Appendix 1 – Response to 60-day comments

CMS Responses to Public Comments Received for CMS-10765: Review Choice Demonstration (RCD) for Inpatient Rehabilitation Facility (IRF) Services. CMS received 35 total comments. A summary of our comments and responses is below.

Many commenters expressed concern about starting a demonstration during the COVID-19 public health emergency (PHE). Commenters stated that the timing and magnitude of the RCD will jeopardize public health goals and will contradict the intent of PHE waivers. The commenters stated that operational activities and resources, as well as patient care services, would be diverted to the demonstration, and it would be burdensome to participate in the demonstration due to the new challenges presented by "long-COVID-19" survivors. One commenter stated that announcing the RCD is inconsistent with other health care programs containing new pre-authorization requirements within CMS that would not apply until 2024. Several commenters stated that at least two years should be given after the PHE to start a demonstration of this nature.

Response:

The CMS is very concerned with the obvious effects of the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) on the healthcare community's ability to deliver care that is immediate and targeted to the specific medical needs of our beneficiaries. During the COVID-19 PHE, CMS has issued several waivers to decrease administrative burden and to provide flexibility for Inpatient Rehabilitation Facilities (IRF) services to efficiently treat patients. Reviews under the demonstration will take into account any applicable waivers in effect on the date of service. For further information, please access the current waiver list covid-19-emergency-declaration-waivers.pdf.

CMS is confident that the IRF demonstration will not impede beneficiary access to care or prohibit providers from delivering services. In addition, CMS has not announced a start date for the IRF RCD. We will continue to monitor the status of the PHE for potential impact on proposed dates.

When the IRF RCD begins, providers do not need to wait to begin services and have options to choose from that to best align with their business model. Once an IRF reaches a pre-claim review affirmation or postpayment review approval rate of 90% or greater after 6 months, they will have additional options. IRFs who show compliance with Medicare rules and meet the threshold can choose to opt-out of reviews, except for a spot check of a small percentage of their claims.

Many commenters stated concerns that the demonstration will increase both administrative and financial burdens. Commenters stated that the demonstration would add an increased paperwork burden on IRFs, taking the focus away from quality measures and enhancing outcomes for patients. Several commenters stated that many smaller and

rural providers would be unable to sustain the financial uncertainty created by this demonstration. Also, commenters stated that CMS fails to consider multiple factors in its burden estimate, including the level of personnel needed for these requirements, the time and expense needed to implement the new processes, tracking ongoing claim requests, expected appeals, and adjustments hospitals will need to make due to the financial implications of this demonstration.

Response:

In an effort to create a process that balances provider burden while continuing our fiduciary responsibility to lower the IRF improper payment rate and prevent fraud, waste, and abuse, CMS structured the demonstration to offer increased flexibility, provider choice, as well as additional risk-based changes.

The pre-claim review option does not create any new documents or administrative requirements and resources should not need to be diverted from patient care. Instead, it requires the currently needed documents to be submitted earlier in the claim process. Ultimately, having an affirmed pre-claim review decision will help the cash flow for the provider as an affirmative decision shows that a claim likely meets Medicare's coverage and payment rules. Absent evidence of fraud or gaming, a provider can anticipate payment as long as other payment requirements are met. IRFs have the flexibility and choice to participate in other options if they do not want to participate in pre-claim review. Under the postpayment review option, the provider will follow all of the standard procedures they currently do and submit the claim for payment. As the provider would already have received payment for the claim, this would not cause a financial hardship for the providers.

In addition, IRFs that reach a pre-claim review affirmation or postpayment review approval rate of 90% or greater after 6 months, will have the additional option of a spt-check review of only 5% of claims, to ensure continued compliance. Providers that demonstrate continued compliance with Medicare rules and regulations may remain in that option for the duration of the demonstration if they choose.

CMS believes that the additional review options, along with the ability to opt-out of reviews once a provider demonstrates compliance with Medicare rules will offer providers the flexibility to choose a review option that will work for them based on their resources and financial needs, no matter the size of their agency. In addition, providers who have not met the threshold will be allowed to change options if they believe another option will work better for their resources. Therefore, CMS does not believe the demonstration will adversely affect IRF business models or cause decrease availability to Medicare beneficiaries.

The commenters stated concern that medical review contractors (MACs) are nurse reviewers who lack training and the expertise to review IRF claims. Many commenters stated that IRFs experience "medical necessity" claim denials from CMS contractors and audit programs that result from misunderstandings or misapplications of Medicare's regulations governing IRF care by non-clinical reviewers. The commenters stated that many of the denials are reversed on appeal before administrative law judges, especially

when the rehabilitation physician participates in the hearing and explains their decision to admit and treat the patient. Commenters stated concern that the combination of reviewers who are not licensed rehabilitation physicians contribute to incorrect review decisions which incorrectly inflate the improper payment rate, as well as the high number of overturned appeals that are considered in the report.

Response:

CMS requires the MACs to use Registered Nurses, therapists, or physicians to make coverage determinations. Reviewers will follow the same review guidelines as they currently do, as no new documentation will be required under the demonstration. The MACs are not substituting their judgment for the physician's, but ensuring that the documentation meets Medicare rules and clearly demonstrates the physician's reasons for ordering services. CMS requires a medical review of beneficiary paperwork and records to verify medical necessity, compliance with Medicare rules, and statutes medical reviewers must complete appropriate education requirements and/or certification and these requirements will not change for the IRF demonstration. CMS has published numerous educational materials to inform IRFs and Medicare beneficiaries of the policies and documentation requirements for IRF services.

CMS will ensure there is continued oversight of all MAC activities under this demonstration. The MAC reviewers will undergo training to ensure consistency prior to beginning the reviews. Both the MAC and CMS will monitor the reviewers' accuracy throughout the demonstration and CMS staff will conduct reviews on a selection of requests/claims to ensure the MAC decisions are accurate and consistent across reviewers. Additionally, these reviews will be subject to accuracy reviews by the designated contractor.

CMS believes that the qualified reviewers for the IRF demonstration will provide the necessary expertise to check records for accuracy and missing or incomplete information in the medical record. If a pre-claim review request is non-affirmed due to a documentation issue, the MAC will proactively reach out to the provider to discuss the issue and encourage the provider to resubmit the request. CMS and the MACs will work together to ensure that errors are evaluated for further action, as in education or the need to investigate for fraud and or waste.

Many commenters expressed concerns that the RCD would disrupt and create delays in care or lack of access for Medicare beneficiaries. Commenters stated that delaying hospital-level IRF care because of the process required by the RCD could have an irreversible, negative effect on patients' course of recovery. Other commenters stated that providers choosing pre-claim review may experience denials or non-affirmation decisions during the course of treatment, and may be forced to discharge patients, creating disruptions in care due to review decisions which may be overturned on appeal.

Response:

CMS does not believe this demonstration will disrupt or create delays in care or lack of access for Medicare beneficiaries. Pre-claim review will allow the beneficiary to begin receiving services before an affirmative (i.e., approved) decision is received, unlike prior authorization,

which ensures that all relevant coverage, coding, and payment requirements are met before the service is rendered to the beneficiary and before the claim is submitted for payment. An IRF may begin providing inpatient rehabilitation therapy services prior to submitting the pre-claim review request and may continue to do so while waiting for a decision. In that way, beneficiary access to treatment will not be delayed. There is no requirement to discharge patients when a non-affirmative decision is received, providers should resubmit any additional information the MAC request. An IRF has an unlimited number of resubmissions for the pre-claim review request to make any needed changes to receive a provisional affirmed decision, though IRF providers should not be admitting patients who don't meet Medicare requirements. In addition, the postpayment review option does not impact care, as services have already been rendered.

Commenters stated that pre-claim review under the RCD is inconsistent with CMS requirements for an individual care plan. The commenters noted that the individualized plan of care is due within four days of a patient's admission, and is required for all pre-claim review submissions. Additionally, commenters are concerned about the 10-day review timeframe for possible resubmissions of pre-claim review requests. If there is a non-affirm decision, there is concern that the IRF stay will be completed before the IRF can receive their decision on the resubmitted request, since the average IRF stay is 12 days. Several commenters suggested that CMS revise the review period so that MACs are required to respond on the same day of the IRF's submission and have the capability to respond 24 hours a day.

Response:

CMS structured the Review Choice Demonstration to offer increased flexibility, provider choice, as well as additional risk-based changes. IRFs are offered a choice between a pre-claim review or postpayment review to meet their individual facility needs. Ultimately, having an affirmed pre-claim review decision will help the cash flow for the provider as an affirmative decision shows that a claim likely meets Medicare's coverage and payment rules. Claims for which there is an associated provisional affirmative pre-claim review decision will be paid in full, so long as the inpatient rehabilitation claim was billed and submitted correctly. Additionally, CMS has changed the resubmission of pre-claim review request with a 5-day turnaround decision from the MACs.

IRFs have the flexibility and choice to participate in other options if they do not want to participate in pre-claim review. Under the postpayment review option, the provider will follow all of the standard procedures currently in place, and submit the claim for payment. As payment have been received for the claim, this would not cause a financial hardship for the providers. In addition, IRFs that reach a pre-claim review affirmation or postpayment review approval rate of 90% or greater after 6 months, will have the additional option of a spot-check review of only 5% of claims, to ensure continued compliance. Providers that demonstrate continued compliance with Medicare rules and regulations may remain in that option for the duration of the demonstration if they choose.

Commenters stated that the CMS resource entitled "Review Choice Demonstration for Inpatient Rehabilitation Facility Services" included a section on "Additional Required Documentation" where documents are no longer required in the FY 2021 IRF PPS Final

Rule (85 Code of Federal Regulations 48424-48463 - Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2021). The commenters stated that the following was removed in the pre-admission screening: expected frequency and duration of treatment, anticipated post-discharge treatments, and other information relevant to the beneficiary's care needs. Commenters stated that the post-admission physician evaluation was entirely removed. One commenter stated that if the post-admission physician evaluation is provided, that the MAC accepts it to support the claim, no matter what timeframe it is performed. Other commenters stated that face-to-face visits have an allowance for use of non-physician practitioners to meet some of the documentation requirements for the visits/encounters by rehabilitation physicians.

Response:

CMS thanks the commenters for bringing this to our attention and agrees that these required documents will not be required as part of the demonstration. This demonstration will not create new clinical documentation requirements; rather, it will only require submission of the same information providers are currently required to maintain. This will help guarantee that all relevant coverage and clinical documentation requirements are met.

Documentation requirements that have been removed in 85 FR 48424 are not required for the demonstration; however, if a provider wants to submit these documents, they will be accepted regardless of the timeframe in which they were completed. For example, the post-admission physician evaluation that was previously required to be submitted within 24 hours of an admission may be completed at any time. During the PHE, pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that broadens the waiver authority under section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS recognizes that the Face-to-Face visits have an allowance of non-physician practitioners to meet some of the documentation requirements for the visits/encounters by rehabilitation physicians under 42 CFR § 412.622(a)(3), (4), and (5).

The commenters stated that CMS has "lack of authority" to implement the RCD under 42 U.S.C. § 1395b-1(a)(1)(J). Commenters stated that the provision explicitly requires fraud to be the target and CMS is not alleging fraud in the information collection notice. Other commenters stated that CMS should allocate its time and resources to target facilities with evidence of fraudulent activities, rather than penalizing all IRFs. Commenters stated that any IRFs in the RCD should be exempt from an audit by an auditing agency unless there is a credible fraud investigation.

Response:

CMS disagrees that it lacks authority to implement this demonstration under 42 U.S.C. § 1395b-1(a)(1)(J). Based on previous CMS experience, the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) reports, and Government Accountability Office (GAO) reports, there is evidence of fraud and abuse in the Medicare IRF benefit. Additionally, a high improper payment rate is seen for IRF services. This demonstration is not intended to change any of the payment requirements or structures in Medicare or to test new value-based purchasing

options to improve and reduce costs. Rather this demonstration will test if implementing a review choice for IRFs that includes pre-claim review, will improve the detection and prosecution of fraud, while reducing improper payments. It is important to note that the improper payment rate is not a measure of fraud. They are payments that did not meet statutory, regulatory, administrative, or other legally applicable requirements, which may include fraudulent occurrences. In 2019, The Medicare Payment Advisory Commission (MedPAC), a nonpartisan, legislative branch agency that provides the U.S. Congress with Medicare program analysis and policy advice, reported that IRFs' marginal profit—a measure of providers' financial incentive to expand the number of Medicare beneficiaries they serve—has risen steadily since 2009. While high profit margins are not inherently indicative of fraud, it could incentivize IRFs to increase inappropriate admissions. While CMS will monitor to ensure appropriate beneficiary access to necessary care throughout the demonstration, the primary intent of the demonstration design is not to improve quality under this Medicare benefit program. Therefore, the most appropriate authority for this demonstration is Section 402(a)(1)(J).

CMS believes this demonstration will also allow the agency to better understand the scope and causes of improper payments and work with IRFs to reduce documentation errors. This will allow CMS to focus on the prevention of improper or fraudulent claims and will reduce Medicare's current reliance on the practice of "pay and chase" for inappropriate billing, which occurs when the service is paid and CMS relies on postpayment review and recoupment of improper payments, particularly through the utilization of pre-claim review.

To evaluate compliance options beyond a "pay and chase" approach, this demonstration will enable CMS to test the level of resources required for an inpatient rehabilitation payment procedure that determines whether applicable Medicare coverage and clinical documentation requirements are met before the claim is submitted for payment. This demonstration will also determine the feasibility of performing either pre-claim review or postpayment review for services that have historically demonstrated high instances of potential fraud and to determine a return on investment (or other metrics) for different types of reviews of IRF claims. CMS believes this approach has the benefit of assuring that IRFs submit evidence demonstrating that the beneficiary's condition meets the Medicare coverage policies for IRF services, thereby ensuring beneficiaries appropriately receive care and reducing the incidence of improper payments. The IRF and beneficiary are also assured that the claim meets Medicare coverage policies for inpatient rehabilitation therapy and is likely to be paid.

IRF claims for which there is an associated provisional affirmative pre-claim review decision will be paid in full, so long as the claim was billed and submitted correctly. Absent evidence of possible fraud or gaming, claims will not be subject to postpayment review by MAC, RAC, or SMRC. Claims could still be selected for review based on potential fraud or for purposes of measuring the Medicare improper payment rate.

One commenter stated that Medicare should require prior authorization for admissions to IRFs.

Response:

CMS thanks the commenter for their feedback. CMS will test different review options through the review choice demonstration, while offering choices to providers to best meet their needs, incorporating risk, and rewarding providers who show compliance with Medicare IRF policies.