# Supporting Statement Part A Review Choice Demonstration for Home Health Services CMS-10599/0938-1311

### **BACKGROUND**

The Centers for Medicare & Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval for the extension of the Home Health Review Choice Demonstration. The demonstration helps assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. The demonstration helps make sure that payments for home health services are appropriate, through either pre-claim or postpayment review, thereby working towards the prevention and identification of potential fraud, waste, and abuse; the protection of Medicare Trust Funds from improper payments; and the reduction of Medicare appeals.

As part of this demonstration, CMS initially allows providers the choice of two options – pre-claim review or postpayment review for every billing period in the demonstration states. 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 the same pre-claim review processes the Review Choice Demonstration for Home Health Services implemented previously. The postpayment review options follow the process outlined in Chapter 3 of the Program Integrity Manual<sup>1</sup>.

## TARGETING FRAUD and IMPROPER PAYMENTS

This demonstration helps assist in developing improved methods to identify, investigate, and prosecute potential fraud in order to protect the Medicare Trust Fund from fraudulent actions and the resulting improper payments. This demonstration adds to the efforts that CMS and its partners have taken in implementing a series of anti-fraud initiatives in these states. Based on previous CMS experience, Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports, Government Accountability Office reports, and Medicare Payment Advisory Commission findings, there is extensive evidence of fraud and abuse in the Medicare home health benefit. OIG home health investigations have resulted in more than 350 criminal and civil actions and \$975 million in receivables for fiscal years (FYs) 2011–2015. In addition, over the past several years, CMS' Comprehensive Error Rate Testing (CERT) program has continuously estimated a significantly high home health improper payment rate. While the improper payment rate for 2024 was 6.7%, this still represents roughly \$1 billion in improper payments. The improper payments were primarily due to "insufficient documentation" errors, and specifically, instances when documentation in the medical record did not meet Medicare's face-to-face encounter requirements.

<sup>1</sup> https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c03.pdf

<sup>&</sup>lt;sup>2</sup> OIG, Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases, OEI-05-16-00031, June 2016

<sup>&</sup>lt;sup>3</sup> This total includes investigative receivables due to the U.S. Department of Health and Human Services (HHS) as well as non-HHS investigative receivables (e.g., amounts due to State Medicaid programs and private health care programs).

## **Demonstration Design**

CMS currently conducts the demonstration in Illinois, Ohio, North Carolina, Florida, Texas, and Oklahoma. The demonstration was extended for an additional five years beginning on June 1, 2024. The goal of this extended review choice demonstration continues to be assisting CMS in analyzing the effectiveness of a review choice process in increasing the ability to identify, investigate, and prosecute fraud as well as reduce improper payments. This demonstration is being conducted 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' home health policies. Providers in the demonstration states may participate in either a 100 percent pre-claim review or a100 percent postpayment review. These providers will continue to be subject to a review method until the HHA reaches the target affirmation or claim approval rate (90 percent, based on a minimum of 10 pre-claim requests or claims submitted). Once the HHA reaches the target pre-claim review affirmation, or post-payment review claim approval rate, it may choose to be relieved from claim reviews, except for a spot check of 5 percent of their claims to ensure continued compliance. The HHA may also instead choose to continue or start participating in pre-claim review or choose to participate in selective post-payment review based on a statistically valid random sample. Until the target rate is reached, review will be required for every home health billing period.

HHAs who choose the pre-claim review option may submit a request for a specific number of billing periods for a beneficiary, instead of submitting a request for each individual billing period. The Medicare Administrative Contractor (MAC) will communicate back to the HHA the number of billing periods that are affirmed on all decisions, which may include all requested billing periods or a lesser number. HHAs or beneficiaries participating in this option must submit a pre-claim review request before the claim is submitted for payment. An HHA may begin providing home health 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 HHA 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.

HHAs may send documentation to the MAC via regular mail, fax, or electronically. This includes any documentation from the patient's medical record that supports medical necessity and demonstrates that the Medicare home health coverage requirements are met. When an HHA submits an initial pre-claim review request, the MAC will have 10 days to inform the HHA 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 HHA 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 HHA may resubmit a pre-claim review request as many times as they wish prior to submitting the final claim for payment. The MAC will have 10 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 documentation requirements are met for the home health

service, then an affirmative decision is sent to the HHA and the Medicare beneficiary. When the HHA submits the claim to the MAC after delivering the home health service(s), it is linked to the preclaim review request via the claims processing system and so long as all requirements are met, the claim is paid. When a submitter submits a pre-claim review request with complete documentation, but all relevant Medicare coverage requirements are not met for the home health service, then a non- affirmed pre-claim decision will be sent to the HHA, and the Medicare beneficiary advising them that Medicare will not pay for the treatment. If the claim is still submitted by the HHA to the MAC for payment, it will then be denied. The HHA 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 HHA and the Medicare beneficiary are notified.

When the HHA provides the treatment to the beneficiary and submits the claim to the MAC for payment without a pre-claim review request being submitted, the home health claim will be reviewed. If the claim is determined to be payable, it will be paid with a 25 percent reduction of the full claim amount. The 25 percent payment reduction, which applies for failure to receive a pre-claim review decision, is non-transferrable to the beneficiary. This payment reduction is not subject to appeal. After a claim is submitted and processed, appeal rights are available as they normally are.

If the HHA chooses postpayment review of all of their claims, the claims will pay according to normal claim processes. The MAC will conduct complex medical review on the claims submitted during a 6-month interval to determine whether the home health service for the beneficiary complied with applicable Medicare coverage and clinical documentation requirements.

## **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 has developed and implemented a revised Medicare demonstration project, which CMS believes helps assist in developing improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among HHAs providing services to Medicare beneficiaries.

## 2. <u>Information Users</u>

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 HHA 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 Medicare contractor will send the provider an ADR asking for the documentation.

The documentation will be reviewed by trained nurse reviewers. They will use the documentation to determine if the beneficiary qualifies for home health services and if they need the level of care requested. The Medicare contractor will also use the documentation to determine if the number of

billing periods requested on pre-claim review is reasonable and necessary.

# 3. <u>Use of Information Technique s</u>

Some of this collection of information could involve the use of electronic 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) and the MAC provides an electronic portal for providers to submit their documentation.

# 4. Duplication of Efforts

CMS as a whole does not collect 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.

## 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 30-day billing period. Providers may request multiple billing periods on one pre-claim review request for an individual beneficiary. For the 100% postpayment review option, providers will submit documentation for each claim they submit. They may do so after they receive an ADR from the MAC. Under the subsequent review options, the provider will submit the documentation following receipt of an ADR. Since home health represents an area where a history of program history vulnerabilities exist, 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/Outside Consultants

The 60-day notice published in the Federal Register on July 17, 2025 (90 FR 31207). A total of zero (0) comments were received.

A 30-day notice published in the Federal Register on September 19, 2025 (90 FR 45216).

No additional outside consultation was sought.

#### 9. Payments/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. <u>Confidentiality</u>

The MAC will safeguard all protected health information collected in accordance with HIPAA and Privacy Act standards as applicable.

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.

#### Sensitive Questions 11.

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

# **Burden Estimate (Hours & Wages)**

The information collection requirements associated with submissions are the required documentation submitted by providers. This includes all relevant documentation necessary to show that the service supports medical necessity, the level of care requested, the number of billing periods requested, and meets applicable Medicare coverage, coding, and payment rules. The burden associated with this process is the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation.

CMS expects that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. 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, which is equivalent to that for normal prepayment or postpayment medical review. CMS anticipates that most submissions would be sent by means other than mail. CMS offers esMD<sup>4</sup> 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 MAC also provides an electronic portal for providers to submit their documentation if they wish to use it<sup>5</sup>. However, CMS estimates a cost of \$5 per request for mailing medical records.

During the demonstration, CMS has the option to expand the included states to all those in the Palmetto/JM jurisdiction. This would include the states of Illinois, Ohio, North Carolina, Florida, and Texas, Oklahoma, Tennessee, Louisiana, Georgia, Alabama, Indiana, Mississippi, Kentucky, South Carolina, Arkansas, and New Mexico. The burden estimate is estimated for both the initial demonstration states and then for JM states.

Burden Estimate- Current Six Demonstration States (Illinois, Ohio, Texas, North Carolina, Florida, and Oklahoma):

<sup>4</sup> www.cms.gov/esMD

<sup>&</sup>lt;sup>5</sup> https://www.onlineproviderservices.com/ecx\_improvev2/

Based on data analyzed while obtaining approval for extending the demonstration, CMS estimated that for the current demonstration states, annually at a minimum there would be 225,950 initial requests mailed during a year. In addition, CMS estimated there would be 62,433 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost was estimated to be \$1,441,915 (288,383 mailed requests x \$5 per request). In addition, CMS also estimated that an additional 3 hours would be required for attending educational meetings, training staff, and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics. Based on the Bureau of Labor Statistics 2024 rate for Healthcare Support Workers, All Others<sup>6</sup>, we estimate an average median clerical hourly rate, CMS estimated an average hourly rate of \$22.14 with a loaded rate of \$44.28. The demonstration does not create any new documents or administrative requirements. Instead, it just requires the currently needed documents to be submitted earlier in the claim process depending on the review choice chosen. Therefore, the estimate used the clerical rate as CMS does not feel that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the demonstration. The hourly rate reflects the time needed for the additional clerical work of submitting the pre-claim review request itself. Therefore, CMS estimated that the total annual burden hours, allotted across all providers, would be731,881 hours (.5 hours x 1,441,915 submissions plus 3 hours x 3,641 providers for education). The annual burden cost would be \$33,849,593 (731,881 hours x \$44.28 plus \$1,441,915 for mailing costs).

HOME HEALTH DEMONSTRATION- 6 States: IL, OH, NC, FL, TX, and OK

Activity	Responses Per Year (i.e. number of reviewed claims)	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- Initial Submissions	903,799	0.5	451,899	\$20,010,099
Fax and Electronic Submitted Requests- Resubmissions	249,734	0.5	124,867	\$5,529,106
Mailed in Requests- Initial Submissions	225,950	0.5	112,975	\$5,002,525
Mailed in Requests- Resubmissions	62,433	0.5	31,217	\$1,382,277
Mailing Costs	288,383	5		\$1,441,915
Provider Demonstration- Education	3,641	3	10,923	\$483,670

<sup>&</sup>lt;sup>6</sup> https://www.bls.gov/oes/current/oes\_nat.htm

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Total		731,881	\$33,849,593
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**Burden Estimate- All 16 States in Jurisdiction M** (Illinois, Ohio, Texas, North Carolina, Florida, Oklahoma, Tennessee, Louisiana, Georgia, Alabama, Indiana, Mississippi, Kentucky, South Carolina, Arkansas, and New Mexico):

Based on data analyzed while obtaining approval for extending the demonstration, CMS estimated that for all states in Jurisdiction M, annually at a minimum there would be 497,215 initial requests mailed during a year. In addition, CMS estimated there would be 137,388 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost was estimated to be \$3,173,016 (634,603 mailed requests x \$5 per request). In addition, CMS also estimated that an additional 3 hours would be required for attending educational meetings, training staff, and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics. Based on the Bureau of Labor Statistics 2024 rate for Healthcare Support Workers, All Others<sup>7</sup>, we estimate an average median clerical hourly rate3

the clerical rate as CMS does not feel that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the demonstration. The hourly rate reflects the time needed for the additional clerical work of submitting the pre-claim review request itself. Therefore, CMS estimated that the total annual burden hours, allotted across all providers, would be 1,600,608 hours (.5 hours x 3,173,016 submissions plus 3 hours x 4,700 providers for education). The annual burden cost would be \$74,047,943 (1,600,608hours x \$44.28 plus \$3,173,016 for mailing costs).

## **HOME HEALTH DEMONSTRATION- 16 States**

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic	1,988,860	0.5	994,430	\$44,033,352
Submitted				
Requests- Initial				
Submissions				
Fax and Electronic	549,553	0.5	274,777	\$12,167,111
Submitted				
Requests-				
Resubmissions				
Mailed in	497,215	0.5	248,607	\$11,008,338
Requests- Initial				
Submissions				
Mailed in	137,388	0.5	68,694	\$3,041,778
Requests-				
Resubmissions				
Mailing Costs	634,603	5		\$3,173,016

<sup>&</sup>lt;sup>7</sup> https://www.bls.gov/oes/current/oes\_nat.htm

Provider Demonstration- Education	4,700	3	14,100	\$624,348
Total			1,600,608	\$74,047,943

# 13. Capital Costs

There is no capital cost associated with this collection.

## 14. Costs to Federal Government

CMS estimates that the annual costs associated with performing reviews for home health services under the demonstration would be approximately \$98.4 million per year during the demonstration period. This figure includes \$98 million for operations in the six current states and \$376 thousand for CMS oversight, which will require 3 fulltime equivalent employees.

# 15. <u>Changes to Burden</u>

The overall burden has changed from 744,514 to 731,881 for the current demonstration states and from 1,357,224 to 1,600,608 for all 16 states).

Due to the addition of a sixth state and an increase in the annual clerical hourly rate and loaded rate, the burden estimate has increased from \$26.9 million to \$33.8 million for the initial demonstration states and from \$49.1 million to \$74 million for all 16 states.

## 16. Publication/Tabulation Dates

There are no plans to publish or tabulate the information collected due to this information being confidential. However, CMS will periodically publish summary level information on the program (such as the number of requests submitted, number of requests affirmed, number of requests non-affirmed, etc.) on the Review Choice Demonstration for Home Health Services website<sup>8</sup>.

## 17. Expiration Date

There is no collection data instrument used in the collection of this information; however, upon receiving OMB approval, CMS will publish a notice to inform the public of both the approval as well as the expiration date.

## 18. Certification Statement

There are no exceptions to the certification statements.

<sup>&</sup>lt;sup>8</sup> https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives/review-choice-demonstration-home-health-services