



October 8, 2021

Submitted electronically via www.reginfo.gov and www.regulations.gov

The Honorable Shalanda Young
Acting Director
Office of Management and Budget
Office of Information and Regulatory Affairs
Washington, DC

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Center for Program Integrity
Washington, DC

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

Dear Acting Director Young and Administrator Brooks-LaSure:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed Review Choice Demonstration for Inpatient Rehabilitation Facility (IRF) Services (CMS-10765/ICR Reference 202109-0938-007).

CPR is a coalition of more than 50 national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities, and chronic conditions may regain and/or maintain their maximum level of health and independent function. We have serious concerns about this proposed demonstration and the consequences it would have for patient access to care in inpatient rehabilitation hospitals and rehabilitation units of acute care hospitals. Unfortunately, these concerns were not adequately addressed by CMS as a result of the initial comment period in February 2021, and CMS continues to signal its intention to move forward with this expansive new demonstration project that disproportionately impacts Medicare beneficiaries with disabilities and chronic conditions.

We therefore urge CMS to withdraw this proposal in its entirety and discuss with stakeholders other, less problematic ways to achieve its program integrity goals. As a coalition of organizations whose members rely on rehabilitation provided in IRFs and other settings covered by Medicare, we are alarmed that CMS has apparently ignored our comments and the comments of numerous other stakeholders representing IRF patients and providers. We continue to believe that implementing the proposed RCD will have a significant negative impact on patients in need of inpatient rehabilitation care.

The Coalition to Preserve Rehabilitation would be pleased to work with CMS as the agency examines other methods to achieve the goal of program integrity without unfairly burdening or

harming patients. The RCD proposal, however, will result in significant harm to patients, and so we cannot support this pathway.

Overview

CMS proposes to implement a “Review Choice Demonstration” (RCD) for IRFs in certain states, during which facilities will be subject to a 100% pre-claim or post-payment review for their Medicare claims. While the demonstration would begin with all IRFs located in the state of Alabama, it would soon be expanded to several other states, eventually encompassing 17 states, three U.S. territories, and the District of Columbia. All IRFs in these Medicare Administrative Contractor (MAC) jurisdictions would be subject to 100% claims review, impacting tens of thousands of Medicare beneficiaries over the five-year period of the demonstration and the rehabilitation hospitals that serve them.

CMS previously opened a stakeholder comment period in December 2020, which closed in February 2021. CMS states in its supporting materials that the agency received 35 comments, including those from CPR [dated February 16, 2021](#). CPR strongly opposed this demonstration in February, as did all other stakeholders submitting comments (save for one anonymous submission). However, CMS has apparently decided to continue to move forward with this problematic demonstration, despite the widespread and very real concerns about the impact this would have on the provision of inpatient rehabilitation care for Medicare beneficiaries.

Given that the agency has offered only minor substantive changes to the proposed demonstration and no adequate response to the numerous concerns raised during the comment period, we reiterate our strong opposition to this proposal below. The Coalition to Preserve Rehabilitation believes this proposal would:

- Significantly limit patient access to IRF care by creating a “gatekeeper” effect on IRF admissions, decreasing access to care both immediately and over time;
- Discriminate against beneficiaries with certain conditions that are not considered “typical” of IRF care; and
- Divert Medicare beneficiaries away from the IRF setting to which they are entitled to less intense settings of post-acute care (PAC) that may not meet their needs and will likely result in worse health outcomes.

The RCD Will Further Limit Patient Access to IRF Care

As stated in our previous comment letter, CPR has significant concerns that the proposed demonstration will severely limit access to inpatient rehabilitation hospital care for Medicare beneficiaries, especially those with certain conditions who are entitled to the high-level medical management and rehabilitation therapy provided in IRFs under the current CMS coverage requirements.

CPR and the patients and providers we represent have long expressed apprehension about the significant and growing barriers to access for patients in need of post-acute care, whether due to the overuse of prior authorization and other utilization management techniques in the Medicare Advantage program, the harmful payment incentives recently implemented in the Home Health

and Skilled Nursing Facility prospective payment systems to deemphasize rehabilitation therapy, the ongoing efforts to flatten disparate settings into a unified post-acute care benefit, or the recurring roadblocks faced by patients seeking maintenance therapy, to which beneficiaries are entitled under the *Jimmo v. Sebelius* settlement.

The RCD demonstration, if implemented, would exacerbate these trends and further limit access to care for beneficiaries in need of treatment in IRFs. Given the historical trends relating to IRF denials, we expect that this demonstration would significantly increase the percentage of denied IRF cases, even when the rehabilitation physician has made a considered medical judgment that a given patient qualifies for this level of care. This will force IRFs to restrict access to their services rather than fighting denial after denial through the years-long appeals process.

We note that this demonstration is yet another example of CMS' seemingly one-sided focus on the supposed overutilization of care; rarely, if ever, does the agency seem concerned with rampant *underutilization* across post-acute care, in particular, the significant barriers that patients in need of rehabilitation face in accessing medically necessary treatment.

CMS states in its response to previous stakeholder comments that the agency "is confident that the IRF demonstration will not impede beneficiary access to care or prohibit providers from delivering services." Hardly any justification is given for this optimistic outlook. It is accurate that under the terms of the proposed demonstration, providers will not be directly prohibited from admitting patients before approval from the MACs, as they would be with a prior authorization model. Nor will they be explicitly forced to discharge patients when a non-affirmative decision is received. However, this merely requires the IRF to either choose to discharge the patient despite the rehabilitation physician's medical judgment, or to assume the risk of continuing to treat that patient as has been determined to be medically appropriate while recognizing that the agency is likely to deny the claim, forcing the provider to undergo a time-intensive appeals process. Over time, if denials for particular types of patients persist, the IRF will have no choice but to reject that patient referral and not admit the patient up front.

In this way, the demonstration appears designed to limit coverage and materially change the IRF benefit without going through a public notice-and-comment rulemaking process to restrict coverage in a transparent manner. As MACs and other contractors such as the Recovery Audit Contractors have done in the past, we expect the contractors under the RCD to deny a significant number of pre-claim and post-payment IRF claims based largely on a lack of expertise by non-physician contract reviewers, as well as arbitrary decisions about the standards for IRF coverage. CMS states that "MACs are not substituting their judgment for the physician's," and seeks to represent their role in the RCD as purely administrative: simply ensuring that the documentation is in order. In the same paragraph, however, CMS admits that the agency is expecting MACs to evaluate medical necessity, an area that is, by definition, the domain of the treating rehabilitation physician.

IRFs already operate under a strict set of coverage criteria, more so than any other setting of post-acute care. Many acute care hospital patients referred to an IRF for services are assessed and sent to other settings of care because they do not meet the strict qualifications for IRF

coverage. CMS has promulgated extensive regulatory criteria defining the requirement for IRF care, including the mandate for care to be led by a qualified rehabilitation physician. In keeping with these regulations, IRFs already go through an extensive pre-admission screening and documentation process to determine which patients are appropriate for IRF admission and who are most likely to benefit from the intensive, coordinated, and multidisciplinary rehabilitation and medical management provided in these facilities. Even so, CMS continues to deny large numbers of IRF claims due to disagreements about medical necessity and this RCD demonstration will simply exacerbate this problem.

We note that many initial IRF denials are overturned in favor of patients and providers through the administrative appeals process, despite the lengthy delays currently plaguing system. CMS also noted that this concern was raised by many stakeholders during the initial comment period, but provides no response to this specific issue, nor any recognition of the clear disconnect that already exists between the denials issued by the MACs and the high overturn rate at the Administrative Law Judge (ALJ) level of review. While some — long-overdue — progress has been made in recent years in reducing the massive Medicare appeals backlog, this RCD will almost certainly result in a return to the years-long logjam.

This practically ensures that initial denials from the MACs will serve as the final word on IRF claims, at least on a short-term basis, as IRFs wait years for neutral ALJs to determine coverage. It will also lead to IRFs preemptively rejecting admission of some patients (i.e., stroke, debility) they expect the MAC will deny, what has been referred to as the “gatekeeper effect.” Despite stakeholder comments to this effect during the previous comment period, CPR is disappointed that CMS does not propose any expedited or separate appeals process to accommodate timely denials under the RCD, which could have a far less negative impact on patients than we expect the current RCD model will have.

IRFs are not able to operate in a vacuum. As the expected pre-claim denials under the RCD pile up, facilities will necessarily be forced to shift their provision of care, likely over the objections of rehabilitation physicians. While we expect that many providers will seek to appeal these denials and justify their medical reasoning for admitting these patients, IRFs can only tolerate so many appeals before rehabilitation physicians begin to limit admissions of patients with conditions that are routinely denied under the RCD — even if the treating rehabilitation physician believes they qualify for and are in need of inpatient rehabilitation care.

The RCD Will Put Patients with Certain Conditions at Risk

We are particularly concerned that patients whose conditions may be atypical of the need for IRF care (but who nonetheless meet the level of medical care provided in an IRF) are likely to be turned away as a result of this “gatekeeping” effect under the RCD. This may lead to large swaths of patient diagnoses or other characteristics being presumptively denied under this demonstration. Restricting coverage through an accountable, public notice and comment rulemaking would be bad enough for CMS to pursue, but deputizing MACs to challenge every single IRF admission to pressure rehabilitation physicians to deny patients access they otherwise believe they qualify for is highly problematic and should not be pursued.

Despite the IRF payment system’s attempt to sort all beneficiaries into neatly defined categories, identifying a single definition of an IRF patient is not a simple task. The current IRF regulations have some recognition of this, requiring 60% of IRF discharges to be admitted with a primary diagnosis or comorbidity of at least one of 13 specified conditions, and leaving additional flexibility for patients in need of intensive rehabilitation without those specific diagnoses. However, these diagnoses do not, in and of themselves, qualify a patient for IRF admission under CMS’ criteria, though the clinical evidence may strongly support this setting of care for such conditions. The IRF regulations place great emphasis on the role of the rehabilitation physician to admit patients who meet the medical necessity criteria for IRF care, and yet, CMS appears — through this RCD — to be undercutting its own process the agency established in a significant revision to the IRF coverage regulations in 2010.

For example, the American Heart Association/American Stroke Association released clinical guidelines¹ for adult stroke rehabilitation and recovery in 2016, which included findings that IRFs are the most appropriate setting of care for all stroke patients. Unfortunately, many IRF claims for stroke patients are denied due to an alleged lack of medical necessity. Similar trends can be seen for patients with so-called “mild” traumatic brain injury (TBI), incomplete spinal cord injury (SCI), and “debility,” which often occurs after a prolonged hospital stay. These injuries, by and large, are not “mild” conditions – they typically have significant, long-term impacts on patients’ health and function, and intensive rehabilitation provided in an IRF is often critical to achieving the best outcomes for these patients. IRFs also often find that patients with initially “mild” conditions face severe long-term outcomes if not provided with early and intensive medical rehabilitation. This demonstration will make it harder for these patients to access appropriate care when they need it.

We expect that the proposed RCD will result in even higher numbers of these patients’ claims being denied through both the pre-claim and post-payment review process. As previously stated, these denials, even if they are eventually overturned on appeal (as many are likely to be), will, over time, serve to curtail IRFs’ ability to accept these patients at the outset and will likely lead to categorical denials based on certain conditions. This runs counter to the requirement under the IRF regulations to make individualized, case-by-case admission decisions and will result in significantly worse outcomes when patients cannot get the care they require.

We remind the agency that such categorical decisions are likely to amount to denials based on “rules of thumb.” As the agency is aware, *Hooper v. Sullivan*² makes it clear that rules of thumb *cannot* be used to deny IRF admission, and that Medicare coverage should be based on an individual assessment of what services are actually required by each patient. This, of course, is the process IRFs are required to follow under the existing coverage regulations, and the rehabilitation teams in these facilities do so based on their examination(s) of the patient, the patient’s record, and their specialized medical judgment.

¹ 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 *STROKE* e46 (2018), <http://stroke.ahajournals.org/content/49/3/e46>.

² *Hooper v. Sullivan*, No. H-80-99 (PCD), 1989 WL 107497 (D. Conn. July 20, 1989).

The RCD Will Impact Other Settings Beyond IRFs

Further, the ripple effects of denying qualified individuals access to IRF care will expand far beyond only the IRF sector. When patients are turned away from IRFs, either due to denials under the RCD or the inevitable gatekeeper effect that will ensue from the program, they will still be in need of care. Patients who should be directed into the post-acute care system in a timely manner but who remain in acute care hospitals are likely to further debilitate, as these facilities will not be able to provide the intensive rehabilitation treatment they need. This is already seen too often in the Medicare Advantage program, when patients are unable to secure a timely approval for an IRF admission, often leading to negative impacts on their long-term health and function.

Acute care hospitals are often in need of available beds to fill with new patients. If IRF admissions are delayed, acute care hospitals will not have the luxury of waiting. They will place the patient in a setting that is willing to take them. In this instance, patients will be funneled to other post-acute care settings that cannot provide the level of intensive rehabilitation provided in an IRF and, thereby, risk worse outcomes. CMS has already reduced the availability of so-called “ultra-therapy” in skilled nursing facilities (SNFs) under the Patient-Driven Payment Model (PDPM), and by the agency’s own admission, access to therapy in these settings has decreased dramatically since the PDPM’s implementation. Similarly, the home health setting is simply not equipped to treat patients with severe injuries, illnesses, disabilities, or chronic conditions – IRF patients, by definition, are not ready to return home. This influx of patients into settings inappropriate for their medical needs will also serve to further exacerbate existing caregiver shortages, which will negatively impact not only those patients denied from IRFs but patients across the post-acute care spectrum.

Necessary Safeguards to Protect Patients Under the RCD

For all the reasons enumerated above, we strongly believe CMS must entirely refrain from implementing this proposal. However, given that CMS largely dismissed the comments submitted after the initial comment period, we also recognize that CMS seems intent on moving forward with this misguided demonstration. Therefore, we offer several critical recommendations for revisions to the proposal in order to minimize (to the extent possible under the RCD structure) the negative impact on Medicare beneficiaries. We have limited these recommendations to only the most essential changes necessary to protect patients, though we note that there are myriad other revisions we would support in order to decrease the risk of patient harm under this proposal.

Robust Audit Process for Contract Reviewers

CMS states in the supporting materials for the RCD that there will be “continued oversight of all MAC activities under this demonstration.” We appreciate that the agency has recognized the need for “auditing the auditors” and ensuring that the MACs are correctly carrying out their expanded duties under the demonstration. We urge the agency to expand the proposed reviews of a “selection” of requests and claims, especially for those denials based on medical necessity. It is critical that these decisions be thoroughly vetted by the agency under a robust audit process,

rather than treated as simple administrative or technical reviews such as those related to fulfilling documentation requirements. We encourage CMS to implement significant training and regular continuing education for reviewers on the IRF coverage criteria, including the role of the rehabilitation physician and care team in conducting clinical evaluations and making medical decisions around the need for a patient's admission to the IRF setting.

Expedited Appeals to Reduce the Gatekeeper Effect

CMS states that if a provider believes a claim is inappropriately denied by a reviewer during the RCD, they can submit the claim for payment under the typical process and, if then denied by CMS, they can appeal the denial. As stated in previous comments, the Medicare appeals process takes years to obtain an independent Administrative Law Judge (ALJ) decision on each denied claim. We expect the uptick in claims denied during the pre-claim or post-payment review process to exacerbate the current ALJ backlog, leading the initial denials to practically serve as the final word on whether a claim can be approved, at least in the short term. In order to minimize the expected "gatekeeper" or "sentinel" effect that, we believe, will result from categorical denials under the RCD, we urge CMS to implement a "discussion" requirement between clinicians at the MAC and the IRF before a claim can be denied. This will allow providers to more quickly address the longstanding disagreements between trained rehabilitation physicians and Medicare's contractors regarding medical necessity and help reduce the likelihood that groups of patients will be denied access to IRF care under the proposed demonstration.

Public Data Reporting to Identify Impact on Access

Though CMS believes that beneficiary access will not be impeded by the RCD, we strongly disagree and question why CMS has taken this position without supporting evidence. If the agency insists on moving forward with this demonstration program, it is critical that CMS collect and publicly report data on IRF admissions, discharges, and denials as soon as possible after the RCD implementation and on a regular basis throughout the five-year duration of the demonstration project. With the significant change in access to IRF care that we expect, the agency should report a broad range of data to ensure that stakeholders and patient advocates are sufficiently able to understand the potential barriers to accessing care under the new program. Additionally, transparent and detailed data will allow stakeholders to identify types of patients and diagnoses that are most at risk for excess denials under the RCD and work to ensure that the MACs do not employ "rules of thumb" to deny access to certain patients based largely on diagnosis.

Conclusion

We again urge CMS to fully withdraw this harmful proposal. We recognize that the agency and its contractors have an important role to play in the investigation and prosecution of fraud and abuse in the Medicare benefit and, again, would welcome discussion on ways to achieve CMS' goals without risking access to patient care. The RCD clearly risks access to patient care in our view. We believe this demonstration is severely flawed, and would have the effect of fundamentally changing the IRF benefit, restricting access for some of the Medicare program's

most vulnerable beneficiaries. Further, it would empower the MACs, private companies intended to assist in administering the Medicare program, to supersede physician judgment and determine medical necessity without ever directly evaluating the patient.

We appreciate your attention to our serious concerns involving this proposed demonstration. Should you have any further questions regarding these comments, please contact Peter Thomas and Joe Nahra, coordinators for CPR, by e-mail at Peter.Thomas@PowersLaw.com and Joseph.Nahra@PowersLaw.com, or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the Coalition to Preserve Rehabilitation.

ACCSES

American Academy of Physical Medicine and Rehabilitation

American Congress of Rehabilitation Medicine

American Music Therapy Association

American Occupational Therapy Association

American Speech-Language-Hearing Association

American Spinal Injury Association

American Therapeutic Recreation Association

Association of Academic Physiatrists

Association of Assistive Technology Act Programs

Association of Rehabilitation Nurses

Association of University Centers on Disabilities

Brain Injury Association of America*

Center for Medicare Advocacy*

Christopher & Dana Reeve Foundation*

Clinician Task Force

Disability Rights Education and Defense Fund

Falling Forward Foundation*

National Association for the Advancement of Orthotics and Prosthetics

National Association of Social Workers (NASW)

National Association of State Head Injury Administrators

National Disability Rights Network (NDRN)

National Multiple Sclerosis Society*

Paralyzed Veterans of America

Rehabilitation Engineering and Assistive Technology Society of North America

Spina Bifida Association

United Cerebral Palsy

United Spinal Association*

**** CPR Steering Committee Member***