Supporting Statement Part A
Pre-Claim Review Demonstration for Inpatient Rehabilitation Facility Services
(CMS-10765/OMB control number: 0938-1420)

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval for the Review Choice Demonstration for Inpatient Rehabilitation Facility (IRF) Services. This demonstration would help assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. By ensuring that payments for IRF services are appropriate through either pre-claim or postpayment review, this demonstration also works toward the prevention and identification of potential fraud, waste, and abuse, as well as protecting the Medicare Trust Funds from improper payments while reducing Medicare appeals.

As part of this demonstration, IRFs have the option of two choices – pre-claim review or postpayment review of every IRF service. A provider's compliance with Medicare billing, coding, and coverage requirements determines that provider's next steps under the demonstration.

This demonstration continues to follow and adopt the pre-claim review processes that currently exist in the Review Choice Demonstration for IRF Services. The postpayment review options will follow the process outlined in Chapter 3 of the Program Integrity Manual;[1] however, providers could submit documentation at the same time as or immediately after the claim submission.

Demonstration Design

CMS implemented the demonstration in Alabama beginning August 21,2023 and expanded to Pennsylvania June 17, 2024. CMS plans to conduct the demonstration in Texas and California, as well as IRFs located in any state that bill to the Medicare Administrative Contractor (MAC) jurisdictions JJ (Alabama, Tennessee, and Georgia), JL (Pennsylvania, New Jersey, Delaware, Maryland, and the District of Columbia), JH (Texas, New Mexico, Colorado, Oklahoma, Arkansas, Louisiana, and Mississippi), and JE (California, Hawaii, and Nevada). The goal of this five-year demonstration is to develop improved methods for the investigation and prosecution of fraud in the provision of care or services, as well as protecting the Medicare Trust Funds from improper payments while also reducing Medicare appeals. This project is being proposed to, in the end, better enable CMS to detect and deter such conduct.

Under this demonstration, CMS offers choices for providers to demonstrate their compliance with CMS' IRF policies. Providers in the demonstration states may participate in either 100 percent pre-claim review or 100 percent postpayment review. Every six months, the provider's pre-claim review affirmation rate or postpayment review approval rate will be calculated. If the IRF provider reaches the target pre-claim review affirmation or post-payment review claim approval rate, they may elect to opt out of future claim reviews, except for a spot check of five percent of their claims to ensure continued compliance. An IRF's target affirmation rate is based on the following sliding scale from the time an IRF starts the demonstration: first review cycle: 80% affirmation rate, second review cycle: 85% affirmation rate, or third review cycle: 90% affirmation rate. Any new IRFs will be subject to the target affirmation rate review cycle that their state has in process at that

[1] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c03.pdf

time. The IRF provider may also instead choose to either continue or start participating in pre-claim review or choose to participate in selective post-payment review based on a statistically valid random sample.

If an IRF chooses to participate in pre-claim review, the IRF initiates the pre-claim review process by submitting a pre-claim review request to the MAC. The MAC will examine the pre-claim review request to determine whether the inpatient rehabilitation service for the beneficiary complies with applicable Medicare coverage and clinical documentation requirements. The MAC will communicate a decision that provisionally affirms or non-affirms the request for approval for the services to both the IRF provider and the beneficiary. An IRF may begin providing 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. If a non-affirmed decision is received, the IRF has an unlimited number of resubmissions for the pre-claim review request in order to make any needed changes to receive a provisional affirmed decision.

IRFs may send documentation to the MAC via regular mail, fax, or electronically (e.g.- portals, standards based application programming interfaces (APIs), or other electronic means). This includes any documentation from the patient's medical record that supports medical necessity and demonstrates that the Medicare IRF coverage requirements are met. When an IRF submits an initial pre-claim review request, the MAC will have two business days to inform the provider that their pre-claim review has been given an "affirmative" or "non-affirmative" decision. An "affirmative" decision means that the documentation submitted has proved medical necessity, and as long as all other requirements have been met, the claim will likely be paid. If the IRF receives a "non-affirmative" decision, the MAC will provide a detailed letter showing the exact reasons why the non-affirmative decision was given, and what, if any documentation needs to be submitted in order to receive an "affirmative decision." The IRF may resubmit a pre-claim review request as many times as they wish prior to submitting the final claim for payment. The MACs will have two business days to provide a decision for any subsequent pre-claim review requests.

The following explains the various pre-claim review scenarios:

When a submitter submits a pre-claim review request to the MAC with appropriate documentation and all relevant Medicare coverage and clinical documentation requirements are met, a provisional affirmative pre-claim review decision is sent to the IRF and the Medicare beneficiary. When the IRF submits the claim to the MAC after delivering the inpatient rehabilitation service(s), the claim is then linked to the affirmed pre-claim review through a Unique Tracking Number (UTN). As long as all requirements are met, the claim will be paid. When a submitter submits a pre-claim review request with complete documentation, but all relevant Medicare coverage requirements are not met for the inpatient rehabilitation service, a non- affirmed pre-claim decision will be sent to the IRF and the Medicare beneficiary advising them that Medicare will not pay for the services. If the claim is still submitted by the IRF to the MAC for payment, it will be denied. The IRF and/or the beneficiary can appeal the claim denial.

In cases where documentation is submitted but is incomplete, the pre-claim review request is sent back to the submitter for resubmission and the IRF and the Medicare beneficiary are notified.

When the IRF submits a claim to the MAC for payment without submitting a pre-claim review request, the inpatient rehabilitation claim(s) will be subjected to prepayment medical review.

If the IRF chooses postpayment review of all of their claims, the IRF will follow its standard intake, service, and billing procedures, and the claims will be paid according to normal claim processes. The MAC will conduct a complex medical review on the claims submitted during a six- month interval. This will determine whether the IRF service(s) for the beneficiary complied with applicable Medicare coverage and clinical documentation requirements. The MAC will send the IRF an additional documentation request (ADR) letter following receipt of the claim for payment.

JUSTIFICATION

1. Need and Legal Basis

Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) authorizes the Secretary to "develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act)." Pursuant to this authority, the CMS seeks to develop and implement a revised Medicare demonstration project, which CMS believes will help assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among IRFs providing services to Medicare beneficiaries.

Based on previous CMS experience, Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports, 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. A 2018 OIG report analyzed Medicare claims data from the calendar year 2013 and estimated that Medicare paid IRFs nationwide $5.7 billion for care to beneficiaries that was not reasonable and necessary. The OIG also noted that the IRF payment system did not align cost with payments, which may have provided IRFs with a financial incentive to admit patients inappropriately.[2] A recent MedPAC analysis showed IRFs' marginal profits were 18 percent for hospital-based IRFs and 39 percent for freestanding IRFs.[3] MedPAC has previously raised concerns that high profit margins may give IRFs a financial incentive to admit patient unnecessarily.[4] Also, over the past several years, CMS' Comprehensive Error Rate Testing (CERT) program has continuously estimated significantly high improper payment rates for IRF services. In 2023, the CERT program reported that IRFs were one of the main drivers of the Medicare Fee for Service improper payment rate at 27.3%, with a projected $1.9 billion in improper payments.[5]

2. Information Users and Use

The information required under this collection is used to determine proper payment or if there is a suspicion of fraud. The information requested includes all documents and information that show the number and level of services requested are reasonable and necessary for the beneficiary. For the pre-claim review option, the MAC will review the information from IRF providers in advance of their claim submission to determine appropriate payment. For the postpayment review option, providers may submit the documentation at the time they submit the claim. If they do not, the MAC will send the provider an ADR asking for the documentation.

[2] https://oig.hhs.gov/oas/reports/region1/11500500.pdf
[3] http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0
[4] https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_v3_SEC.pdf
[5] https://www.cms.gov/files/document/2023medicarefee-servicesupplementalimproperpaymentdatapdf.pdf

The documentation will be reviewed by trained nurse reviewers. They will use the documentation to determine if the beneficiary qualifies for IRF services.

3. Improved Information Techniques

Some of this collection of information could involve the use of electronic data or other forms of information technology at the discretion of the submitter. Where available, providers may submit their pre-claim review requests and/or other documentation through electronic means. CMS offers electronic submission of medical documentation (esMD)[6] and the MACs provide electronic portals for providers to submit their documentation. Other electronic means may include standards based application programming interfaces (APIs) such as Fast Healthcare Interoperability Resources (FHIR), or other interoperable technologies.

4. Duplication and Similar Information

CMS as a whole does not collect all of the information in any existing format. With the exception of basic identifying information such a beneficiary name, address, etc., there is no standard form or location where this information can be gathered. CMS will use readily available data to make informed review decisions when possible, such as data submitted through the IRF Patient Assessment Instrument (IRF PAI).

5. Small Businesses

This collection will impact small businesses or other entities to the extent that those small businesses bill Medicare in a manner that triggers review under one of the review choice options. Consistent with our estimates below, we believe that the total claims impact on all businesses is less than one-tenth of one percent of claims submitted. We do not have the number of small businesses that will be impacted. This collection will only impact small business and all respondents in that they must work with providers to obtain the necessary medical documentation to support their claims.

6. Less Frequent Collections

Under the pre-claim review option, a pre-claim review request is submitted for each IRF admission. For the 100% postpayment review option, providers will submit documentation for each claim they submit after receiving an ADR from the MAC. Under the subsequent review options, the provider will submit the documentation following receipt of an ADR. Since IRF services represents an area where a history of program history vulnerabilities exists, less frequent collection of information on these items under the initial review options would be imprudent and undermine the demonstration. However, providers who have demonstrated compliance with Medicare rules can choose one of the subsequent review options, which would allow for a less frequent collection of information for those providers.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice

A 60-day notice published in the Federal Register on December 17, 2024 (89 FR 102149). Responses to comments re

[6] www.cms.gov/esMD

are summarized in Appendix 1. A 30-day notice published June 27, 2025 (90 FR 27539). No additional outside consultation was sought.

9. Payments or Gifts to respondents

No payments or gifts will be given to respondents to encourage their response to any request for information under this control number.

10. Confidentiality

Medicare contractors have procedures in place to ensure the protection of the health information provided. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allows for the disclosure of health records for payment purposes. The MAC will safeguard all protected health information collected in accordance with HIPAA and Privacy Act standards as applicable.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimate

Wage Estimates:
To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (May 2023 Occupational Employment Statistics report). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. Based on the Bureau of Labor Statistics report (Miscellaneous Health care support occupations), we estimate an average hourly rate of $20.62 with a loaded rate of $41.20.

Mean Hourly Wage (p/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
$20.62	$20.62	$41.20

CMS anticipates that most submissions will be sent through electronic means. The burden associated with this demonstration is the time and effort necessary for the submitter to locate and obtain the supporting documentation for the Medicare claim and to forward the materials to the MAC for review. CMS expects that this information will generally be maintained by providers as a normal course of business and that this information will be readily available.

The documentation submitted is the documentation from the medical record that supports medical necessity, the level of care requested, and demonstrates that the Medicare IRF coverage requirements are met. IRFs are required to have this information on file. CMS anticipates clerical staff will collect the information from the medical record and prepare it to be submitted for review. CMS estimates that the average time for office clerical activities associated with this task to be 30 minutes, equivalent to that for prepayment review. An additional three hours of time is estimated for attending educational meetings and reviewing training documents about the demonstration.

The estimate below is based on full implementation of the demonstration. Due to the COVID-19 and a staggered start for the states, we have not currently expanded to all states in the demonstration as expected. Since the demonstration must ramp up, the first several years numbers will be lower than the remaining years; however, we assumed full implementation numbers for the purposes of estimating.

IRF DEMONSTRATION- Year Three- Full Implementation of All Providers That Bill to Jurisdictions: JJ, JL, JH, and JE

Activity	Responses Per Year (i.e. number of pre-claim review request reviewed)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests	Submissions 181,458	0.5	90,729	$3,738,037
	Resubmissions 53,587	0.5	26,793	$1,103.88
Mailed Requests	Submissions 1,833	0.5	916	$37,758
	Resubmissions 541	0.5	271	$11,150
Mailing Costs	Total Submissions 2,374	$5	n/a	$11,871
Provider Education	IRF Providers 536	3	1,608	$66,250
IRF Demonstration Total				$4,968,954

CMS estimates the cost of mailing medical records to be $5. CMS offers the electronic submission of medical documentation (esMD) system to providers who wish to use an electronic alternative for sending in medical documents. Additional information on esMD can be found at www.cms.gov/esMD. The MACs also provide an electronic portal for providers to submit their documentation if they wish to use it. Based on calendar year 2023 data, CMS estimates that under this demonstration, at a minimum there will be 1,833 initial pre-claim review requests and responses to ADRs mailed during the third year the jurisdictions JJ, JL, JH, and JE. In addition, CMS estimates there will be 541 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost when all the states in the MAC jurisdictions are implemented is estimated to be approximately $11.9 thousand. We estimate the total cost for year three would be approximately $4.9 million. This impact is allocated across providers and the applicable jurisdictions states.

13. Capital Costs

There is no capital cost associated with this collection.

14. Costs to Federal Government

CMS estimates that the costs associated with performing the reviews for IRF services under the demonstration would be approximately $.9 million over the five-year demonstration period.

15. Changes in Burden

Burden hours have increased due to the change in the number of IRFs which increased from 526 to 536. Overall burden hours increased from 91,533 to 120,317 hours. Costs have also increased as a result of the change in IRFs from $3,144,909 to $4,922,031 for all states in the demonstration.

16. Publication or Tabulation

There are no plans to publish or tabulate the information collected due to this information being confidential. CMS will periodically publish summary level information on the demonstration such as the number of requests submitted, number of requests affirmed, number of requests non-affirmed, etc.

17. Expiration Date

Each instrument displays the expiration date and OMB control number on the first page, top right corner.

18. Certification Statement

There are no objections to the certification statement.