Supporting Statement Part A
Pre-Claim Review 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 renewal 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 three options – pre-claim review, postpayment review, or minimal review with a 25% payment reduction for all home health services in the demonstration states. If either of the first two options are selected, pre-claim or postpayment review will be required for every billing period. A provider's compliance with Medicare billing, coding, and coverage requirements determines that provider's next steps under the demonstration.

This demonstration followed and adopted the pre-claim review processes that existed in the previous Pre-Claim Review Demonstration for Home Health Services. The postpayment review options follow the process outlined in Chapter 3 of the Program Integrity Manual[1].

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.[2][3] 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

[1] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c03.pdf
[2] OIG, *Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases*, OEI-05-16-00031, June 2016
[3] 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).

improper payment rate for 2020 was 9.3%, this still represents roughly $1.8 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.

Demonstration Design

CMS currently conducts the demonstration in Illinois, Ohio, North Carolina, Florida, and Texas. The goal of this five-year review choice demonstration is to assist 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 100 percent pre-claim review or 100 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 a 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 episode.

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.

Providers who do not wish to participate in either 100 percent pre-claim or post payment reviews have the option to furnish home health services and submit the associated claim for payment without undergoing such reviews; however, they will receive a 25 percent payment reduction on all claims submitted for home health services and could be subject to potential Recovery Audit Contractor (RAC) review. Providers who choose this option will remain under it for the duration of the demonstration and may not select another option. This will allow for operational consistency among the review and payment of the provider's claims.

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 MACs will have 20 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 after delivering the home health service(s) to the MAC, it is linked to the pre-claim 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.

Demonstration Pause

Due to the Public Health Emergency (PHE) for the COVID-19 pandemic, CMS announced a pause on March 30, 2020 of certain claims processing requirements for the Review Choice Demonstration (RCD) for Home Health Services in Illinois, Ohio, and Texas. In addition to the pause, the demonstration also did not begin in North Carolina and Florida on May 4, 2020 as previously scheduled. Beginning on August 31, 2020, CMS began discontinuing exercising enforcement

discretion for the demonstration and home health claims in Illinois, Ohio, and Texas with billing periods beginning on or after August 31, 2020, were subject to review under the requirements of the review choice the provider selected. This includes pre-claim review, prepayment review, and postpayment review. In addition, CMS began the demonstration in North Carolina and Florida on phased-in basis. Providers were allowed to participate in the demonstration if they chose, but were not required to do so. CMS extended the phased-in participation of the Review Choice Demonstration for HHAs in Florida and North Carolina until 8/31/21. Beginning September 1, 2021, full implementation of the of RCD began for providers in North Carolina and Florida.

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 HHAs providing services to Medicare beneficiaries.

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 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 episodes requested on pre-claim review is reasonable and necessary.

3. Improved Information Technique s

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)[i] and the MAC provides an

electronic portal for providers to submit their documentation.

4. Duplication and Similar Information

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 business 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 remaining initial and 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, if a provider does not wish to submit documentation or undergo frequent review, they can choose the minimal review option with a 25% payment reduction on all payable claims whether or not chosen for review. In addition, 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 was published in the Federal Register on November 26, 2021 (86 FR 67473). CMS received two comments in response to the 60-day notice. Comments have been addressed in Appendix 1- Response to 60-Day Comments.

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

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.

11. Sensitive Questions

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

12. Burden Estimate

The information collection requirements associated with submissions is 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 now offers esMD to providers who wish to use a less expensive 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[4].

[4] https://www.onlineproviderservices.com/ecx_improvev2/

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- Initial Five Demonstration States (Illinois, Ohio, Texas, North Carolina, and Florida):

Based on calendar year 2020 data, CMS estimated that for the initial demonstration states, annually at a minimum there would be 231,288 initial requests mailed during a year. In addition, CMS estimated there would be 62,160 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost was estimated to be $1,467,243 (293,449 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 information, CMS estimated an average hourly rate of $17.13 with a loaded rate of $34.26. 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 be 744,514 hours (.5 hours x 1,467,243 submissions plus 3 hours x 3,631 providers for education). The annual burden cost would be $26,974,309 (744,514 hours x $34.26 plus $1,467,243 for mailing costs).

HOME HEALTH DEMONSTRATION- 5 States: IL, OH, NC, FL, and TX

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	925,153	0.5	462,576	$15,847,865
Fax and Electronic Submitted Requests-	248,642	0.5	124,321	$4,259,232

Resubmissions				
Mailed in Requests- Initial Submissions	231,288	0.5	115,644	$3,961,966
Mailed in Requests- Resubmissions	62,160	0.5	31,080	$1,064,808
Mailing Costs	293,449	5		$1,467,243
Provider Demonstration- Education	3,631	3	10,893	$373,194
Total			744,514	$26,974,309

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 calendar year 2020 data, CMS estimated that for the initial demonstration states, annually at a minimum there would be 425,054 initial requests mailed during a year. In addition, CMS estimated there would be 111,999 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost was estimated to be $2,685,264 (573,515 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 information, CMS estimated an average hourly rate of $17.13 with a loaded rate of $34.26. As with the initial demonstration states, expanding the demonstration would not create any new documents or administrative requirements. Instead, it would require the currently needed documents to be submitted earlier in the claim process depending on the review choice chosen. Therefore, the estimate again 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 be 1,357,224 hours (.5 hours x 2,685,264 submissions plus 3 hours x 4,864 providers for education). The annual burden cost would be $49,183,763 (1,357,224 hours x $34.26 plus $2,685,264 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 Submitted	1,700,217	0.5	850,108	$29,124,711

Requests- Initial Submissions				
Fax and Electronic Submitted Requests- Resubmissions	447,995	0.5	223,997	$7,674,150
Mailed in Requests- Initial Submissions	425,054	0.5	212,527	$7,281,178
Mailed in Requests- Resubmissions	111,999	0.5	55,999	$1,918,538
Mailing Costs	537,053	5		$2,685,264
Provider Demonstration- Education	4,864	3	14,592	$499,922
Total			1,357,224	$49,183,763

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 review for home health services under the revised demonstration would be approximately $443.5 million over the 5-year demonstration period.

15. Changes in Burden

With the implementation of the Home Health Patient-Driven Groupings Model (PDGM), effective on January 1, 2020, claims are now submitted every 30 days instead of 60 days. Providers now submit two claims for each of the 30- day billing periods, where they previously submitted one for the whole 60-day episode of care. This has led to a significant increase in the number of claims submitted. While providers in Choice 1- Pre-Claim Review, may request more than one billing period at once to limit the number of reviews, providers may still request each billing period separately. In addition, there are more claims to review under the other review options. The overall burden has increased as a result of the change to submitting claims every 30 days instead of 60 days (from 1,132,772 to 1,357,224 for all 16 states).

16. Publication or Tabulation

There are no plans to publish or tabulate the information collected.

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.

[i] www.cms.gov/esMD