FAIR FUND
Fund for Access to Inpatient Rehabilitation

October 8, 2021

VIA ELECTRONIC SUBMISSION: WWW.REGULATIONS.GOV & WWW.REGINFO.GOV

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Comments in Response to Agency Information Collection Activities; Proposed Collection; Comment Request; CMS–10765**

Dear Administrator Brooks-LaSure:

The Centers for Medicare and Medicaid Services (CMS) must withdraw its proposed Review Choice Demonstration (RCD) project for inpatient rehabilitation facilities (IRFs). The RCD will shrink the IRF benefit by excluding certain types of patients. The RCD is an improper end run around CMS's obligation to promulgate coverage requirements for IRF services through notice and comment regulations.

We have seen this before. The Fund for Access to Inpatient Rehabilitation (FAIR) was formed in 2007 during the Recovery Audit Contractor (RAC) demonstration project. Leaders in the IRF field formed FAIR because they were extremely alarmed that the RAC assigned to California was improperly denying thousands of IRF claims. The California RAC targeted certain types of patients, in particular patients receiving IRF care following a lower-extremity joint replacement. In response to concerns by FAIR and other IRF organizations, CMS paused the RAC demonstration project in California, and that RAC reassessed and reversed its denials of 40% of IRF claims. Most of the remaining denials were repaid to IRFs on appeal.

But the assault on joint replacement patients—a diagnostic category of patients—did not end there. CMS simply shifted it to Medicare Administrative Contractors (MACs) and other audit contractors, who continued to audit these claims aggressively, denying thousands of these patients access to an IRF level of care to which they were entitled. IRFs appealed, usually successfully, and eventually vindicated their admissions decisions. IRFs could not, however, continue over time to admit patients that were known targets of Medicare auditors. All IRFs must cover their costs and, like any organization, cannot provide free services and survive. The burden of systematically appealing these cases was too much to endure, and joint replacement patients in the aggregate lost access to IRF care.

We raise this history not to debate the relative merits of treating joint replacement patients in IRFs. Rather, we see the joint replacement example as a clear sign—and a disturbing pattern—that CMS intends to mold the IRF benefit through restrictive audits rather than through

regulations. The result is that, today, the chances of a Medicare beneficiary who has a lower extremity joint replacement receiving rehabilitation in an IRF are slim-to-none, regardless of their comorbidities. This coverage preclusion is not written down in any policy that a beneficiary can see. It is a de facto policy that CMS imposed under cover of darkness through aggressive auditing practices.

CMS apparently intends to use this same basic tactic to exclude other types of patients from IRFs through the RCD. In recent years, we have seen disturbing patterns in Medicare audits that very much echo CMS's earlier preclusion of joint replacement patients. The target more recently has been stroke patients, patients suffering from debility, and other conditions. These are patients that meet the IRF coverage requirements because they have lost significant functional abilities and are medically compromised, so they need intensive rehabilitation that is overseen by a physician with training and experience in rehabilitation. Indeed, both the American Heart Association and the American Stroke Association recommend IRF care for ***all*** stroke patients.[1]

Yet, over and over we see auditors denying coverage for these cases, either asserting that the patients are too sick to participate in intensive rehabilitation or are not sick enough for physician supervision. These findings usually fly in the face of medical records showing that the patients did, in fact, participate in intensive rehabilitation and need physician supervision. Auditors apply what IRFs call the "Goldilocks Rule" in which patients are either too sick or not sick enough for IRF admission, and virtually no patient fits between these confines. CMS officials have admitted to this unwritten rule in conversations with IRF stakeholders but do not acknowledge it publicly. IRFs and admitting rehabilitation physicians see it in practice all the time.

The heart of the problem is that IRF admission decisions are complex medical judgments. The admitting physician must weigh both the patient's need for intensive rehabilitation and physician oversight and supervision while the patient undergoes a rigorous therapy program. The rehabilitation physician manages not just the patient's comorbid conditions but leads the rehabilitation team to ensure that the patient can complete the IRF program. CMS requires IRF admissions to be decided by physicians with training *and* experience in rehabilitation.[2] Yet, CMS requires nothing of the sort from its audit contractors, which typically employ nurses or therapists to second-guess the admission decisions of the rehabilitation physicians who actually see and treat Medicare patients.

FAIR and other IRF stakeholders have complained to CMS again and again about substandard audit contractors who do not understand IRF care and do not employ qualified reviewers. CMS has changed nothing. We can only conclude that these contractors are doing

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[1] *See* William J. Powers, et al., 2*018 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] 42 C.F.R. § 412.622(a)(3)(iv), (a)(4)(i)(A), (c).

exactly what CMS wants: they are auditing and denying IRF claims using preconceived, secret rules of thumb to deny the IRF benefit to certain types of patients they deem unworthy of IRF care.

Thus, the high error rates that CMS cites as justification for the RCD have no credibility in the IRF field.[3] We see these alleged "error" rates as simply building a pretext justifying the end goal of reducing the IRF benefit: CMS sends auditors to deny certain types of claims; the auditors deny large numbers of these claims, asserting high error rates; CMS uses these ginned-up error rates to justify an RCD that will audit 100% of claims in the targeted states; and IRFs are forced to stop treating the targeted patients or risk major financial consequences, even closure.

We know what will happen if the RCD goes forward. We saw it before with joint replacement patients. MACs will deny thousands of claims for patients with targeted conditions. IRFs will suffer high error rates. Cash flow will dwindle as payment is denied and the appeals process clogs with new appeals. Some IRFs will close. The rest will have no choice but to alter their admission decisions and stop treating the types of patients targeted by the auditors. In the end, the IRF benefit will be altered once again, yet Medicare beneficiaries will not know it. CMS will have imposed another de facto IRF coverage screen through the force of audits.

This is wrong. CMS owes the American people honesty about Medicare coverage. If CMS wants to shrink the IRF benefit to a particular subset of current patients, it should tell Medicare beneficiaries and IRFs exactly what it is doing and why, instead of hiding behind its audit contractors. CMS should enter into an open discussion with medical professionals, beneficiary organizations, and other stakeholders about which patients should and should not be treated in an IRF. The rules should be clear, medically sound, and easy to find. The rules should not be imposed by unqualified auditors making conclusory statements about the patient's need for physician supervision or intensive rehabilitation.

What CMS is pursuing with the RCD is not just wrong, it is also unlawful. The Medicare statute requires CMS to determine coverage by regulation or national coverage determination (NCD):

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[3] 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*, 4 (citing CERT reports), *available at* https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10765. CMS also cites an audit by the Office of Inspector General (OIG). *Id.* (citing OIG, *Many Inpatient Rehabilitation Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements* (Sept. 2018)). We acknowledge that OIG is separate from CMS. However, OIG has admitted to IRF stakeholders that it lacks the expertise to audit IRF claims and therefore relies on contractors. The OIG audit in question was performed by Maximus, which has a long history as a CMS contractor. Thus, the OIG audit also lacks credibility because OIG simply relies on the same cast of rotating contractors as CMS.

> 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 . . . .[4]

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 NCD.[5] The Medicare statute imposes even greater procedural requirements on CMS than the Administrative Procedure Act.[6] 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.

CMS is also forbidden from denying IRF coverage using "rules of thumb."[7] Over thirty years ago, CMS entered into a settlement agreement in which it committed not to deny IRF "admissions, services, and/or Medicare coverage based upon numerical utilization screens, diagnostic screens, diagnosis, specific treatment norms, the 'three hour rule,' or other 'rules of thumb' . . . ."[8] This should by now be a bedrock principle of IRF coverage, but we are very concerned that the RCD will result in diagnostic screens and other inappropriate "rules of thumb" in violation of *Hooper v. Sullivan*.

People's lives are at stake. Quality of life is also at stake. Treatment in an IRF has been demonstrated to increase longevity.[9] IRF care also greatly increases a patient's chances of living at home.[10] IRFs accomplish this with a wholistic approach to care that is provided by a multidisciplinary team of professionals. Not everyone needs IRF care, but the decision about who gets access to IRF care should be left to qualified rehabilitation physicians, rather than non-physician auditors who have little training in the field of medical rehabilitation or clinical experience in caring for IRF patients. CMS's restrictive audits inappropriately take patients out of IRF care and instead put them in non-hospital settings where they will receive inadequate rehabilitation therapy and no meaningful physician oversight. Patients will suffer. Some may die, and others will remain institutionalized and never return to their homes and communities to live as independently as possible, ironically, a goal of the current administration.

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[4] 42 U.S.C. § 1395hh(a)(2).
[5] *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).
[6] *Id.*
[7] *Hooper v. Sullivan*, No. H-80-99 (PCD), 1989 WL 107497 (D. Conn. July 20, 1989).
[8] *Id.*
[9] Dobson DaVanzo & Assocs., LLC, *Assessment of Patient Outcomes of Rehabilitative Care Provided in Inpatient Rehabilitation Facilities (IRFs) and After Discharge*, E-3 (2014), https://www.sutterhealth.org/pdf/services/physical-therapy-rehabilitation/patient-outcomes-of-irf-vs-snf.pdf.
[10] *Id.*

CMS must withdraw its proposed RCD for IRFs. The RCD is misguided, unlawful, and will harm patients. 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 questions or would like to contact FAIR, please call or email FAIR's counsel, Ron Connelly, at (202) 872-6762 or Ron.Connelly@PowersLaw.com.

Sincerely,

Mary Beth Walsh, M.D.
President, FAIR

Attachment

Attachment

FAIR FUND
Fund for Access to Inpatient Rehabilitation

February 16, 2021

VIA ELECTRONIC SUBMISSION

Elizabeth Richter
Acting Administrator
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10765 (OMB Control Number 0938–NEW)
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments in Response to Agency Information Collection Activities; Proposed Collection; Comment Request; CMS—10765

Dear Acting Administrator Richter:

The Fund for Access to Inpatient Rehabilitation ("FAIR") appreciates the opportunity to comment on the proposed information collection activity by the Centers for Medicare and Medicaid Services ("CMS") entitled Review Choice Demonstration for IRF Services ("RCD").[1] The RCD outlines a proposed demonstration project involving 100% review of claims submitted by inpatient rehabilitation hospitals and units (commonly referred to as "inpatient rehabilitation facilities" or "IRFs") located within certain selected states. FAIR is a non-profit organization of inpatient rehabilitation hospitals that is devoted to ensuring patient access to inpatient hospital rehabilitation under the Medicare program. Medicare beneficiaries with significant disabling conditions, such as stroke, brain injury, multiple sclerosis, spinal cord injury, and amputation, rely on IRFs to provide critically important rehabilitative care to improve beneficiaries' health status and ability to function.

The RCD would critically impact FAIR's members and likely reduce access to care for vulnerable Medicare patients. For several reasons based on law and policy, we strongly urge CMS to withdraw the RCD proposal.

The proposed RCD has numerous flaws that are detailed below. The IRF field fundamentally disagrees with CMS's audit contractors about the proper standards for admitting patients. CMS should seek consensus with the IRF community before launching such a broad-based demonstration. Moreover, implementing a sweeping revision to Medicare audit

[1] 85 Fed. Reg. 81,208 (Dec. 15, 2020).

procedures through an information collection request, rather than through formal rulemaking, is inappropriate.

The scope of this demonstration program is breathtaking. CMS identifies the target population of respondents as all IRFs located within Alabama, Pennsylvania, Texas, and Florida, a total of 526 IRFs according to the information collection notice. CMS estimates the "Number of Responses"—which we interpret to mean claims to be reviewed under the RCD—at nearly 180,000, coincidentally the approximate number of all claims currently pending in the Administrative Law Judge ("ALJ") backlog. This is an enormous number of claims, averaging 342 charts per IRF across those states. The information collection notice also indicates CMS's intention to expand the demonstration further, without any timeline or framework to evaluate the outcome and impact of the demonstration.

Additional safeguards are necessary to ensure that CMS complies with statutorily-prescribed procedures for promulgating certain Medicare rules, requirements, and other statements of policy and that CMS not use its authority to implement demonstration projects as a means of instituting a brand new de facto auditing mechanism outside the appropriate processes and procedures for doing so. We also have serious concerns about CMS's authority to implement the RCD and the relative wisdom of doing so as outlined in the information collection notice.

CMS Must Come to a Consensus With the IRF Field and Improve the Quality and Qualifications of Its Reviewers Before Undertaking Such a Sweeping Revision to Audit Procedures

CMS and its contractors have been actively auditing IRFs for over 15 years. This long, unfortunate history of IRF audits has revealed that the medical professionals (i.e., rehabilitation physicians) who actually treat Medicare beneficiaries have good faith disagreements with the often unqualified audit contractors about the medical necessity of IRF services. CMS should work with IRFs to come to a consensus about how to apply the standards for IRF care and the qualifications necessary for its reviewers. We contend that only rehabilitation physicians are qualified to review the admission decisions of other rehabilitation physicians.

In 2005, CMS unleashed the Recovery Audit Contractor ("RAC") demonstration project in three states, including California. The California RAC focused almost exclusively on IRFs and improperly denied thousands of claims, severely damaging rehabilitation care in that state. CMS eventually had to step in and halt the IRF audits and ordered the RAC to immediately repay nearly half of the denied claims. Most of the remaining denials were appealed and overturned in favor of IRFs.

In 2010, CMS issued a revised IRF coverage regulation that CMS claimed would bring clarity to coverage and place more emphasis on physician judgment. Instead, CMS's contractors used the regulation to deny medically necessary care through trivial documentation errors, and contractors continued to impose subjective medical necessity standards that are not stated in the

regulation. Typical examples include denials based on the assertion that the care "could have been provided in a less intensive stetting" or that the patient did not need physician supervision because he or she was stable on admission. The first rationale is not stated in the regulation. The second rationale is flatly wrong because the regulation actually requires the patient to be stable in order to be admitted to an IRF.

In 2018, the Office of Inspector General ("OIG") conducted an audit of nationwide IRF claims from 2013 and alleged that 84% of the claims were improperly paid. Although this was not a CMS audit, OIG uses the same audit contractors as CMS, and OIG has admitted that it lacks the expertise to audit IRF claims itself. The OIG's findings are not credible. In fact, in the same year, 2013, the Comprehensive Error Rate Testing ("CERT") contractor, found a 17.2% IRF error rate. OIG found an IRF error rate five times higher than the contractor tasked with determining error rates for various types of providers, underscoring the inconsistency in IRF claim reviews. Our review of several of the OIG reviewers' decisions leaves us with serious doubts about the reviewers' qualifications.

Furthermore, CMS has tacitly acknowledged reservations about the actions of the contractors. In June 2019, CMS announced a global settlement that permitted many IRFs to settle their outstanding claim appeals for 69% of the Medicare allowed amount of each claim (and 100% for certain categories of denied claims). This settlement was the highest percentage ever in a CMS global settlement for payment of Medicare claims, clearly demonstrating at least some reservations by CMS about the accuracy of its contractors' determinations—the very same contractors that were involved in the 2018 OIG audit and will likely lead claim reviews under the RCD. In fact, for CMS to agree to reimburse providers 100% for certain IRF claims is an implicit admission that these denials were simply wrongly decided and never should have been denied in the first instance.

IRF care is unique and defined both by standards of medical practice and regulation. To be appropriate for rehabilitation in an IRF, a patient must need intensive rehabilitation and medical management. Crucially, however, the two cannot be evaluated in isolation. The standards for medical management in an IRF are not the same as in a general acute care hospital. Patients who require an acute care level of medical management are generally not capable of participating in intensive rehabilitation. Medical management must be evaluated *in conjunction* with the patient's rehabilitation needs. Likewise, the patient's need for rehabilitation therapies and ability to participate in intensive therapy must be assessed in light of the medical management available in the IRF. This is a complex, nuanced judgment that can only be made by a rehabilitation physician. This is no doubt why CMS requires by regulation that IRF care be provided by a physician with training and experience in rehabilitation.

Yet, after establishing this standard for rehabilitation physicians, CMS inexplicably intends to hire audit contractors who employ nurses or non-rehabilitation physicians to second guess the medical judgment of the experts who CMS has deemed appropriate to admit patients to IRFs. Not surprisingly, these unqualified reviewers typically get it wrong more often than not. In the experience of FAIR's members, these reviewers deny claims because a patient is not sick

enough for a general acute care unit, failing to understand the interplay between medical management and therapies in an IRF. Or reviewers deny claims by asserting that the patient's functional deficits are too severe or not severe enough without considering how the rehabilitation physician's medical management plays into the patient's rehabilitation program. IRF patients are complex, and there is a wide continuum of medical and rehabilitation needs that can qualify a patient for IRF care. This complexity is simply lost on most CMS auditors who lack professional knowledge and experience with inpatient rehabilitation.

CMS now proposes to compound these errors by starting a 100% review demonstration with nurse reviewers. CMS would be extremely irresponsible to launch a 100% review of IRF claims without first coming to a consensus with the IRF field about the standards for IRF care and committing to hiring qualified reviewers. If CMS proceeds with the RCD as currently described, thousands of medically necessary claims will be denied, and patients will be harmed because IRFs will have no choice but to restrict admissions to placate audit contractors to avoid recoupments and a years-long appeals process.

CMS Lacks the Authority to Implement the Review Choice Demonstration

CMS cites 42 U.S.C. § 1395b-1(a)(1)(J) as the source of its authority to implement the RCD. This statute does not support the implementation of the RCD. Section 1395b-1(a)(1)(J) permits the development of demonstration projects for "improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." The provision explicitly requires fraud to be the target—not simply payment error or problems with medical record documentation. Nowhere in the information collection notice does CMS allege that the IRFs to be subject to the RCD are suspected of committing fraud. It is implausible that CMS could make such a sweeping allegation against more than 500 individual, unrelated IRFs.

Even in a largely unfavorable audit of the IRF field performed by the OIG in 2018 (the findings of which we strongly dispute), OIG made no allegations of fraud, only payment error and technical documentation deficiencies. Allegations of fraud require, among other elements, at least a preliminary showing that the individual had knowledge that the statements made were, in fact, false and that the individual intended to deceive the alleged victim.[2] IRFs' submissions of claims that they believe to be the result of providing medically necessary and reasonable care (as defined by the service-specific coverage criteria) cannot meet these requirements.

And yet, fraud is the rationale CMS uses to justify the expansive RCD by stating: "This demonstration will assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud." However, in the very next sentence, CMS

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[2] *See, e.g.*, *Herrera-Roca v. Barber*, 150 F.Supp. 492, 494 (N.D. Cal. 1957) (citing *Reilly v. Pinkus*, 338 U.S. 269, 276 (1949)) ("An erroneous statement in itself does not establish fraud in the absence of proof of both knowledge and intent to deceive.").

clarifies that by "fraud" it really means simple payment error. CMS states, "The demonstration will ensure that payments for IRF services are appropriate through either pre-claim or postpayment review, thereby working towards the prevention and identification of potential fraud, waste, and abuse, as well as protecting the Medicare Trust Funds from improper payments while reducing Medicare appeals." Thus, CMS's allegation of potential fraud is merely cover for it to develop a demonstration project that it otherwise lacks the authority to implement.

Moreover, even if 42 U.S.C. § 1395b-1(a)(1)(J) could justify the RCD in general, it could not justify denials for technical documentation deficiencies. The statutory provision explicitly limits its reach to "fraud in the provision of care or services," which does not extend to mere deficiencies in documentation if the overall care can otherwise be determined to be medically necessary. This is an important limitation in the statutory authority for demonstration projects that CMS must respect because CMS contractors commonly deny IRF claims for technical documentation errors, which is not "the provision of care or services."

There Is No Basis for Imposing 100% Claim Review on IRFs

In its Program Integrity Manual ("PIM"), CMS itself notes the severe nature of 100% claim review as an auditing tool, particularly on a pre-payment basis.[3] The PIM explicitly recommends that Medicare Administrative Contractors ("MACs") reserve the "most substantial administrative actions available, such as 100 percent prepayment review of claims" for serious problems. To impose such a review now, through a demonstration project, without any prior finding that any specific IRF has serious compliance problems is inconsistent with CMS's own auditing policies.

To our knowledge, the 526 IRFs that would be subject to the demonstration project (as well as the other IRFs to be included upon expansion) have not had the benefit of any probe audit to determine whether they are individually responsible for any payment errors. To the contrary, it is extremely likely that many of these IRFs have already successfully completed audits under CMS's Targeted Probe and Educate ("TPE") program. Any IRFs that successfully completed their TPE audits should not now be subject to the draconian requirements of 100% review; those IRFs that did not successfully complete their TPE audits have presumably been identified for further action, pursuant to the requirements and procedures of the TPE program.

Though it does not specifically cite the grounds for its focus on IRFs (or the particular states selected for the demonstration), possible sources for CMS's focus are the aforementioned OIG audit—Audit A-01-15-00500, issued in September 2018—and the CERT audits referenced by the OIG. While the payment error rate identified by the OIG audit and CERT audits are indeed high, as already discussed, the IRF field widely disagrees with the conclusions of these audits and CMS tacitly acknowledged the IRF field's position by agreeing to such favorable terms in the IRF global settlement. In fact, CMS itself has discredited the use of CERT audit results to identify payment error-prone providers, finding that "CERT data was ineffective for

[3] CMS Pub. 100-08, ch. 3, § 3.1.A.

this purpose" because the measurement guidance used in the CERT audits lacks proper precision guidance with respect to provider-level data.[4]

The RCD Would Be Incompatible With the Mandamus Order in *AHA v. Azar* to Eliminate the ALJ Backlog

On November 1, 2018, the U.S. District Court for the District of Columbia ordered the Department of Health and Human Services ("HHS") to eliminate the lengthy backlog of appeals pending before ALJs. The District Court established annual percentages for HHS to reduce the backlog and to eliminate it entirely by the end of Fiscal Year 2022. Contrary to CMS's statement in the RCD that this demonstration project will reduce Medicare appeals, the RCD will result in a flood of new appeals into the system, which is inconsistent with the mandamus order and will force IRFs to wait years to vindicate their admissions and receive payment.

The RCD will certainly cause a tremendous spike in appeals. CMS estimates that the demonstration will result in the review of almost 180,000 claims over the course of a year. Such an increase would have a detrimental impact on HHS's ability to clear the appeals backlog as ordered by the District Court, and it is irresponsible of CMS to consider implementing a program that is likely to jeopardize its successful satisfaction of the court's order.

Moreover, CMS should take into account the results of any appeals when calculating the impacted IRFs' error rates,[5] and the resulting delay in appeal decisions would jeopardize the ability of IRFs to escape the onerous requirement of 100% review. It is unclear from the information collection notice what impact a single denied claim upon follow up review might have on an IRF's status under the demonstration. Again, in such situations, access to a timely appeals process will be critical to an IRF's ability to avoid the unjustified re-imposition of 100% review.

CMS's Proposed Review Choice Demonstration May Incorporate Elements that Are Contrary to Law

The information collection notice issued by CMS contains little in the way of meaningful detail about the actual operation of the RCD. However, CMS has provided additional clarification in its supporting documents. These two issuances leave us with grave concerns that the demonstration will run afoul of several legal requirements applicable to CMS.

[4] Letter from Seema Verma, Administrator of CMS, to Christi Grimm, Principal Deputy Inspector General, dated November 23, 2020.

[5] If CMS proceeds with the RCD, we urge CMS to incorporate mechanisms in the final demonstration that explicitly and timely account for each IRF's successful appeals.

First, the regulations governing admission to an IRF explicitly require an individualized determination of each patient's need for admission.[6] Given the severity of 100% claim review and its potential to cripple an IRF's Medicare reimbursement based on skewed interpretations of the coverage criteria, IRFs impacted by the RCD may be left with little option but to decline admission of entire categories of patients based on nothing more than their etiological diagnosis rather than an individualized review of their condition and care needs. The RCD thereby forces rehabilitation physicians and IRFs to deny admission based on "rules of thumb" which are expressly prohibited under federal case law.[7] To do otherwise will subject the IRFs to predictable, but unreasonable, denials.

For a smaller IRF unit, even a single denied claim could ruin its chance of achieving 90% compliance or cause it to be re-subjected to 100% review. To avoid such detrimental consequences, IRFs will be forced to limit or even eliminate admissions of patient types that are the focus of contractor denials. This allows contractors to browbeat providers into compliance with their narrow view of coverage (especially if access to timely appeals does not exist).

Second, the supporting documents provided by CMS specify that the reviews carried out under the RCD will be performed by trained nurse reviewers. As we have explained, an IRF admission is a complex medical judgment that must be made by a rehabilitation physician. Since the decisions of the reviewers is a de facto decision about whether a patient should be admitted to an IRF (especially in the context of pre-payment claim reviews), and the regulations explicitly require such decisions to be made by a rehabilitation physician,[8] the use of nurse reviewers is contrary to the regulation.

Nurses trained in rehabilitation play an important role in delivering IRF care, but they should not be placed in the position of systematically superseding the medical judgment of treating rehabilitation physicians, especially based solely on the written record. Therefore, all IRF claims should be reviewed exclusively by rehabilitation physicians who meet the same regulatory requirements as rehabilitation physicians making admission decisions.

Finally, but not least importantly, neither the information collection notice nor the supporting documents provided by CMS include any information for evaluating the impact of this so-called demonstration project. There is no assessment methodology provided and no timeframe for review of the program's utility and effectiveness. Nor is there any review methodology to assess its effectiveness prior to expanding it in later years. Rather than a demonstration, CMS appears to be rolling out what amounts to a new auditing program. This is contrary to the statutory provisions cited by CMS as the source of authority for the RCD. Consequently, CMS must either reformat the demonstration so that it actually resembles a

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[6] *See* 42 C.F.R. § 412.622(a)(3), (b); *see also* Medicare Benefit Policy Manual, CMS Pub. 100-02, ch. 1, § 110 ("Medicare requires determinations of whether IRF stays are reasonable and necessary to be based on an assessment of each beneficiary's individual care needs.").
[7] *Hooper v. Sullivan*, No. H-80-99 (PCD), 1989 WL 107497 (D. Conn. July 20, 1989).
[8] *See* 42 C.F.R. § 412.622(a)(4)(i)(D).

demonstration (rather than the initial stages of a permanent shift in auditing for IRFs) or cease its efforts to implement the RCD.

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Thank you for the opportunity to comment on the information collection notice introducing CMS's proposed RCD for IRFs. If you have questions or would like to contact FAIR, please contact FAIR's counsel, Peter Thomas (Peter.Thomas@PowersLaw.com) or Ron Connelly (Ron.Connelly@PowersLaw.com).

Sincerely,

Mary Beth Walsh, M.D.
President, FAIR