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January 28, 2021

Liz Richter
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-10765
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted via regulations.gov

Re: CMS-10765, "Review Choice Demonstration for Inpatient Rehabilitation Facility (IRF) Services," December 15, 2020

Dear Acting Administrator Richter,

On behalf of Uniform Data System for Medical Rehabilitation (UDSMR) and the more than nine hundred inpatient rehabilitation facilities we provide services to, we welcome the opportunity to present our comments on CMS-10765, "Review Choice Demonstration for Inpatient Rehabilitation Facility (IRF) Services," which was published on December 15, 2020, in the *Federal Register*. With over thirty years of experience, UDSMR provides coding, clinical, compliance, quality improvement, outcomes management, and technical support services to IRFs and other postacute care (PAC) providers. UDSMR appreciates the opportunity to provide ongoing feedback to CMS and hopes to work with CMS to create solutions that meet the needs of IRF providers and patients.

UDSMR urges CMS to reconsider implementation of its proposed Review Choice Demonstration for IRF Facility Services. This demonstration is premised by high overpayment or error rates reported by contractors that have conduced medical reviews of IRF claims, including recovery audit contractors (RACs), Medicare administrative contractors (MACs), the Supplemental Medical Review Contractor (SMRC), and the Comprehensive Error Rate Testing Contractor (CERT), as well as Office of Inspector General (OIG) reviews completed by independent contractors. Due to pervasive issues with the reviews, as described below, and the high rate of denial overturn on appeal, these error rates are highly likely to be overstated. Additionally, the 100% pre-claim or postpayment review is an extraordinarily burdensome proposal, particularly during this time of a public health emergency.

UDSMR urges reconsideration of the proposed Review Choice Demonstration for IRF services for the following reasons:

1. The IRF error rate is likely overstated due to pervasive issues with IRF reviews, including rendering nonspecific findings using generic statements, issuing denials not based on IRF regulations, issuing conflicting findings, and utilizing

inconsistent and arbitrary thresholds of medical and functional acuity for a reasonable and necessary IRF admission.

2. The high rate of overturning IRF denials on appeal supports the need to address issues with IRF reviews prior to implementation of a 100% review demonstration.
3. Recent IRF regulation changes, along with the implications of Azar v. Allina on medical reviews with the potential for payment denials, require revisions to CMS's training and guidance materials for IRFs and extensive retraining for any reviewing contractors. In order to promote consistent understanding of the IRF regulations, guidelines, and clarifications among providers and contractors and to narrow the gap in understanding and applying IRF regulations that currently exists between IRFs and contractors, this training and education should be consistent and transparent and should not be conducted in "silos."
4. A 100% review of IRF claims is extraordinarily burdensome, is counter to the "Patients over Paperwork" initiative, and will divert operational focus and resources away from patient and community needs, especially during the current public health emergency.
5. Aspects of the proposed demonstration are not well suited to IRF documentation requirements and do not conform to the latest IRF regulation changes. In addition, the burden on IRFs is underestimated.
6. Without a significant overhaul to address issues with current IRF reviews, a facility's error rate under this demonstration will likely be overstated, making it difficult for the IRF to reach a 90% affirmation or approval rate and therefore increasing the number of appeals.

UDSMR consistently attends CMS's trainings, analyzes and summarizes CMS's regulation and guidance, and frequently solicits the assistance of CMS resources, including multiple help desks, in order to support the accuracy and integrality of IRF documentation, compliance with CMS regulations and guidelines, and accurate coding and completion of the IRF-PAI for accurate billing and payment. We conduct frequent educational events, publish educational guides, and staff clinical and technical help desks in order to keep IRFs up to date. We have also helped IRFs appeal over 1,900 denied claims since 2010, which has allowed us to review the findings of Medicare contractor and OIG medical record reviews firsthand. We review each medical record and the associated review findings in detail and compare both against the IRF regulations and guidance in the Code of Federal Regulations (CFR 42, §412.622) and the *Medicare Benefit Policy Manual* (*MBPM*, Publication 100-02, Chapter 1, §110), in addition to clarifications and training resources issued by CMS.

The nationwide IRF error rate, as estimated annually by the CERT, has dropped significantly since 2016 and is currently reported at 30.8% for both IRF hospitals and units, but this rate is still likely overstated due to common, pervasive issues with IRF reviews, including the following:

1. **Nonspecific findings for not meeting reasonable and necessary admission criteria.** The *Medicare Processing Claims Manual* instructs contractors to include "explicit rationale that describes why the items or services at issue do not meet Medicare guidelines. Merely stating that an item or service is 'not medically reasonable and necessary under §1862(a)(1)' or 'not medically reasonable and necessary under Medicare guidelines' does not provide any rationale. The rationale should include a description of the logic that led to the decision, references used to support the decision, and other information that is relevant to support the decision in the case." Despite this instruction, many IRF claim denial rationales use identical

generic statements regardless of the facts of the case. Statements such as these, made without any references to the case specifics that led to these conclusions, are commonly used to deny IRF claims:

- "The documentation did not support intensive therapy was reasonable or necessary."
- "The material submitted did not report medical or nursing needs so complex that close physician supervision was required."
- "The Pre-Admission Screen (PAS) did not describe complex functional impairments that required the intensity of IRF."
- "The documentation submitted for review did not support the beneficiary required an intensive rehabilitation therapy program."

These nonspecific and repetitive rationales are used to deny cases with a wide range of medical and functional acuity, often without any consideration of the patient's unique and specific circumstances. These general types of statements also do not address why the patient did not specifically meet the five criteria for a reasonable and necessary admission, as established in CFR 42, §412.622. The 2017 IRF audit conducted by the SMRC provided a particularly egregious example of this. SMRC issued only generic statements to IRFs in its "individual review results" and did not provide any case-specific information except for the beneficiary's name and the dates of service.

Generic rationales do not provide any useful feedback to IRFs, and they marginalize the medical and functional aspects unique to each case—aspects that do, in fact, support a reasonable and necessary admission.

2. **Denials not based on IRF regulations.** Many denial rationales fall outside of IRF regulations. The most common erroneous denial rationale is that the patient did not have any clinically unstable medical issues or comorbid conditions. The third criteria established in CFR 42, §412.622, for a reasonable and necessary IRF admission states that the patient "is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation therapy program." Perhaps the fact that §110 of the *MBPM* eliminated this criteria altogether has caused confusion among the contractors. Contractors tend to apply an erroneous standard of complex acute care need to IRFs even though this standard is clearly not what CMS intended and even though meeting this erroneous standard would render a beneficiary unable to participate in the intense effective course of therapy that is unique to IRFs. In accordance with the CFR, patients must be sufficiently stable in order to undergo intensive rehab, which is the primary reason for IRF care. If any given medical condition rendered a patient unstable, intensive rehab would be contraindicated. According to section 110 of the *Medicare Benefit Policy Manual*, "A patient who has not yet completed the full course of treatment in the referring hospital is expected to remain in the referring hospital, with appropriate rehabilitative treatment provided, until such time as the patient has completed the full course of treatment. Though medical management can be performed in an IRF, patients must be able to fully participate in and benefit from the intensive rehabilitation therapy program provided in IRFs in order to be transferred to an IRF." Despite this instruction, reviewers frequently cite a lack of acute, exacerbated, and/or unstable medical conditions as a reason for denying a case. Any denial rationale that cites a lack of unstable medical issues and/or comorbidities directly contradicts the CFR and is therefore invalid. In

the 2017 US District Court case Cumberland County Hospital Inc. v. Price, elaborated on below, the Court noted "as this [CFR] requirement indicates, a patient's status as stable would tend to substantiate that IRF care is reasonable and necessary, not the converse."

Another frequently cited reason for denying an IRF case is the reviewer's opinion that the patient could have been treated in a lesser level of care. Prior to 2010, IRF coverage criteria indicated that "it must be reasonable and necessary to furnish the care on the inpatient hospital basis rather than in a less intensive facility such as a skilled nursing facility or on an outpatient basis," but CMS eliminated this criteria when it instituted major IRF regulatory changes beginning in January 2010. During CMS's November 12, 2009, IRF training call, which is currently posted on CMS's IRF coverage requirements site, CMS stated, "Nowhere in this presentation are we going to talk about whether the patient could have been treated in a skilled nursing facility or another setting of care. Under the new requirements, a patient meeting all of their required criteria for admission to an IRF would be appropriate for IRF care whether or not he or he could have been treated in a skilled nursing facility." Accordingly, a denial rationale is invalid if it fails to address how the beneficiary did or did not meet IRF criteria as stated in CFR 42, §412.622, but instead states that services could have been provided in a lesser level of care.

Some contract reviewers insert denial statements that represent their own opinion, are not based on the IRF regulations stated in the CRF, and do not follow the guidance in the *MBPM*. A recent OIG audit that resulted in multiple IRF denials stated the following, in addition to stating in their rationales that the patient's medical conditions had stabilized: "The patient had a primary diagnosis of debility which did not support the medical necessity of acute level rehabilitation." Not only is this statement outside of regulation, as CMS does not restrict IRF access on the basis of the primary diagnosis, but also the majority of the patients with this denial rationale did not have a primary diagnosis of debility.

Additional cases have been overturned for erroneous denials such as the following:

- Stating that the patient did not require occupational therapy even though the patient had significant deficits in basic activities of daily living
- Citing that documentation such as the preadmission screen and the postadmission physician evaluation were untimely even though they met CMS's specifications
- Stating that the admission was not medically necessary because the patient had cognitive deficits, among others

Unfortunately, erroneous denials, despite being brought to the next reviewer's attention in an appeal, are often not overturned at the first two levels of the appeals process and therefore require an administrative law judge (ALJ) hearing to resolve. This creates an increased and unnecessary burden on not only the facility, but also the entire appeals system.

3. **Conflicting findings.** Reviewers often provide conflicting denial rationales implying that the beneficiary was too ill or that the beneficiary's functional level was too low to allow the patient to participate in the intensive rehabilitation program, but the same notification will state that the patient's functional or medical complexity did not warrant IRF care. For example, in a recent OIG audit, the independent reviewer frequently cited that "the patient had a primary rehabilitation diagnosis of debility which does not support the medical necessity of acute level rehabilitation" and then proceeded to state that the same patient,

because of the severity of the patient's debility and comorbid conditions, was "not able to fully participate in and benefit from the required intensity of an acute rehabilitation therapy program." For the multiple cases with this denial rationale, the patient actually tolerated and benefitted from the intense schedule of three hours of therapy a day for five days a week, which is standard for IRFs. In our experience, the first- and second-level appeal contractors are reluctant to overturn an OIG finding even if it is erroneous and conflicting. Again, this unnecessarily increases the burden on facilities and the appeals system alike.

4. **Establishing inconsistent and arbitrary thresholds for medical and functional acuity.** Claims denied for the reasons identified in paragraph 1 above can vary considerably in their scope of medical and functional acuity. CMS has not established any absolute threshold of medical or functional acuity or involvement to qualify for IRF care; instead, it has repeatedly emphasized the physician's judgement in admitting patients according to regulations based on the preadmission and postadmission processes. CMS, in turn, adjusts the base IRF payment up or down in order to account for variations in patient acuity and function. Denied cases are not often in the lowest-paying category for their diagnosis. In other words, CMS recognizes, categorizes, and pays IRFs for patients who have less functional and medical involvement than patients whose cases are denied payment. Arbitrary determination of whether a case meets a reviewer's subjective medical and functional threshold for a reasonable admission does not support absolute payment denial when CMS has established adjusted payment rates for the patient's specific characteristics.

   In its February 2017 Cumberland decision, the US District Court weighed in regarding reasonable and necessary criteria for IRF admissions, stating, "Where level of care is at issue the attending physician's opinion as to the level of care required by a patient's needs ordinarily is given great weight if there is no evidence to the contrary." By failing to provide details about cases, using generic statements, and making arbitrary determinations about reasonable and necessary criteria that are not based in medical standards of IRF regulations, contractor reviewers are giving neither due weight nor due consideration to the admitting physician's decision. Regarding the reviewer's assertion that one patient involved in the Cumberland decision did not require close physician supervision, the US District Court emphasized that "the requirement . . . means that the rehabilitation physician must conduct face to face visits with the patient at least 3 days per week" and "does not specify any other circumstances that satisfy this requirement." The district court additionally stated that "it is not for the Departmental Appeals Board (the reviewing body that upheld the denial in these cases before the Court) to insert its own medical conclusions into a case in place of those of the beneficiary's physician."

The aforementioned issues with the IRF medical review process and results are further supported by the overturn rate of appealed IRF cases. In UDSMR's database alone, which represents a sample of IRFs involved in Medicare appeals, over 1,200 cases have been appealed, and over 80% of denials have been overturned.

In addition to the above issues, which must be addressed prior to implementation of further IRF audits and service reviews, the review contractors require reeducation in light of the Supreme Court's June 2019 decision in Azar v. Allina. In its decision, the Supreme Court confirmed that Medicare guidance that has not undergone proper notice and comment rulemaking could not create substantive rules, including establishing payment criteria for services. In the two earlier district court decisions regarding the three IRF cases referenced above—Cumberland County

Hospital System v. Price, February 2017—the US District Court ruled that making payment requirements out of certain *MBPM* elements (specifically §110 pertaining to IRFs) created substantive criteria, which is erroneous because these elements did not undergo notice and comment rulemaking. The particular *MBPM* elements at issue in this decision included frequency and duration of therapies and expected level of improvement, elements cited in the *MBPM* but not contained in the CFR. Azar v. Allina further validated the premise behind the district court's decision in Cumberland v. Price. Prior to FY 2021, *MBPM* elements that were not contained in the CFR involved elements of the preadmission screen (PAS), the postadmission physician evaluation (PAPE), and the individualized overall plan of care (IOPOC). Omission of one of these elements has often resulted—and continues to result—in full payment denial. Contractors continue to assert that CFR and *MBPM* elements carry the same weight in determining payment decisions. In November 2020, for example, an AdQIC reviewer, on behalf of CMS, asserted that both CFR elements in 42 CFR §412.622 and *MBPM* elements in the *MBPM*, Publication 100-02, Chapter 1, §110, carried the same weight of law and thus could be used to deny a claim. The AdQIC stated, "The PAS must include the patient's expected level of improvement and expected length of time necessary to achieve that improvement. The PAS must also include an evaluation of the patient's risks for clinical complications. The ALJ's failure to consider all of these requirements resulted in an error of law." The PAS elements cited by the AdQIC reviewer were not contained in the CFR during this patient's admission. The AdQIC's assertion that IRF CFR and *MBPM* elements carried the same force of law was invalid per Azar v. Allina. Medicare enforcement actions, including denial of payment, based solely on policies that did not undergo notice and comment rulemaking are invalid. The Supreme Court's ruling validates the district court's decision that strict application of *MBPM* exclusive elements is erroneous.

The FY 2021 IRF final rule codified several PAS elements, eliminated some PAS elements from the *MBPM*, and eliminated the PAPE requirement altogether. These changes, along with the implications of Azar v. Allina on medical reviews with the potential for payment denials, require revisions to CMS's training and guidance materials for IRFs and extensive retraining for any reviewing contractors. In order to promote consistent understanding of the IRF regulations, guidelines, and clarifications among providers and contractors and to narrow the gap in understanding and applying IRF regulations that currently exists between IRFs and contractors, this training and education should be consistent and transparent and should not be conducted in "silos." A 100% claim review, as proposed in the Review Choice Demonstration for IRF Services, should not move forward given the overabundance of existing issues with the current state of IRF reviews and IRF regulation change.

A 100% medical review of IRF claims is also counter to the fundamental goals of the "Patients over Paperwork" initiative, whose goal is to ease the paperwork burden on providers so that they can spend more time with their patients, improve beneficiary outcomes, and decrease burden and costs while maintaining a high quality of care. In the FY 2021 IRF PPS proposed rule, CMS stated, "CMS recognized it is imperative that we develop and implement policies that allow providers and clinicians to focus the majority of their time treating patients rather than completing paperwork." A medical review is extremely burdensome to a provider even when a small percentage of its claims are affected. The process of compiling, submitting, tracking, and appealing erroneous denials is time- and labor-intensive. The burden of additional complex medical reviews is certainly amplified during the current public health emergency, during which IRFs across the country have had to evaluate and adjust their operations in order to not only

maximize their contributions to strained hospital systems, but also best serve their communities in crisis. The regulatory burden has increased due to the pandemic alone, with new waivers superimposed on top of the normally high compliance demands on IRFs. Neither the proposed Review Choice Demonstration for IRF Services nor any other 100% review for any provider type during this time should be considered.

Aspects of the proposed demonstration detailed in CMS's support documents[*] for CMS-10765, particularly the pre-claim review process, are modeled after the review choice demonstration for home health services. As such, they are not well suited to IRF documentation requirements and do not conform to the latest IRF regulation changes finalized in the FY 2021 IRF PPS final rule. In addition, the burden on IRFs is underestimated. The burden estimates assume that IRFs, including small units, have clerical staff devoted to managing the review process and documenting exclusively in electronic medical records that can easily be submitted electronically. Many inpatient rehabilitation units use clinical staff to complete clerical tasks, such as IRF-PAI completion and transmission, in addition to their clinical duties and use paper or hybrid (paper and electronic) medical records due to the unique documentation requirements that exist in an IRF—requirements that differ from those for acute hospital–based medical records. Adding clerical staff is not feasible in some units, and the process of collecting, scanning, compiling, submitting, and tracking medical record submissions, particularly paper or hybrid records, will require clinical staff to spend more than the projected thirty minutes to complete these tasks.

According to the demonstration-supporting document, "Documentation will be reviewed by trained nurse reviewers. They will use the documentation to determine if the beneficiary qualifies for IRF services and if they need the level of care requested." CMS has repeatedly emphasized the rehabilitation physician's judgement, utilizing the preadmission screening and approval process, in admitting patients according to IRF regulations. Nurse reviewers can assess whether the required PAS elements and the timeliness of the document were met but should not be allowed to overrule a rehabilitation physician's decision to admit based on their own subjective and arbitrary criteria.

The support document CMS-10765, "Inpatient Rehabilitation Facility (IRF) Instrument," specifies documents that should be submitted in a pre-claim review but requires the inclusion of medical record elements that are no longer required according to the FY 2021 IRF PPS final rule. Some elements of the PAS—the expected frequency and duration of treatment in the IRF, the anticipated postdischarge treatments, and other information relevant to the patient's care needs—are no longer required, and the same is true of the PAPE. These instructions also include an element that is not included and has not previously been part of IRF regulations: a requirement that the PAS state why conditions causing the need for rehabilitation require monitoring by a physician.

The demonstration allows an IRF to have an unlimited number of resubmissions for the pre-claim review request in order to make any needed changes so that it can receive a provisional affirmative decision. Unlike the home health services this demonstration is modeled after, however, it is unclear how an IRF would be able to make "needed changes," other than submitting a document that was inadvertently missed when a record was initially submitted. According to CMS-10765, the required documents for pre-claim review include the PAS, which

[*] "Inpatient Rehabilitation Facility (IRF) Instrument" and "IRF Supporting Statement."

is completed prior to the patient's admission, and the IOPOC, which is completed within four days of the patient's admission. In transmittal 119, when most current IRF regulations were effectuated, CMS reiterated that as a matter of policy, "the decision to admit the patient to the IRF is the key to determining whether the admission is reasonable and necessary." According to section 110.1 of the *MBPM*, which has not yet been updated to reflect the FY 2021 changes as of the writing of these comments, "A/B MACs must consider the documentation contained in a patient's IRF medical record when determining whether an IRF admission was reasonable and necessary, specifically focusing on the preadmission screening, the post-admission physician evaluation, the overall plan of care, and the admission orders." It would be more beneficial for the facility to have the option to request a discussion between the facility and the reviewer when a non-affirmative decision is received and the facility feels it has met all the requirements in 42 CFR §412.622. This should be a true discussion—not a phone call for the reviewer to read the *MBPM* or a request for additional written information, as some recent contractor "discussions" have been. Rather, this discussion should provide the reviewer with an opportunity to explain their case-specific rationale for their decision and should allow the facility to explain why it believes the case meets CMS's IRF criteria. If conducted equitably, such discussion would foster lower appeal rates, and facility error rates would be more accurate.

If this demonstration is initiated without a significant overhaul that addresses the aforementioned pervasive issues with current IRF reviews, a facility's error rate would likely be overstated and would therefore make it difficult for the facility to meet the 90% affirmation or approval rate. Furthermore, a significant increase in appeals would likely result. Most IRF denials are overturned on appeal, but these overturns are not reflected in reported IRF error rates. Because most cases are overturned at the ALJ level, which currently has a processing time of *over four years*, the true error rate is overstated. In its current state, the appeals process would not help establish a facility's true error rate because it does not include erroneous denials that are challenged and overturned. The Office of Medicare Hearings and Appeals is following a court order to reduce its backlog in the hopes of returning to its statutory ninety days for adjudicating appeals, but low overturn rates and perpetuation of problematic denials must be addressed at the redetermination and reconsideration levels of appeal. CMS needs to include appeal contractor reviewers in reeducation efforts related to IRF regulations, including FY 2021 changes, the applicability of Azar v. Allina to IRF regulations and guidance, and reconsidering the ability of nurse reviewers to subjectively override the rehabilitation physician's decision to admit in the absence of evidence that the decision violated a reasonable standard of care. Overturned denials on appeal should be factored into each facility's approval rate.

Due to the high burden associated with a claim review—especially one with a 100% review rate—alternatives to a six-month review interval should be considered for facilities that demonstrate a high approval rate. For example, if a facility reaches a 90% threshold of affirmation or approval after ten consecutive claims, which is the minimum number of claims CMS uses to calculate this threshold, it should be allowed to undergo review at a lower rate, such as the 5% "spot check" rate. If the facility continues to perform well, "spot checks" should become optional.

In summary, due to pervasive issues encountered with IRF medical reviews and a high denial overturn rate on appeal, the reported IRF error rates spurring the proposed Review Choice Demonstration for IRF Services are likely overstated. In light of these existing issues, the IRF regulation changes made in the FY 2021 IRF PPS final rule, and the implications of the Supreme

Court's decision in Azar v. Allina for IRF reviews that determine payment, revision of training and education materials and extensive retraining of IRF review contractors is required. Implementing a 100% review before adequate, consistent, and transparent education can be provided to IRFs could have the unintended consequence of limiting beneficiary access to IRF services if reviewers continue to apply nonregulatory, nonspecific, and arbitrary thresholds for reasonable and necessary care. Whether pre-claim or postpayment, a 100% review during the current public health emergency will place an extraordinary burden on providers and will divert operational focus and resources away from patient and community needs.

We recommend that CMS suspend implementation of the proposed Review Choice Demonstration for IRF Services.

We appreciate both the opportunity to comment on this proposed demonstration and CMS's careful consideration of the concerns and issues raised in this letter. If you have any questions about these comments or require additional information, please contact us at 716-817-7800.

Sincerely,

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