a less intensive setting, such as a skilled nursing facility." IRFs found themselves defending the care that they provided based on comparisons to an idealized SNF, which rarely, if ever, existed in practice. We anticipate the same scenario under the proposed demonstration project.

In 2010, CMS issued new coverage regulations for IRF services, which are applicable today. These regulations emphasize the admitting physician's judgment and documentation and process.² IRF coverage is determined "at the time of the patient's admission," based on a rehabilitation physician's reasonable expectations regarding the patient's need for intensive, multidisciplinary therapy services under the supervision of the rehabilitation

STROKE e46 (2018), http://stroke.ahajournals.org/content/49/3/e46.

¹ See William J. Powers, et al., 2018 Guidelines for the Early Management of Patients with Acute Ischemic Stroke: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association, 49

² Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010, 74 Fed. Reg. 39,762 (Aug. 7, 2009); 42 C.F.R. § 412.600 *et seq.*



physician, and with the assistance of an interdisciplinary care team, in order to participate in and achieve a significant benefit from those therapy services.³ The regulation recognizes a priori the physician's judgment when admitting a patient to an IRF and does not create black-and-white coverage rules that can be applied mechanically by auditors.

Each Medicare patient treated in an IRF must meet several medical necessity coverage criteria. To be covered in an IRF, the patient must need an interdisciplinary approach to care and be stable enough at admission to participate in intensive rehabilitation.⁴ In addition, there must be a "reasonable expectation" that the patient will need multidisciplinary therapy, intensive rehabilitation, and supervision by a rehabilitation physician.⁵

The IRF coverage requirements established in 2010 were accompanied by significant new documentation requirements. Since 2010, the medical necessity of IRF care must be demonstrated by the following documents in the patient's medical record: a preadmission screening, a post-admission physician evaluation (which has recently been determined to be no longer required), and an individualized overall plan of care. All of these documents have deadlines and content requirements. In addition, CMS requires that each patient's medical record contain the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), a document that records a wide variety of patient data, focusing on functional and cognitive impairments.

The regulation acknowledges that the decision to admit a patient to an IRF is a complex medical judgment by the rehabilitation physician. The physician makes this decision not only by reviewing medical chart notes, but also by reviewing the pre-admission screening document that includes a justification for admission, establishing functional goals, and expected progress. This document must be approved by a rehabilitation physician for a patient to be admitted. Additionally, there may be a direct examination of the patient by the rehabilitation physician. Sometimes, the rehabilitation physician has

⁶ *Id.* § 412.622(a)(4).

³ 42 C.F.R. § 412.622(a)(3); Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-04, ch. 1, § 110.2.

⁴ *Id.* § 412.622(a)(3), (5).

⁵ *Id*.

⁷ MBPM, ch. 1, §§ 110.1.4, 110.1.5. Until recently, IRFs also had to maintain a timely admission order in the patient's medical record.



treated the patient previously and is familiar with the patient's medical history. A review exclusively of documentation, after the fact, cannot replicate the depth of experience of the rehabilitation physician who makes the admission decisions. The proposed demonstration project is premised on error rates identified by Medicare contractor reviews of IRF claims, commonly known as CERTs, or Comprehensive Error Rate Testing contractors. In the past decade, the CERT's error rates for IRFs have fluctuated dramatically, despite a very stable regulatory IRF landscape. Medical necessity review by all of CMS's contractors has produced thousands of IRF appeals in the past decade, a high percentage of which were settled in favor of IRF providers (between 69% and 100% depending on the type of denial) in 2018. It is clear there is a lack of understanding by Medicare contractors in this type of care and the types of patients practicing rehabilitation physicians believe would medically and functionally benefit from IRF care.

III. Delay of the Demonstration is Necessary Due to COVID-19

Physiatrists and other direct care workers on the front lines of the COVID-19 public health emergency (PHE) have been working alongside their colleagues for nearly a year to combat the SARS-CoV-2 virus and its aftermath. The waivers granted by Congress and CMS due to the PHE on the so-called 3-hour rule and 60% rule have been invaluable in permitting IRFs the flexibility to serve the immediate needs of their communities, including COVID-19 survivors who spent time in ICUs and on ventilators, and it is likely the COVID-19 pandemic will continue into the foreseeable future. In short, this is no time for implementation of a new IRF pre-claim or post-payment review of this magnitude.

Physicians cannot be expected to spend critical hours compiling documentation and convincing Medicare contractors of the appropriateness of their IRF admission decisions at a time when all efforts are needed on the front lines of the pandemic. In addition, with the waivers not likely to be lifted at least until the end of the PHE, which is expected no earlier than the end of the calendar year, it is not clear what review standard would apply to IRF audits in 2021. For this reason, CMS should refrain from embarking on any demonstration projects for at least two years after the end of the PHE, to allow IRFs to return to some semblance of normal operations.

IV. Unnecessary Burden on IRF Providers

AAPM&R has long expressed our significant concerns with the outsized and unnecessary administrative burden placed on physicians in IRF settings. Far too much of a rehabilitation physician's time in an IRF is spent documenting



medical necessity and meeting arbitrary timelines that often bear little clinical relevance to the patient's treatment. In fact, data related to physician burnout clearly demonstrates the toll that compliance requirements and other administrative burdens place on physiatrists. We appreciate that in recent years, CMS has recognized the importance of reducing provider burden across the Medicare program, such as eliminating the Medicare requirement for a physician to sign a post-admission physician evaluation (PAPE) within two days of IRF admission in the 2021 IRF Prospective Payment System final rule. Reducing burdens will make a difference to our members and the patients they serve.

However, we are concerned that the proposed demonstration would present a significant additional documentation burden on IRF rehabilitation physicians. In the supporting statement accompanying the Federal Register notice, CMS estimates that preparing documentation for an individual claim will take clerical staff an average of 30 minutes per claim. This estimation seriously understates the amount of time and effort required for the physician to review the patient file and defend the medical necessity of each claim at issue. In both the pre-claim and post-payment context, we anticipate that rehabilitation physicians will be required to help prepare and submit documentation defending each challenged claim, further taxing already overworked physicians and, even worse, taking away from their already limited time working directly with their patients.

The additional review process will likely result in unnecessary denials, requiring rehabilitation physicians to spend inordinate amounts of time appealing MAC decisions. Providers are already forced to undertake significant efforts in appealing decisions through the typical appeals process, which are likely to be exacerbated by the additional pre- or post-claim review under the proposed demonstration. We urge CMS to ensure that any IRF review demonstration that is finalized will avoid forcing physicians to spend more time away from their patients to fulfill additional administrative requirements.

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⁸ Medscape National Physician Burnout, Depression & Suicide Report 2019, Medscape, January 16, 2019. Retrieved from: https://www.medscape.com/slideshow/2019-lifestyle-burnout-depression-

^{6011056?}src=WNL_physrep_190116_burnout2019&uac=306605AJ&impID=1861588&faf =1#3 (finding physiatrists ranked as the third-most burnt out specialty among the 50 ranked specialties, with 52% of reporting physiatrists feeling burnt out. The average percentage of burnout for all physician specialties was 44%).



V. 100% Review of Medicare Claims and Selection of Reviewed Facilities

Under the proposed demonstration, IRFs in the targeted states will be required to opt for either 100% pre-claim review or 100% post-payment review, with the stated intent of assisting in "developing improved procedures for the identification, investigation, and prosecution of Medicare fraud." This is problematic for two reasons. First, CMS demonstrates no substantive foundation of fraud for justification of a demonstration program that includes review of every single claim for certain IRFs. Second, exposing IRFs covered under the demonstration to 100% review of their Medicare claims is wholly unnecessary to accomplish CMS's goals.

Further, 100% claim review will result in the previously stated significant undue burden levied on physicians. 100% review of all IRF claims within hospitals that have the misfortune of being within the jurisdiction of a particular MAC involved in the demonstration program is a draconian sanction that can only be justified by a clear evidence of fraud. From the justification in the information collection, CMS has failed to meet this standard.

We implore CMS to dramatically lower this percentage of claim review in future iterations of this demonstration program. There are numerous methodologies to achieve CMS's goals that create much less burden on rehabilitation physicians, IRF providers, and Medicare beneficiaries. For instance, a sampling of Medicare claims for participating hospitals should be sufficient to determine whether an individual facility has ongoing compliance concerns that should be addressed via more detailed review. MACs could also probe certain claims by requesting the pre-admission screening only of a sample of claims and, once reviewed, further request additional documentation of claims that do not clearly establish medical necessity without further consideration.

While AAPM&R does not endorse one specific pathway for appropriately sampling claims for review, we note that CMS has engaged in narrower claims review processes in the past, including the Targeted Probe and Educate (TPE) program. We believe that a more targeted approach could accomplish CMS's goals while reducing burden on the IRFs under review, rehabilitation physicians, and Medicare beneficiaries. If certain IRF claims are identified as problematic in the smaller sample, CMS could expand its reviews of those IRFs to help ensure compliance with Medicare requirements.



CMS also proposes that the RCD for IRFs will first be implemented in Alabama, then expanded to Pennsylvania, Texas, and California. In the third year of the demonstration, the demonstration will apply to all providers in four MAC jurisdictions in numerous states. Under the proposal, all IRFs within these jurisdictions, regardless of their compliance history, will be required to undergo either pre- or post-claim review of all their Medicare claims. CMS should include measures to adjust the pilot in subsequent years based on lessons learned.

In addition to our concerns with 100% claims review for targeted IRFs, it is inappropriate to require all IRFs in the applicable jurisdictions to undergo this burdensome review, without any consideration of their history and commitment to meeting Medicare requirements. CMS has significant historical information on IRF compliance rates, including rates of claims denials, appeals, and eventual overturned denials. Subjecting all IRFs in the jurisdiction of certain MACs to 100% claims review regardless of historical compliance unnecessarily burdens physicians at those hospitals. If CMS proceeds with some form of this demonstration project, we strongly encourage the agency to consider methods that do not indiscriminately target IRFs and rehabilitation physicians simply based on their geographic location.

VI. Qualifications of Reviewers

CMS provides few specific details on the review process to be conducted by the MACs under this demonstration program. However, CMS does note that the documentation will be reviewed by "trained nurse reviewers" to determine if the beneficiary qualifies for IRF services and if they need the level of care requested. AAPM&R strongly opposes any demonstration that would allow denials to stand without explicit review and agreement by qualified, experienced rehabilitation physicians.

The IRF coverage requirements clearly state the need for a "rehabilitation physician" to direct IRF care, mandating a licensed physician with specialized training and experience in rehabilitation to make the determination on admission of and supervise care furnished to IRF patients. We see no reason that the same requirements should not apply to the reviewers who aim to supersede the judgments of treating rehabilitation physicians during either pre- or post-claim review for IRF admissions. Any final demonstration should mandate that denials cannot be made without the express review and approval of an appropriately credentialled rehabilitation physician who meets all the requirements established in 42 C.F.R. § 412.622.

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This requirement would reduce the amount of denied claims that ultimately are reversed in favor of providers through the administrative appeals process. In addition, upon an initial denial and a request for additional information by the MAC's rehabilitation physician, a rehabilitation physician-to-rehabilitation physician conversation should be required before a second and final denial is issued for a particular patient. This would allow clarification of misunderstandings, explanation of documents, development of nuanced reasons for IRF admission, and discussions of other factors between rehabilitation physicians before these cases become subject to the lengthy backlog of the administrative appeals process. This face-to-face physician meeting requirement has a precedent in the "discussion period" that was included as part of the original RAC demonstration project.

Without these safeguards, this demonstration project, as proposed, has the potential to allow corporate contractors of the federal government to practice medicine, overruling the medical judgment and clinical decision-making of treating rehabilitation physicians across the county. With 100% review of IRF claims and a dysfunctional appeals process that precludes timely, independent decisions by neutral third parties, the decisions of MAC reviewers will literally transform the kinds of beneficiaries who have access to IRF care and the way physicians practice inpatient hospital rehabilitation.

VII. Appeals Process and Timeliness of RCD Denials of IRF Claims

AAPM&R believes it is patently unfair and illogical for CMS to implement this new audit demonstration program while the extensive backlog of ALJ appeals prevents providers' use of a functioning appeals system. A functioning and timely appeals system that determines ALJ appeals within 90 days, as required by current federal law, would help settle disputes between Medicare contractors and rehabilitation physicians when they disagree about the appropriateness of inpatient rehabilitation admission.

Without a functioning appeals system, the treating physician must take the MAC's decision as, effectively, the last word on medical necessity, denying future patients with similar conditions access to IRF care over his or her professional judgment, or place at significant financial risk the IRF in which he or she works. As already noted, we expect this gatekeeping effect to create a material restriction on IRF admissions. For this reason alone, CMS should indefinitely delay this demonstration project until the Department of Health and Human Services has satisfied the court-ordered Writ of Mandamus to clear the ALJ backlog.



Restrictions on IRF admissions will be compounded by the length of time the proposed demonstration allows for pre-claim reviews to be decided. CMS states that the MAC will render a decision on initial requests within five business days. For review requests that need to be resubmitted with additional documentation, MACs will have ten business days to provide their decision. Taking into account weekends and holidays, this is an inordinate amount of time to wait for a medical necessity decision while the IRF continues to treat the patient, especially when the average length of stay in a rehabilitation hospital is approximately 13 days. While CMS notes that IRFs opting for pre-claim review will be able to admit patients and provide services before receiving MAC approval, it is crucial for the MACs to make more timely decisions.

We strongly urge CMS to decrease the timeframe for MACs to review preclaim submissions, and to ensure that MAC reviewers are available beyond business hours, on weekends, and over holidays as clinician members of patient teams are. IRFs do not cease to operate outside of typical business hours, and it is critical that the MACs making decisions regarding the availability of patient care keep to the same schedule.

Additionally, we believe it is absolutely necessary to develop specific procedures under this demonstration project to help expedite answers to resubmissions and, eventually, appeals at the redetermination, reconsideration, and ALJ levels. This would require CMS to work with the Office of Medicare Hearings and Appeals to coordinate appeal acceleration of demonstration-related IRF denials in some manner. The IRF field has long experienced the numerous problems with the existing appeals process. Many cases still take years to get through the appeals process, resulting in massive provider and patient burden. The recent global settlement by CMS and the IRF field for IRF cases indicates that the agency recognizes that many initial denials are eventually overturned in favor of providers and patients.

If CMS moves forward with this demonstration proposal to substantially expand audits of IRF claims, the agency should accompany the demonstration program with a designated process for timely and expedited appeals of associated denials by the MACs.



VIII. IRFs Standard of Care and the Definition of a Rehabilitation Physician

In your consideration of these comments, we would like to offer an alternative solution to ensure Medicare dollars are appropriately and efficiently spent in IRFs. AAPM&R is concerned that the regulatory definition of an IRF rehabilitation physician is too broad, resulting in physicians not actually experienced or qualified in rehabilitation filling these roles. Due to the complex care provided in IRFs and the costly nature of treating these medically complex patients, it is the Academy's position⁹ that it is imperative to ensure physiatrists are filling these positions and assessing who would best benefit from IRF care. As stated, several times throughout these comments, IRFs provide intensive, comprehensive, 24-hour interdisciplinary care to a patient population that is medically complex. IRF patients have suffered a wide variety of injuries, chronic illness, disabilities, and their associated co-morbidities. These patients and the interdisciplinary team treating them need to account for these conditions, pace of treatment, associated risks, optimizing function, and discharging to a higher quality of life. As such, having an experienced rehabilitation expert determine which patients should be admitted to this level of care could help reduce inappropriate admissions and the burden associated with denied claims. AAPM&R would be glad to work with CMS to create tighter regulatory standards for the role of rehabilitation physician.

Thank you for your consideration of these comments. For more information, please contact Reva Singh, Director of Advocacy and Government Affairs at AAPM&R at rsingh@aapmr.org or 847.737.6030.

Sincerely,

Stuart M. Weinstein, MD

MISM

President

⁹ SR. Laker et al. / PM R 11 (2019) 98-102. https://doi.org/10.1002/pmrj.12052.