AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

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Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: AMRPA Review and Comments on Inpatient Rehabilitation Facility Review Choice Demonstration Program Documents

Dear Ms. Leonard and Ms. Cinquegrani:

On behalf of the American Medical Rehabilitation Providers Association (AMRPA), we write to offer our feedback on the documents released to date by the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity (CPI) regarding the Inpatient Rehabilitation Facility (IRF) Review Choice Demonstration (RCD). We thank your team for your engagement with AMRPA and other stakeholders and for your consideration of our feedback prior to initiating the demonstration. We believe this type of continuous communication between CMS and the IRF field will be critical throughout the duration of this demonstration, particularly in light of our extensive questions regarding the current program documents. The sizeable concerns that we outline below continue to reflect our belief that this demonstration (initially built for the home health benefit) cannot be applied to the IRF setting without a direct and serious impact on patient access and care delivery. We are hopeful that our questions and comments can address some of the most concerning aspects of the demonstration in its current state, and we look forward to continuing to work with you to ensure that the RCD causes the least possible disruption for impacted patients and providers.

While we acknowledge that CMS is only seeking feedback on program documents, we would like to briefly reiterate AMRPA's global concerns with the RCD. Our member hospitals continue to believe that this demonstration will essentially substitute inadequately qualified contractor discretion for physician judgment on medical necessity, and, we believe, inappropriately restricting access to the inpatient rehabilitation benefit for Medicare enrollees while diverting sorely needed care resources to administrative tasks. The majority of these concerns remain unchanged since the initial announcement of the RCD, and our previous statements on the demonstration can be found here and here.

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Our comments primarily focus on the documents that CMS has publicly posted and/or shared with AMRPA since announcing the start date of the RCD in Alabama in early May 2023, including (1) the IRF RCD Operational Guide, (2) the IRF RCD Process Flow Chart, (3) the IRF Review Decision Flow Chart, and (4) the IRF RCD Review Guidelines (we understand that the latter two documents are still in draft form and have only been shared with AMRPA and several other stakeholders). AMRPA has closely reviewed all program documents and conferred extensively with our membership to ascertain the potential impact of the demonstration from a clinical, operational, and financial perspective. Unfortunately, however, the documents released thus far raise more questions than answers, and there is still a severe lack of clarity for hospitals, physicians, and other stakeholders as to how this program will be operationalized. Using the documents provided so far, IRF providers simply do not have the details they need to make informed decisions about their review track selection nor to prepare their hospitals and staff for the implementation of the RCD.

Our primary questions and concerns are summarized below, and in Attachment A, we include a comprehensive review of our current questions regarding these documents. Given the demonstration's pending start date, we urge CMS to provide detailed answers to and significantly more clarity on each of these questions. We specifically recommend that CMS utilize these questions, and their answers, for the formation of a "Frequently Asked Questions" document that can be posted to the IRF RCD website at the earliest possible date, as well as revising other programmatic materials as necessary to reflect these clarifications. Further, we urge CMS to work with stakeholder organizations to prepare hospitals (especially small and rural entities) for the far-reaching impact of this program, particularly if certain questions are not answered prior to the demonstration's start date.

We look forward to meeting with you and your staff soon to discuss these matters further.

I. Pre-Claim Review Track

CMS intends to offer impacted IRFs a choice between 100% pre-claim or 100% post-payment review for their Fee-for-Service ("traditional") Medicare claims. Under the pre-claim review track, IRFs would be required to submit documentation for each admitted patient for review "at any time prior to the submission of the final claim," which would result in an affirmed or non-affirmed decision by the Medicare Administrative Contractor (MAC). IRFs would be allowed to modify and resubmit their pre-claim requests to address any issues identified by the MAC. Based on the documents released thus far and statements from the CMS staff, the agency has portrayed the pre-claim review track as one that it expects to be chosen by providers, offering the ability to resolve any inconsistencies in claims by working in concert with the MAC(s) and avoiding unnecessary denials and appeals. For numerous reasons, we question whether this track can operate as intended, even if the questions raised below are comprehensively answered.

Impact on Patients of Pre-Claim Review Track

One of AMRPA's largest concerns in the pre-claim track is the fact that CMS omits any discussion of what will or should happen with patients whose stays are "provisionally non-affirmed" under this track. As we understand, an IRF will continue to admit patients based on the

clinical judgment of the rehabilitation physician and clinical team, and proceed with the standard, intensive therapy program for at least six days during the initial pre-claim submission and MAC review timeframe. If the IRF then receives a provisional non-affirmation from the MAC, the IRF and the providers treating the patient will presumably be forced to decide between maintaining the patient's medically necessary course of treatment and assuming all financial risk for the stay, or discharging the patient back to an acute care hospital or lower-acuity setting, which may be unable to meet the patient's needs. This would obviously create massive care disruptions and place IRF patients – some of the most complex patients in the Medicare program – at high risk for adverse outcomes.

Despite the implications of this scenario, CMS provides no guidance on how such discharges should be handled. Furthermore, none of the documents address the potential for significant capacity issues at acute care hospitals, nursing facilities, or subacute rehabilitation settings in impacted states. In addition to the clinical impacts, these patients are likely to incur greater costs to the Medicare system when factoring in the likelihood of longer acute care stays, readmissions, and subsequent care needs that could have been avoided or mitigated with proper rehabilitation in the right setting, at the right time. As providers consider the pre-claim review track, CMS must clarify what type of safeguards will be in place to ensure that these types of care disruptions do not occur, consistent with its stated goals for the program. As detailed more fully in Section VII, we urge CMS to closely monitor and publicly report on the impact of the RCD on beneficiary access to care throughout the course of the demonstration.

Timelines for MAC Determinations in Pre-Claim Review Track

CMS states that MACs will "communicate" a decision to affirm or non-affirm a pre-claim review request within two business days and follow up with a "detailed" decision letter within ten business days. The documents released so far do not indicate what level of information will be provided in the initial decision and what additional information may be reserved for the detailed decision letter. We strongly encourage CMS to ensure that IRFs receive sufficient, claim-specific information in the initial call, including specific denial reasons (beyond simply "medical necessity" or "technical error"). This communication should specify exactly what information is missing, challenged, inconsistent, or otherwise deemed insufficient to affirm the claim, and give the IRF enough direction to begin the process of resubmission, if they so choose.

If and when CMS standardizes and finalizes the draft Review Guidelines to be used by the contractors, AMRPA encourages CMS to require that the MAC correlate the denial to the specific step in the guidelines that they deem not to have been met (AMRPA believes this type of step-by-step overview could be more helpful than the current flow chart). Unless IRFs receive sufficient detail in the initial communication to identify the reasons for a non-affirmed decision, the flexibility to try and resolve any inconsistencies and resubmit is not practical. We also note that IRFs continue to face common difficulties with receiving mailed communications from CMS and MACs, including mail delays and outdated or incorrect addresses, and encourage CMS to ensure that MACs use multiple forms of communication whenever possible so that valuable information is not lost or delayed in receipt.

As AMRPA has discussed with the CPI team, IRFs and other providers typically find it exceedingly difficult to obtain timely, useful information from MACs on reasons for denials.[1] We question whether MACs implementing the RCD will in fact provide the necessary details within the stated timelines to support IRFs revising and resubmitting claims. For these reasons, we urge CMS to ensure that MACs provide the reason(s) for a non-affirmed decision and sufficient, patient-specific detail as to how an IRF could address these issues in the initial decision to avoid waiting the full ten business days before they can attempt to resolve any inconsistencies.

Documentation Requirements in Pre-Claim Review Track

We appreciate that CMS explicitly states that IRFs in the pre-claim review track may submit their review requests "at any time prior to the submission of their claim." This flexibility will be critical as IRFs in this track institute new operational procedures to collect and submit documents prior to submitting a Medicare claim. We urge CMS to maintain this standard and allow IRFs the opportunity to determine when to begin the pre-claim review process.

We further note that the Operational Guide states that the medical record submitted during pre-claim review must include elements such as the individualized overall plan of care (IPOC). Under the current Medicare coverage requirements, IPOCs are to be developed based on the evaluations and assessments completed of the interdisciplinary team members within the first four days of a patient's stay; many IRFs do not complete the IPOC until the end of the fourth day. Thus, if IPOCs are in fact a required element for all pre-claim review submissions, IRFs may not be able to submit pre-claim review requests until at least four or five days into a patient's stay, and the initial decision will take at least another two *business* days. Given the average IRF stay is only approximately 13 days in total, it appears that IRFs subject to the RCD will be unable to tell whether their admissions are likely to be affirmed until halfway (or more) through the average stay.

In addition to the IPOC, CMS also indicates in the Operational Guide that pre-claim review requests must include documentation that "supports the required therapy services begin within 36 hours of midnight from the day of admission" and documentation that supports the rehabilitation physician began the three times per week face-to-face visits with the beneficiary. Each of these categories of documentation focus on the course of the beneficiary's *stay in an IRF*, not the *decision to admit* the patient in the first place. To align the pre-claim review track with its apparent intent as portrayed by CMS, we urge the agency to specify that documentation *required* for pre-claim review be limited to data available upon admission – such as the preadmission screening (PAS), the patient's history and physical, and documentation that there is a "reasonable expectation" that the patient requires, can participate in, and will benefit from the intensive course of therapy provided in an IRF (preserving IRFs' flexibility to submit other data beyond these minimum requirements). IRFs make admission decisions based on the totality of

[1] AMRPA has previously shared numerous examples of MAC and auditor denials where the contractor summarily asserts, without analysis, that the patient did not meet one or more medical necessity requirements, most recently in May 2023.

patient information available and the MACs should review the same information when an IRF submits supporting materials.

Summary of Key Concerns with the Proposed Pre-Claim Review Track Structure:

- To increase the likelihood that IRFs and MACs can engage in timely and effective communication about non-affirmed decisions, IRFs must receive a detailed, case-specific rationale upon the MAC's initial communication.
- The MAC's decision to affirm or not affirm an admission must only be based upon the information available to the IRF at the patient's admission (e.g., the PAS, history and physical, and other documentation showing the "reasonable expectation" that the patient is appropriate for an IRF stay).
- Significantly more information is needed as to how patients and IRF providers are expected to respond to a non-affirmed decision without placing patients at risk of serious harm and creating capacity issues for other providers.
- MACs must establish a uniform, minimum list of documents to be collected in the pre-claim review track to lessen provider burden and limit the likelihood of inaccurate documentation requests.

II. Post-Payment Review Track

Under the post-payment review track, IRFs would be required to submit their claims on the standard timeline, at which point the IRF would be paid, and Additional Documentation Requests (ADRs) would be sent for each individual claim. If the MAC denies the claim, the standard payment recoupment procedures would apply and IRFs would only be afforded the standard appeals process. Despite CMS' expectations about IRFs' potential preferences for the pre-claim track, CMS intends to make post-payment review the default option.

Timelines for MAC Determinations in Post-Payment Review Track

CMS states that once an ADR is sent in response to a claim, IRFs would have 45 days to respond to the ADR and then the MAC(s) would have 60 days to review the documentation and communicate a decision. There is no timeline provided as to how long MACs may take to send an ADR. We have serious concerns with the extended timeframe between claim submission and a final determination under this track. Under this timeline, there may be as many as 105 days between the submission of a claim and the communication of the MAC's decision, and this may stretch even further if there are delays in the MAC preparing and sending an ADR after receiving a given claim. This means that within a six-month review cycle, more than half of an IRF's claims may be in flux at any given time, with the IRF lacking clarity on how their claims will be treated. This substantially lessens any opportunity for IRFs to assess their own performance during the RCD and make potential operational changes to address any common denial reasons levied by the MAC(s). Further, we question how the MACs intend to calculate IRF performance at the end of review cycles when a majority of claims within the applicable dates may not be adjudicated until months after the cycle ends.

Additionally, we question whether the specified timelines are truly necessary to make the required determinations. Under the pre-claim review track, CMS asserts that the MAC(s) will be able to produce a preliminary decision on a given patient's records within two business days, with a full detailed decision provided within ten business days. As noted previously, the pre-claim review track is currently expected to involve significant documentation across the medical record – a level of documentation that is not substantially different from that involved in the post-payment review track. Thus, we do not believe it makes sense to have a dramatically different timeframe for MACs to make determinations on similar documents between the two tracks.

One potential avenue for shortening the timeframe for the post-payment review is the elimination of the ADR. If 100% of claims under this track will result in an ADR, we question whether it is necessary to send these requests at all. Eliminating this procedural step will not only allow for a more expedited review process but may address our concerns about the consistency and accuracy of documents that may be requested (detailed in the following section).

In all, we strongly urge CMS to hold the MACs to a similar turnaround time on post-payment review decisions as will be required under the pre-claim review track to ensure IRFs can meaningfully assess their performance and make informed decisions on their desired track across different review cycles. For both tracks, we encourage CMS to closely monitor the timely production of MAC determinations and ensure that decisions are communicated to IRFs according to the specified deadlines.

Documentation Requirements in Post-Payment Review Track

In the Operational Guide, CMS does not offer any standardized list of documents that will be required for each claim submitted for post-payment review during the RCD. Instead, the Guide indicates that ADRs might request different documentation for each claim, stating that "Records *may* include documents such as: Plan of Care, Inpatient Rehabilitation Facility Records, Progress Notes, [and] Nursing Visit Notes." Given the vast size of this demonstration and the administrative burden already facing providers, AMRPA urges CMS to adopt a standard list of documents that will be requested by the ADR (if CMS maintains this step in the first place). We also note that most MACs use a standardized list of documents that are sought in the ADR process, which would better align the demonstration with current review practices.

The need for a standardized documentation list is also important considering the consistent reports from the field that MACs nationwide are inappropriately requesting outdated documents through ADRs. Examples of such erroneous documentation requests include the post-admission physician evaluation (PAPE, removed from the IRF coverage requirements as of Fiscal Year 2021) and the Functional Independent Measure (FIM) scores, which were replaced with the new Section GG system as of Fiscal Year 2020. A standardized list developed with stakeholder feedback would eliminate concerns that these issues would carry into the RCD. As with the pre-claim review track, we urge CMS to issue a *minimum* list of documentation that will be requested across post-payment reviews, but allow IRFs the flexibility to submit additional documentation that may support a given patient's need for IRF-level care, and require the MAC(s) to review this documentation when submitted.

Summary of Key Concerns with the Proposed Pre-Claim Review Track Structure:

- We urge CMS to significantly shorten the timeframe outlined in the post-payment review track to provide IRFs with more timely information on their performance. This could be achieved by:
    - Requiring MACs in the post-payment track to adhere to a review timeframe identical or more similar to the pre-payment review track (ten business days); and
    - Eliminating the ADR step given that 100% of claims will be subject to review.
- Regardless of whether CMS maintains the ADR as a procedural step, MACs must establish a uniform, minimum list of documents to be collected in the post-payment review track to lessen provider burden and limit the likelihood of inaccurate documentation requests.

III. Review Cycles

In the Operational Guide, CMS details a process of six-month "review cycles," in which IRFs will have their performance evaluated against a target affirmation rate. CMS appears to indicate that meeting the target rates will allow IRFs to graduate into less stringent review choices for subsequent cycles. However, the actual progression of these cycles is exceedingly unclear based on the public documentation CMS has released thus far.

We understand that CMS has identified internally specific "Important Dates," indicating some specific projected timelines for at least the first two review cycles, including review dates, analysis timelines, and more. It is extremely concerning that this information, however, has not in any way been made publicly available (as of the date of this submission), either through CMS' own website or through Palmetto's. We are concerned that this piecemeal delivery of key information may be creating confusion across the field and among our members.

Progression Between Cycles

Based on the currently released documents, if an IRF meets the target affirmation rate after the first six-month cycle, it will have the option to progress to a more curtailed review choice for the subsequent cycle(s). However, it is much less clear what will happen after the first cycle concludes for those IRFs that do meet the target rate. For example, when an IRF meets the first target rate and selects a more limited review choice, are those smaller samples then subject to the higher target rate in the next cycle? If so, what happens if an IRF does not meet the higher target rate in a subsequent cycle – do they then revert back to one of the two initial review choices, and what target rate then applies? More importantly, if IRFs meet all three target rates in three subsequent cycles, are they then "released" from the RCD, or do they continue with their spot

check or selective post-payment review indefinitely?[2] Given CMS' stated purposes in pursuing the RCD, we strongly support an exit path from the RCD for IRFs once they consistently demonstrate compliance with the Medicare coverage requirements during the demonstration.

Timelines and Calculations Within Cycles

We also have significant outstanding questions with the timing of the cycles themselves. Particularly with the post-payment review track, IRFs will presumably have a large number of claims with service dates within a given six-month cycle that have not been affirmed or denied by the time the MAC begins calculating an IRF's affirmation rate. CMS has not provided any indication as to how these claims will be treated – will they be incorporated into the review cycle based on their service dates, rolled into the subsequent review cycle, or removed from the sample altogether? It is unclear how CMS intends to align the significantly longer turnaround time for post-payment review with the much shorter affirmation rate analysis period CMS appears to be using. Nor is it clear how CMS will account for any claim denials that are successfully appealed. It is critical that CMS provide clarity on how affirmation rates will actually be calculated, primarily so IRFs can understand their own performance. The fact that IRFs in the post-payment review track will have to wait a minimum of three months (105 days) into the first review cycle before a single decision may be turned around will make it exceedingly difficult for IRFs to adapt their practices to address any patterns identified by the reviewing MAC – which itself calls into question the intended educational component of this program.

Though this information has not yet been published on the RCD website, CMS appears to be instituting a two-month gap between the end of the first review cycle (on February 29, 2024) and the beginning of the second review cycle (May 1, 2024). CMS provides no information about how the demonstration will or will not operate during this period. As just one example, it is unclear if IRF services in demonstration states will be subject to heightened review during this time period, or whether these periods between cycles constitute "breaks" in the RCD entirely. With Alabama IRFs being expected to select pre-claim or post-payment review tracks next month, it is paramount that CMS provide clarity on the functioning of this demonstration and the review cycles as soon as possible.

Summary of Key Concerns with the Proposed Review Cycles:

- More information is required regarding when and how IRFs will progress between cycles and whether and when IRFs are at risk of transitioning between the selective and 100% review levels.
- AMRPA strongly urges CMS to create an "exit ramp" from the demonstration after IRFs have achieved a certain compliance record in the interests of fairness and reducing provider burden.
- CMS must clarify the claims that will be used to assess an IRF's performance each cycle and how the demonstration will function during the designated review period. It is imperative that CMS also determine a methodology for calculating the affirmation rate

[2] We note that a document presented at a stakeholder conference indicated that IRFs would stay in a more limited stage of review for the "duration" of the demonstration, but that language was removed in subsequently posted documentation.

that takes into account any favorable outcomes of appealed claims, whether that be retroactive recalculation of an IRF's affirmation rate (and potential reassignment to a different review tier) or credit in calculating the IRF's most recent affirmation rate.

IV. Selective Post-Payment and Spot-Check Review Choices

When IRFs meet their target affirmation rates, they will be afforded the option to move to a less expansive review choice of either a "selective" post-payment review, with a "statistically valid random sample" being calculated every six months, or a "spot-check" pre-payment review. However, even less information has been provided about these subsequent options than the initial two review choices. Once again, we urge CMS to provide clarity about these processes in a timely fashion so that IRFs can prepare to make an informed decision about their selections.

Selective Post-Payment Review

AMRPA has significant concerns with the lack of clarity around the selective post-payment review choice. For example, CMS has not provided any information about the criteria that will be used to create a statistically valid random sample of claims. In particular, we urge CMS to recognize the importance that such a sample be representative of critical patient characteristics, such as Rehabilitation Impairment Group (RIC)/Case-Mix Group (CMG), discharge location(s), and length of stay, as well as account for short stays and/or early transfers. Instead of a simple random sample, CMS and the MAC(s) should consider utilizing a stratified or clustered random sample to ensure that the results of the review are representative of the total population of claims at a given IRF.

Further, we urge CMS to clarify how this review track will unfold at a practical level. CMS states that IRFs will render services and submit claims according to their "normal process;" we question whether this means that MACs will create a random sample, then issue ADRs for each of those claims, or whether some other process will apply. CMS provides no information as to how long the sampling process will take, nor is there clarity as to the timeline for the distribution of ADRs, the IRF's response, and the subsequent MAC review. We again note that if CMS intends to use the same timeline as the 100% post-payment review track, it may take more than three months to determine the IRF's performance on any given claim, much less the calculation of the total affirmation rate for the given cycle. This timeline does not account for the sampling process to unfold, raising serious concerns as to how the MACs feasibly calculate an IRF's performance under this track within the timelines CMS envisions for the review cycles.

Spot-Check Pre-Payment Review

Similarly, AMRPA is concerned with the open questions surrounding the spot-check review choice. We again question what criteria or methodology CMS intends to use to create the 5% spot-check. The conspicuous absence of the "statistically valid" qualification in this track as compared to the selective post-payment review may indicate that CMS is not intending to validate this sample at all. AMRPA believes this is an entirely inappropriate way to review IRF performance under this track and we strongly discourage the use of a simple, unadjusted, "random" sample for spot-checking purposes. Instead, we urge CMS to ensure that this sampling

process, like the selective post-payment process, is statistically valid and account for patient characteristics to ensure a truly representative sample of the IRF's claims. This is particularly critical if failing to meet the compliance threshold results in a return to 100% claims review.

We also note that this track involves review at the "prepayment" stage, not the pre-claim or post-payment stages, and thus appears to be unlike any of the other three tracks detailed in the Operational Guide. However, CMS offers no details as to which processes and time frames will be used for this wholly new review track, creating a series of new questions that must be addressed in the near term.

Summary of Key Concerns with the Selective Review Processes

- AMRPA urges CMS to provide greater information about its approach to reviewing samples of claims and ensure that all sampling processes (across review tracks) be statistically valid and account for certain patient characteristics.
- AMRPA urges CMS to respond to a number of questions regarding the proposed "prepayment" review stage, such as:
    - Will this involve ADRs being sent for claims selected for the spot-check sample, and if so, how long will IRFs have to respond and how long will MACs have to make a decision?
    - How will these decisions be made, and will this process allow for education and resubmission like the pre-claim review track? If not, will there be an appeals process for IRFs to challenge incorrect MAC determinations?

V. Timeliness of MAC Determinations

In addition to our specific comments around the proposed timelines for different components of the RCD, we continue to hold serious concerns around CMS' and the MACs' reliance on "business days" as the proper measure of timeframes for this demonstration. As we have noted consistently in past comments to CMS, IRFs are hospitals and operate 24 hours per day, 365 days per year. Requests for IRF admissions come at all times during the day or night, with no regard for weekends, holidays, or other traditional business operations. Unlike other settings of care, such as home health, *hospital-level care* requires immediate and continuous intervention, with doctors and nurses working around the clock to care for patients. While other provider types may be able to delay care until a pre-claim review is completed, delaying care is never an option for IRF beneficiaries. We, therefore, continue to urge CMS to hold MACs carrying out the RCD to the same standard that IRFs themselves are held to. Decisions on whether to affirm or deny IRF services at the pre-claim, pre-payment, or post-payment stages must be made as close to real-time as possible, ideally within 24 hours.

VI. Appeals Process for RCD Determinations

As expressed in previous comments regarding the RCD, the lack of any proposed separate and accelerated appeals process for RCD claims will cause significant issues for impacted IRFs and patients. Despite consistent findings from the federal government that IRF denials are overturned in favor of IRF providers at a very high rate, too many IRFs already face significant financial

struggles with unpaid claims while awaiting a hearing to receive their reimbursement for an erroneously denied claim. In this RCD, IRFs will face reviews of all of their claims, at least for the initial six-month review cycle, and we have seen nothing to suggest that rates of improper denials by MACs will be lessened under the demonstration compared with the standard review process. Even so, CMS continues to state that IRFs will only be afforded the standard appeals process to challenge what will almost certainly be exponentially greater MAC denials, simply due to the 100% claim review process. The Office of Medicare Hearings and Appeals has only recently cleared a years-long backlog at the Administrative Law Judge (ALJ) level, and without additional outlets for RCD-specific appeals, we expect the backlog may soon re-emerge.

Even in the absence of a separate appeals process once a claim has been definitively denied under the RCD, we urge CMS to develop a process within the pre-claim review track to challenge inappropriate MAC decisions. Under this process, CMS staff have consistently referred to the opportunity for IRFs to resolve any inconsistencies in their claim and resubmit, but there is no similar avenue for an IRF to respond if and when a MAC returns a non-affirmation decision in error. According to the current documents, even if a non-affirmation decision is provided in clear violation of the Medicare coverage criteria (an all-too-common occurrence in the standard review process that will likely occur in the RCD as well), the only option an IRF has is to give up and cede payment for services that are medically necessary and compliant with the regulations, or to submit the claim anyway, receive an automatic denial, and only then begin the arduous and lengthy appeals process. This is simply not feasible for the volume of claims that could be inappropriately denied under 100% claim review. In sum, a demonstration of this size and with significant financial implications for IRFs requires a separate, dedicated appeals process to facilitate timely and meaningful review. At a minimum, CMS should have a process for monitoring the number of overturned RCD claims, as we detail in our section on oversight below.

VII. Oversight of the RCD

Over the course of the RCD, and especially during the initial phase(s) when the RCD is being tested and potentially revised, it is critical that CMS closely oversee the implementation of the demonstration and monitor its impact on patient access, its contractors' performance, the disposition of appealed claims, and other aspects of the program. We appreciate that CMS has indicated a willingness to engage with stakeholder groups and receive feedback during the demonstration as impacted hospitals encounter operational issues. When the demonstration begins, we urge CMS to commit to ongoing engagement and communications with hospitals and other stakeholders. Instituting regular recurring meetings would be an important step to ensure that the agency is aware of all potential difficulties that may arise from the RCD and to offer a forum for stakeholders to raise questions and feedback stemming from the review process.

Oversight of Impact on Patient Access

As AMRPA and other stakeholders have consistently communicated, we continue to believe that this demonstration will have direct and significant impacts on Medicare beneficiaries' access to inpatient rehabilitation services. We expect that many of the recurring patterns in the current auditing process will likely arise in the RCD as well – allowing nurse reviewers to second-guess

the medical necessity determinations of physicians with years of experience and expertise in medical rehabilitation, as well as misinterpretations and misapplications of existing coverage criteria leading to erroneous denials. As patterns of MAC denials under the RCD emerge, especially in the pre-claim review track, IRFs will be placed into the impossible positions of either deciding to continue treating patients they have deemed to require an IRF level of care or putting the patient through a harmful disruption of care by discharging them in the midst of treatment. Many IRFs will simply not have the financial resources to bear such risk of non-payment or go through the standard appeals process, even when they are confident that the patient meets the admission criteria and would eventually be approved for IRF coverage and payment.

As CMS intends to move forward with this demonstration regardless of these concerns, it is essential that the agency take concrete steps to monitor and oversee the impact this demonstration has on patient access and move swiftly to remedy any barriers that prevent beneficiaries from receiving the care they need. In the materials released thus far, CMS has provided no information as to whether and how the agency will take account of the program's impact on patient care and patient outcomes, beyond a vague commitment that the agency will regularly assess data. The IRF field needs to understand whether and how this data will be made public, how often data will be assessed, and the levers the agency intends to employ if and when reductions in patient access are demonstrated. We urge CMS to commit to publicly issuing specific reviews and disclosures of the RCD's impact on quality, outcomes, and access throughout the demonstration. At the very least, data regarding admissions and denials (both pre-claim and post-payment denials), as well as information about any trends identified by the agency when comparing admissions prior to and after the implementation of the RCD in impacted states, should be included in these disclosures, so that stakeholders can evaluate the impact on patient access.

Oversight of MAC Performance

In recent months, AMRPA has engaged extensively with CMS staff regarding consistent patterns of errors by MACs in reviewing and auditing IRF claims, including concerning behavior by the MACs involved with the RCD. Among these issues, MACs have repeatedly relied on outdated or objectively incorrect interpretations of the IRF coverage criteria, sought documents that are no longer required by Medicare, and relied on language or standards to deny payment for IRF services that do not appear in regulation or guidance issued by CMS. In this environment, we continue to have serious concerns that these patterns encountered nationwide may be replicated in the RCD, significantly jeopardizing patient access to care as well as impacting IRF's financial stability. It is paramount that CMS have in place consistent, wide-ranging, and responsive processes to ensure that MACs are carrying out the RCD as intended and only utilizing the current Medicare coverage criteria to evaluate IRF claims.

On numerous occasions, CMS has stated that the agency will "review MAC decisions to ensure accuracy" and "regularly assess MAC data" during the course of the RCD. While we applaud CMS' commitment to oversight, we urge CMS to provide additional detail on these reviews and assessments, and to provide regular public updates throughout the RCD on the MACs' own error and affirmation rates. This would include, for example, a detailed overview of denial and

overturn rates by Rehabilitation Impairment Category (RIC). Additionally, providing stakeholders with additional transparency into how the MACs are being evaluated and compensated would help avoid concerns about perverse financial incentives (such as MACs being rewarded based on the number of denials they hand down) that could supersede contractors' reliance on the Medicare coverage criteria alone to evaluate IRF services. We also reiterate our recommendation that CMS create a pathway for IRFs to report and receive timely responses regarding incorrect MAC determinations at the pre-claim, pre-payment, or post-payment review levels.

Further, we encourage CMS to provide additional details regarding documents and training that have been provided directly to the MAC(s) in preparation for the RCD. We believe that transparency across all stakeholders is critical for a demonstration of this size and scope. Offering stakeholders the chance to review and comment on these documents will help ensure not only that MACs are abiding by the strictures they have been provided by CMS, but to ensure there are no errors in the documents themselves. We note that in several instances throughout the current documentation available on the CMS website (detailed further in the Appendix), language appears to be lifted directly from similar documents used in the Home Health RCD, and in some instances the language carries over terminology or requirements that do not apply to IRFs. We further note that in the initial materials released by CMS when the RCD was first announced in 2020, there were several examples of outdated documentation listed in the "Additional Required Documentation" section. When commenters brought these errors to the agency's attention, they were revised and removed, as cited in CMS' formal Response to 60-day Comments document issued in August 2021. Allowing stakeholders to evaluate the materials the agency intends to govern the RCD will help avoid any similar confusion as reviews begin.

Oversight of Claims Post-RCD

In addition to oversight of claim affirmations, denials, and resubmissions within the RCD, CMS must also monitor and publicly report on the treatment of claims that progress outside of the RCD. Under the current program stipulations, IRFs who seek to challenge an inappropriate denial (or non-affirmation) by a MAC under the RCD must rely solely on the standard Medicare appeals process. As detailed in Section VI, this process can take years to complete even without a backlog.

Though the federal government has consistently found that IRF denials are overturned in favor of IRF providers at a very high rate, CMS appears to state that overturns will not be incorporated back into the RCD review cycles or into calculations of IRFs' target affirmation rates, even if IRFs face similar patterns of significant overturns in their favor. Thus, if a MAC denies a claim under the RCD, even if appellate authorities find that denial was in error, IRFs will still be penalized under the RCD, potentially (and inappropriately) subjecting them back to a cycle(s) of 100% claim review. At a minimum, CMS must monitor the disposition of all IRF claims subject to the RCD through the full appeals process, if and when IRFs choose to avail themselves of that process. CMS should regularly and publicly report information on how many of these denials are overturned, and as patterns emerge, must address any inconsistencies between the decisions made by the RCD MACs and appeals bodies in a timely fashion.

Reviewer Qualifications for RCD

AMRPA continues to urge CMS to institute qualification standards for reviewers employed by the MACs implementing the RCD. Long before this demonstration was proposed, AMRPA has discussed our experience with Medicare contractors whose staff do not have the requisite expertise and experience in rehabilitation to appropriately evaluate IRF claims. Under the IRF coverage criteria, only specialized rehabilitation physicians can approve an admission to an IRF for Medicare beneficiaries. Despite this, CMS continues to allow lesser trained clinicians to second guess and override practicing rehabilitation physicians in IRF audit and review programs.

CMS has directly recognized and addressed these concerns in other facets of the Medicare program. In the recently finalized Medicare Advantage (MA) final rule, CMS instituted a requirement that reviewers employed by MA plans have specialized training, certification, or clinical experience in the applicable field of medicine in order to determine whether a requested item or service is medically necessary.[3] In fact, the final rule specifically references how these standards should apply to IRF admissions, stating, "the plan reviewer reviewing a request for IRF care would need to have the background and knowledge to determine that the enrollee's medical condition requires intensive rehabilitation, continued medical supervision, and coordinated care."[4]

While we appreciate that the MAC instituting the first phase of the RCD has recently hired a rehabilitation physician to oversee the demonstration, one staff physician will not be able to personally review potentially thousands of claims subject to the RCD in Alabama alone. It is essential that CMS mandate all reviewers involved in carrying out the RCD meet the standards set by the agency for MA plans to have specialized training, certification, and/or clinical experience in rehabilitation medicine, especially as practiced in the IRF setting.

Summary of Key Concerns Regarding Program Oversight

- AMRPA urges CMS to define specific, robust, and consistent processes for publicly and regularly reporting data on how inpatient rehabilitation hospital patients (i.e., admissions and services) are impacted by the implementation of the IRF RCD over the course of the demonstration.
- AMRPA urges CMS to provide clarity on the training provided to the MACs in preparation for the RCD, the specific processes the agency expects to undertake to review the MACs' performance during the RCD, and to publicly report information on the MACs' own error and affirmation rates.
- AMRPA urges CMS to develop a pathway for IRFs to report incorrect MAC determinations at all review stages during the RCD.
- AMRPA urges CMS to institute qualification standards for MAC reviewers to ensure that clinicians potentially overriding the judgment of the treating physician have sufficient

[3] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, Final Rule, 88 Fed. Reg. 22120, 22217 (Apr. 4, 2023).
[4] *Id*. at 22220.

experience and expertise in IRF care, consistent with the requirements recently finalized for the review of admissions in the Medicare Advantage program.

VIII. Non-Standard MAC Billing in RCD States

AMRPA is aware that in some circumstances, IRFs geographically based in Alabama (and potentially other RCD target states) may typically send their claims to a MAC that is not the assigned MAC implementing the RCD in that state (in this case, Palmetto GBA). In at least one instance, we understand that an Alabama-based hospital has been told by their (non-Palmetto) MAC that they should *not* expect to be subject to the RCD beginning on August 21, 2023. CMS' RCD website, however, states that the RCD will begin on that date "for IRF services **in Alabama**." The Operational Guide similarly states that IRFs "**located in Alabama** are subject to the RCD." In contrast, Palmetto's website on the RCD states that "the demonstration will begin for IRFs that are physically located in Alabama **and bill to Palmetto GBA's Jurisdiction J (JJ) A/B MAC**."

We urge CMS to clarify exactly which IRFs are subject to the RCD in August. If IRFs that do not typically bill to Palmetto are expected to participate in the RCD, CMS must issue clear guidance as to how this will unfold – will claims be transferred by the usual MAC to Palmetto, or must IRFs in these circumstances newly develop a relationship with Palmetto? Will these IRFs solely deal with Palmetto, or do they need to prepare to submit their claims to two different MACs simultaneously during the demonstration? Finally, how will claims be handled for these hospitals during the interim periods between cycles of the RCD? These questions must be answered as soon as practical given that the demonstration stands to start in two months.

IX. Reliance on Regulatory Criteria

Based on AMRPA's review of the RCD Operational Guide, the RCD Review Guidelines, and the IRF Review Decision Flow Chart, we have serious concerns about the standards that Medicare contractors will be permitted to use to assess IRFs' compliance with Medicare coverage and documentation requirements. In certain instances, AMRPA believes that incorrect regulatory criteria or standards are being applied (e.g., the criteria being used to determine the appropriateness of the IRF admission); in other circumstances, the guidance inappropriately points to subregulatory guidance (rather than IRF coverage regulations) to essentially establish substantive new coverage standards within the demonstration.

To that end, AMRPA aligns itself with the redline versions of the RCD documents submitted by other rehabilitation stakeholders. AMRPA strongly urges CMS to revise the RCD program documents in accordance with the corrections and recommendations offered in those redlines and stands ready to offer any technical assistance to CMS in this process.

X. Broader Process-Related Concerns

While we appreciate that CMS staff have been in direct contact with AMRPA and certain other stakeholder groups regarding updates and sharing draft documents, we want to ensure that all

stakeholders and the general public, especially those who will be directly impacted by the RCD, are able to fully understand the magnitude of the demonstration and prepare as comprehensively as possible for how it may upend their operations. As stated above, only some of the documents that have been provided to AMRPA have been publicly posted on CMS' website, and many stakeholders may not have access to the full slate of resources available. In some cases, contradictory information from what is currently available on the CMS RCD website has been provided during conferences. We greatly appreciate CMS' willingness to modify portions of the RCD in response to stakeholder concerns and share the agency's hope that some of the programmatic materials can be updated to reflect refinements and changes as the RCD evolves. However, we believe it is necessary to ensure that all hospitals and stakeholders have at least a baseline understanding, directly from CMS, about how the demonstration will work and what is expected of them, especially nearing the start date for Alabama IRFs.

We have serious concerns about hospitals' and units' ability to properly prepare for this demonstration if information is not shared in a timely and transparent way. With less than a month until the selection period begins for providers in the first phase of the RCD, and only two months before the demonstration begins, we do not believe that impacted providers have been afforded sufficient opportunity to make informed choices and prepare their hospital operations for the dramatic upheaval that will come with the demonstration. We urge CMS to use all available avenues to address the questions and recommendations in this document as soon as possible and ensure that all providers have sufficient clarity about all aspects of the RCD before the program is levied on their operations.

Summary of Key Process-Related Concerns:

- CMS must publicly issue clarifications regarding the numerous open questions detailed in our and other stakeholders' comments so that IRFs subject to the RCD can approach the project with a clear understanding of how it will operate.
- CMS should immediately clarify which additional materials, if any, are expected to be released ahead of the RCD start date and confirm when the public will be able to review these materials.
- CMS should schedule multiple live stakeholder education sessions before the end date of the selection period, with sufficient technical capacity to allow all interested parties' attendance. These sessions should include opportunities for questions and answers from stakeholders and CMS should publish materials from these sessions in a timely manner.
- CMS should commit to recurring meetings with program stakeholders throughout the demonstration to ensure concerns with contractor reviews and other behavior are conveyed (and addressed) in real time.
- CMS should publicly clarify the process for all stakeholders to provide formalized feedback on the RCD, both ahead of the start date and once the demonstration begins.
- CMS should ensure that any revisions to program documents and/or operations are publicly reported so that stakeholders can adapt to changes as they unfold.

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Thank you for your consideration of our feedback. We greatly appreciate your time and look forward to our upcoming meeting to discuss these issues further. If you have any questions, please contact Kate Beller, AMRPA Executive Vice President for Government Relations and Policy Development at kbeller@amrpa.org.

Sincerely,

Anthony Cuzzola
Chair, AMRPA Board of Directors
VP/Administrator, JFK Johnson Rehabilitation Institute, Hackensack Meridian Health

Attachment A: AMRPA's Detailed Comments and Outstanding Questions on Inpatient Rehabilitation Facility Review Choice Demonstration

AMRPA
AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

Attachment A

AMRPA's Detailed Comments and Outstanding Questions on Inpatient Rehabilitation Facility Review Choice Demonstration

As stated previously, AMRPA and our members maintain a wide range of fundamental questions about the intended functioning of the RCD. The documents and statements released by CMS thus far have pivotal gaps across almost every aspect of the RCD, and IRFs are simply not equipped to make informed decisions or preparations for the RCD with this level of information. While we summarized many of the key areas where clarity is needed above, along with certain recommendations for the RCD, we have provided below a comprehensive list of questions AMRPA has identified that are raised by the current program documents. We believe it is absolutely essential that CMS review these questions carefully and provide detailed answers as soon as possible – certainly before the end of the selection period for Alabama IRFs, and hopefully before the period begins on July 7.

We expect that certain program documents may have to be revised to address these questions, and we urge CMS to do so publicly and to report any and all changes that are made to documents. Additionally, we encourage CMS to use these questions, and any others received by stakeholders, to form a "Questions & Answers" or "Frequently Asked Questions" document as soon as possible, which should be posted on the RCD website and provided directly to the MACs implementing the RCD. We appreciate that CMS has recently announced an Open Door Forum call where IRFs and other stakeholders may have the opportunity to ask some questions "live," but given the breadth of these questions and the need for clear, standardized answers, this call and any future educational sessions cannot substitute for written documentation responding to these concerns.

General Process Questions for the RCD

- What additional documents and materials does CMS expect to issue in preparation for the RCD, and when will these documents be made available?
- Will CMS commit to holding multiple educational sessions on the RCD and ensuring that all interested stakeholders are able to participate? Will these sessions include the opportunity for stakeholders to submit questions directly to CMS, and will CMS publicly release transcripts and other materials relating to these sessions?
- Will CMS detail a formal process for stakeholders to submit specific questions, comments, and feedback on the materials released thus far (as well as future materials)?
- Will CMS publicly report and log any revisions, corrections, or additions made to existing and future documents and/or the RCD process?
- Through discussion with our stakeholder partners, we understand that CMS will use an "accuracy review contractor" as part of its RCD oversight. Will CMS provide further written guidance about the duties of this contractor and whether/how stakeholders will be able to communicate directly with this entity?
- What method(s) will CMS use to ensure consistent engagement with stakeholders and impacted IRFs over the course of the RCD?

- How will CMS oversee the implementation of the RCD and the decisions made by the MAC(s) during the demonstration?

Timeline Questions for the RCD

- When does CMS expect to release information about the timelines for applying the IRF RCD to Pennsylvania, Texas, and California?
    - Does CMS expect to apply the RCD to these three states simultaneously?
- Does CMS expect to apply the RCD to all four MAC jurisdictions (JJ, JL, JH, and JE) simultaneously, or are IRFs who bill to these jurisdictions simply eligible to be in the pool for the third phase of the RCD?
    - When does CMS expect to release information about the timelines for expanding the IRF RCD to these jurisdictions?

Coverage Regulation Questions

- On page 4 of the Operational Guide, Section #4 describing the IRF rehabilitation physician supervision requirement **omits** the flexibility to have a non-physician practitioner with specialized training and experience in inpatient rehabilitation conduct one of the three required face-to-face visits with the patient per week, beginning with the second week of admission to the IRF. [§412.622(a)(3)(iv)]
- On page 8 of the Operational Guide, CMS notes that "Above codes [subject to the RCD] are subject to change." Does CMS anticipate reducing the scope of the IRF RCD from 100% claim review to only certain CMG codes in the future?
- On page 11 of the Operational Guide, CMS states that "A non-physician practitioner can fulfill the IRF services and documentation requirements currently required to be performed by the rehabilitation physician in 42 C.F.R. § 412.622(a)(3), (4), and (5)." It is unclear what this statement refers to.
    - The cited sections of the IRF regulations refer to the coverage requirements for IRF admissions, the documentation requirements, and the interdisciplinary team approach to care. Only the exception regarding face-to-face visits after the second week of admission explicitly involves the role of a "non-physician practitioner," such that the CMS regulatory citation should be narrowed.
    - Some of the IRF documentation requirements cited in (a)(4) are not required to be performed by the rehabilitation physician, such as the preadmission screening in (4)(1) which can be completed by a "licensed or certified clinician(s)." Importantly, the current coverage requirements do **not** require that this clinician have the same "specialized training and experience in inpatient rehabilitation" as must the non-physician practitioner who can conduct one of three weekly required face-to-face visits.
    - Is CMS indicating that it is revising the coverage and documentation requirements within the scope of the IRF RCD to further expand the role of a non-physician practitioner compared to a rehabilitation physician?

- On page 11 of the Operational Guide, it is unclear what the following sentence means: "**Therefore, of a non-physician practitioner with the current definition of a rehabilitation physician in that we expect the IRF to determine** if the non-physician practitioner has specialized training and experience in inpatient rehabilitation and may perform any of the duties that are required to be performed by a rehabilitation physician, provided that the duties are within the non-physician practitioner's scope of practice under applicable state law."

Pre-Claim Review Track Questions

- CMS details a minimum list of data elements and "additional required documentation" that is required during a pre-claim review submission. Does this process include any opportunity for MACs to submit ADRs to IRFs beyond this list as part of their pre-claim review, and if so, how would these requests impact the timing of decisions throughout this track?
- As stated above, the list of required documentation for pre-claim review (beginning on page 11 of the Operational Guide) includes the individualized plan of care, as well as documentation that "supports the required therapy services begin within 36 hours of midnight from the day of admission" and documentation that supports the rehabilitation physician began the three times per week face-to-face visits with the beneficiary.
    - Are IRFs required to refrain from submitting any pre-claim requests until all of these documents are available in the medical record, potentially four or more days into the beneficiary's stay?
- If and when a pre-claim review request is non-affirmed, will CMS provide guidance for IRFs on how discharges should be handled for patients who have likely been admitted for at least six or more days prior to the decision?
- When the initial decision to affirm or non-affirm a pre-claim review request is communicated within two business days, will this be provided in writing or through any other means besides a telephone call?
- When a MAC communicates a decision within two business days, what and how much information will be provided in the initial communication? Will MACs provide sufficient detail for IRFs to begin revising their submission during the initial communication, or will IRFs have to wait for the full detailed decision letter?
    - Will CMS provide a specific accounting of what details will be provided in the initial telephone call and which will be reserved only for the written decision letter?
- How will CMS/the MAC(s) determine the current contact information for the initial phone call, and what process will be afforded for IRFs to update contact information?
- On page 12 of the Operational Guide, CMS states that responses will be sent to submitters via the same method as the initial request was sent, and that "Otherwise the response will be sent via mail." Later in the Operational Guide, CMS states that responses will be sent both via phone and/or the MAC Provider Portal as well as a written decision via mail.

  - Will there be any instances in which an IRF would **only** receive pertinent information from the MAC via traditional mail and no other method?
  - If so, what are CMS' plans to mitigate mail delays, lost mail, or mail being sent to outdated hospital contacts?
  - Will timelines be revised to account for the potentially lengthy delay between sending and receiving traditional mail decisions?
- On page 13 of the Operational Guide, the subsection titled "3. Timeframe for Decisions" appears to apply only to cases where another payer is primary and Medicare is secondary, and the timeframes listed are distinct from the timeframes detailed in the following sections.
  - This section includes a caveat that the two-business-day timeframe excludes federal holidays, but this exclusion is **not** listed later in the Guide applying to cases where Medicare is the primary payer. Will the standard timeframes for all decisions include or exclude federal holidays?
  - This subsection also does not differentiate between the communication of an initial decision and the distribution of a detailed decision letter, which are separated on different timeframes later in the Guide. Will IRFs receive the same separate decisions when they submit a pre-claim review request for which Medicare is the secondary payer, and will those decisions follow the same timeframes detailed for primary Medicare claims?
- On page 12 of the Operational Guide, CMS states that "Resubmissions will require additional documentation, when available." CMS further describes that resubmissions should be responsive to the decision letter provided by the MAC.
  - Do IRFs who are responding to a non-affirmed decision only need to resubmit with modifications to respond to the initial decision letter, or do they also need to update the documentation from the patient's medical record reflecting services provided and other developments between the initial pre-claim review submission and the receipt of the initial non-affirmed decision?
- CMS states that beneficiaries will also receive a copy of the decision letter. Will CMS be sending the beneficiary a decision letter each time a new decision is produced during the resubmission process?
  - Will the decision letters sent to the beneficiary include any information explaining why their claims are undergoing pre-claim review, and preparing them to potentially expect rapid reversals in the approval process for their care if the IRF resubmits the request?
- CMS indicates that IRFs who submit "incomplete" requests will receive information about what is missing from the request during the initial telephone decision, as well as through the detailed decision letter. How quickly will this information be provided to the IRF?
  - If the MAC determines that certain documentation is "insufficient," a common reason for denial in current auditing practices, will this be considered an incomplete request or justification for a "non-affirm" decision?

- CMS states on page 16 of the Operational Guide that the MAC will provide "notification" of a decision on a resubmitted claim "through a decision letter" sent within two business days. Does this indicate that the secondary decision sent on a resubmitted claim will include the same level of detail as a decision letter on a newly submitted request?
    - Will the MAC provide direct notification of a decision on a resubmitted claim via telephone or any other real-time method, or will IRFs have to wait to receive a written letter in the mail only?
- CMS states that if a claim is submitted for payment after a non-affirmed pre-claim review, it will be denied, but the standard appeals process will apply. If the IRF seeks an initial redetermination, will that redetermination be handled by the RCD staff or different reviewers at the same MAC who are handling non-RCD claims?

Post-Payment Review Track Questions

- What is the expected timeframe for MACs to issue an ADR after a claim is submitted for payment?
- If MACs are able to complete their full approval or disproval of IRF services within 10 business days for pre-claim review, why is it necessary to provide 60 days to make the same determinations for post-payment review?
- Will CMS provide standardized guidance on which documents will be requested for post-payment claim reviews?
- If the ADR components for post-payment review are standardized, will CMS allow IRFs to submit the necessary documentation along with their claims when they are submitted for payment, in order to cut down on unnecessary delays waiting for an ADR and response?
- CMS has stated that claims submitted for pre-claim review will be excluded from future medical review by the MAC or Recovery Audit Contractor and will only be subject to additional review if fraud or gaming is suspected (Unified Program Integrity Contractor review) or if selected for Comprehensive Error Rate Testing (CERT) review. Will this exclusion also apply to claims under the post-payment review track, i.e., will claims reviewed post-payment for the RCD be subject to a potential "double review"?

Selective Post-Payment Review Track Questions

- What criteria will be utilized to create a statistically valid random sample of claims?
- Will the random sample be representative of the following patient characteristics:
    - Impairment/RIC/CMG?
    - Discharge Location?
    - Length of Stay?
    - Short Stays/Early Transfers?
- Will CMS use a stratified random sample or clustered random sample to ensure that the results of the review are representative of the total population of claims at a given IRF?
- Is there a minimum number of cases to be selected as part of the statistically valid random sample of claims? The Operational Guide states that an IRF must have submitted

at least ten claims during the review cycle in order to be eligible for either of the narrower review choices, but no minimum number of claims is indicated for this track specifically.

- Will this track involve the same processes and time frames as the 100% Post-Payment Review track?
    - How long will the MAC(s) have to conduct the random sampling process, and when will this occur?
    - Will the MAC(s) send ADRs simultaneously for all claims selected as part of the random sample?
    - How long will IRFs have to respond to ADRs in this track?
    - How long will the MAC(s) have to make determinations regarding the claims in this sample?
- How will these timelines impact the ability of IRFs to move through the various review cycles and make determinations regarding subsequent review choices?
- CMS has stated that claims submitted for pre-claim review will be excluded from future medical review by the MAC or Recovery Audit Contractor and will only be subject to additional review if fraud or gaming is suspected (Unified Program Integrity Contractor review) or if selected for Comprehensive Error Rate Testing (CERT) review. Will this exclusion also apply to claims under the selective post-payment review track, i.e., will claims reviewed post-payment for the RCD be subject to a potential "double review"? Will IRFs subject to the RCD be excluded from all additional review, or will this exclusion only apply to the selective sample of claims reviewed under this track?

Spot-Check Pre-Payment Review Track Questions

- What criteria will be utilized to create the 5% spot-check sample of claims?
- Will the sample be statistically valid? If so, will CMS use a stratified random sample or clustered random sample to ensure that the results of the review are representative of the total population of claims at a given IRF?
- Will the sample be representative of the following patient characteristics:
    - Impairment/RIC/CMG?
    - Discharge Location?
    - Length of Stay?
    - Short Stays/Early Transfers?
- How will the spot-check sampling methodology handle instances where a given IRF's population may not be the same as the previous six months' claim volume? For example, if the IRF population in the previous six months' claim volume was comprised of 20% debility patients, but the subsequent cycle's claim volume only includes 10% debility patients, how will the 5% spot-check sample handle the changing population?
- What processes and time frames will be involved in this track? How will the processes for the **pre-payment** review differ from the other tracks, which involve either pre-claim or post-payment review?
    - Will ADRs be sent for each claim selected for the spot-check sample? If so, how long will IRFs have to respond to the ADR, and how long will the MAC(s) have to make a decision?
    - How will decisions on pre-payment review be made and communicated to IRFs?

    - Will the pre-payment review process include any opportunity for education, revision, and resubmission of claims, as in the pre-claim review track?
- CMS has stated that claims submitted for pre-claim review will be excluded from future medical review by the MAC or Recovery Audit Contractor and will only be subject to additional review if fraud or gaming is suspected (Unified Program Integrity Contractor review) or if selected for Comprehensive Error Rate Testing (CERT) review. Will this exclusion also apply to claims under the spot-check pre-claim review track, i.e., will claims reviewed pre-claim for the RCD be subject to a potential "double review"? Will IRFs subject to the RCD be excluded from all additional review, or will this exclusion only apply to the selective sample of claims reviewed under this track?

Review Cycle Questions

- When will CMS be publicly releasing information on the review dates, analysis periods, and subsequent cycles that has been shared at private conference presentations?
- Which claims will be included in the calculations for each six-month review cycle?
    - Especially for post-payment review (when there may be more than 100 days between claim submission and a final decision), how will the affirmation rate calculations address claims that have not yet been determined by the end of the review cycle?
    - How will the calculations account for pre-claim review submissions that are being resubmitted by the IRF but have not received a final decision by the end of the calculation period?
- How are IRFs subject to the RCD intended to handle claims that arise between the end of a given review cycle and the beginning of the next review cycle? Will these periods constitute breaks in the RCD entirely, or will IRFs continue to submit all claims for pre-claim or post-payment review during these periods?
- How will the MAC(s) handle claims with dates of service that cross between review cycle dates and the interim periods?
- For subsequent review cycles, if an IRF has met the initial target affirmation rate and selected a narrower review choice, will the higher target rates for the following cycles be applied to only their selective post-payment or "spot check" sample? Or do these higher rates only apply to IRFs who did not meet the initial affirmation rate?
- If an IRF selects a narrower review choice after meeting the initial affirmation rate, but fails to meet the target rate for a subsequent cycle, will they then "revert" back to their initial review choice for the following cycle, and which target affirmation rate will apply?
    - If the selective post-payment or spot-check samples do not meet the target affirmation rate in a subsequent review cycle, will the MAC(s) retroactively review the full slate of claims for the review cycle to see if the target rate was met in the aggregate? Or will the IRF automatically be reverted back to the initial review choice only based on the narrower sample?
- If an IRF meets or exceeds the target affirmation rate in each of the three review cycles, are they then "released" from the RCD, or do they continue with their narrower review choice indefinitely?
    - How long will IRFs be subjected to the RCD if they continue to meet or exceed the target affirmation rates?

- CMS states on page 5 of the Operational Guide both that "An IRF's target affirmation rate is based on the following sliding scale **from the time an IRF starts the demonstration**" and that "Any new IRFs will be subject to the target affirmation rate review cycle that their state has in process at that time."
    - If a new IRF opens in an RCD state midway through the second, third, or subsequent review cycles, will they immediately be subject to the higher target affirmation rate?
    - If so, will they also move to the next cycle and target affirmation rate at the same time as other IRFs in the state that had been open for the entire duration of the RCD, or will they be subject to a full six-month review cycle beginning from their opening date?
    - If a new IRF opens midway through the three-cycle period that other IRFs in the state are subject to, are they then able to satisfy the higher affirmation rates and move on to subsequent phase(s) of the RCD without undergoing three full six-month review cycles?

Miscellaneous Additional Questions

- How will the RCD be applied, if at all, to IRFs located in target states that do **not** typically bill to the MAC operating the RCD in that state?
    - Will IRFs in these circumstances be required to participate in the RCD?
    - If so, will their claims be transferred to the RCD MAC by the IRF's standard MAC, or does the IRF need to prepare to submit their claims directly to the RCD MAC for the duration of the demonstration?
    - Will IRFs in these circumstances need to submit claims to multiple MACs simultaneously during the RCD?
    - If these IRFs are required to "switch" MACs during the RCD, should they continue submitting claims to the RCD MAC even if and when they move to a narrower selective or spot-check review? Or when they are in the interim periods between review cycles?
- At times, IRF beneficiaries will gain Medicare coverage status partway through their stay. How will the RCD be applied (or not) to claims for these beneficiaries? If they are admitted under a non-Medicare payer, and then Medicare coverage begins partway through the stay, will IRFs still be subject to RCD review for the admission decision that was made prior to Medicare coverage?
- On page 6 of the Operational Guide, CMS states that IRFs under UPIC review are not eligible for participation in this demonstration, but that "all IRFs are encourage to make a choice selection."
    - If an IRF in an impacted state is undergoing a UPIC audit that ends while the RCD is still ongoing, will that IRF then be subject to the RCD?
    - Given the ongoing burden of extensive SMRC and TPE audits, including many reports of overlapping TPE audits that appear to go against program directives, will CMS consider also excluding IRFs undergoing SMRC and TPE audits from the RCD, at least until these audits are completed?

- Throughout the Operational Guide, there are several instances where some language appears to be lifted directly from documents used in the Home Health RCD.
    - On the CMS website, the PDF for the Operational Guide appears to be titled "Pre-Claim Review Demonstration for Home Health Services."
    - On page 4 of the Operational Guide, the fourth footnote links to Chapter 7 of Medicare Benefit Policy Manual covering Home Health Services, *not* Chapter 1 of the MBPM covering IRF services.
    - On pages 5 and 21 of the Operational Guide, CMS states that "If the IRF's rate is less than the target affirmation rate or they have not submitted at least 10 requests/claims, the IRF must again select from one of the **initial three choices**." The rest of the information CMS has released indicates that IRFs will only have **two** choices in the initial phase – pre-claim or post-payment review.
        - Does CMS intend to release information on a third choice that has not yet been unveiled, or does reflect an instance of CMS inadvertently copying language from the extant Home Health Review Choice Demonstration, which did offer three initial choices to impacted Home Health Agencies?
            - If the latter, is there additional information throughout the IRF RCD documents released so far that is "carryover" language from the Home Health RCD and does not apply to the IRF RCD?
    - Will CMS be issuing corrections to these materials to ensure that the official documentation applies to the IRF RCD and not other demonstrations for other settings of care?
    - Will CMS be allowing stakeholders an opportunity to review other documents being used for the RCD, including those intended to educate and train the MAC(s), to ensure that there are not any similar errors that impose substantive changes to the IRF coverage criteria?