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 revised Pre-Claim Review Demonstration for Home Health Services now called the Review Choice Demonstration. This revised demonstration would help assist in developing improved procedures for the identification, investigation, and prosecution of potential Medicare fraud. The demonstration would help 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 the proposed revisions to this demonstration which will be renamed the Home Health Review Choice Demonstration, CMS proposes initially allowing HHAs 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 episode of care. A provider's compliance with Medicare billing, coding, and coverage requirements determines that provider's next steps under the demonstration.

This demonstration would follow and adopt the pre-claim review processes that exist in the paused Pre-Claim Review Demonstration for Home Health 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.

TARGETING FRAUD and IMPROPER PAYMENTSs

This revised demonstration will help 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 would add 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

[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).

addition, over the past several years, CMS' Comprehensive Error Rate Testing (CERT) program has continuously estimated a significantly high home health improper payment rate, ranging between 32% - 59%. The high rates of 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 will conduct the revised 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 project revision is being proposed to, in the end, better enable CMS to detect and deter such conduct.

Under this demonstration, CMS proposes to offer 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 episodes for a beneficiary, instead of submitting a request for each individual episode of care. The Medicare Administrative Contractor (MAC) MAC will communicate back to the HHA the number of episodes that are affirmed on all decisions, which may include all requested episodes 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. A 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 a 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 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, which will be beginning three months into the demonstration in each state, 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. The HHAs are asked to submit medical records automatically at the time of claim submission, although if the HHA fails to automatically submit medical records, the MAC will send the HHA an ADR letter.

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 Techniques

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 60-day episode. Providers may request multiple episodes 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 notice will publish in the Federal Register on May 31, 2018.

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

Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.

CMS anticipates that most submissions will be sent in 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 that supports medical necessity, the level of care requested, the number of episodes requests, and demonstrates that the Medicare home health coverage requirements are met. HHAs 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 3 hours of time is estimated for attending educational meetings, and reviewing training documents. Based on Bureau of Labor Statistics information we estimate an average hourly rate of $16.00 with a loaded rate of $32. This equates to a cost of $24 million for each of the 5 years for the states of Illinois, Ohio, North Carolina, Florida, and Texas. During the demonstration, CMS has the option to expand the included states to all those in the Palmetto/JM jurisdiction. This would equate to a cost of $40 million for each of the 5 years for the states of Illinois, Ohio, North Carolina, Florida, and Texas, Oklahoma, Tennessee, Louisiana, Georgia, Alabama, Indiana, Mississippi, Kentucky, South Carolina, Arkansas, and New Mexico. This impact is allocated across providers and the applicable Palmetto/JM states.

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
Home Health Demonstration Fax and Electronic Submitted Requests	Submissions 702,828 Resubmissions 184,492	0.5 0.5	351,414 92,246	$11,245,248 $2,951,872
Home Health Demonstration Mailed in Requests Mailing Costs	Submissions 351,414 Resubmissions 92,246 Total Submissions 443,660	0.5 0.5 $5	175,707 46,123	$5,622,624 $1,475,936 $2,218,300
Home Health Demonstration-Education	Home Health Agencies 4,885	3	14,655	$468,960
Home Health Demonstration Total				$23,982,940

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
Home Health Demonstration Fax and Electronic Submitted Requests	Submissions 1,157,606 Resubmissions 303,871	0.5 0.5	578,803 151,936	$18,521,696 $4,861,952

Home Health Demonstration Mailed in Requests	Submissions 578,803 Resubmissions 151,936	0.5 0.5	289,402 75,968	$9,260,864 $2,430,976
Mailing Costs	Total Submissions 730,739	$5		$3,653,695
Home Health Demonstration-Education	Home Health Agencies 13,221	3	39,663	$1,269,216
Home Health Demonstration Total				$39,998,399

The estimate above is based on the second year of the demonstration period. Due to a staggered start date for the states, year two is the first full year of participation for all states. Since the demonstration must ramp up, year 1 numbers are expected to be lower than the remaining years; however, we assumed year 2 numbers for the purposes of estimating.

CMS also estimates the cost of mailing medical records to be $5. 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]. Based on calendar year 2016 data, CMS estimates that under this demonstration at a minimum there will be 351,414 initial pre-claim review requests and responses to ADRs mailed during a year in the states of Illinois, Ohio, North Carolina, Florida, and Texas. In addition, CMS estimates there will be 92,246 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost is estimated to be $2.2 million. For all of the states in the Palmetto/JM jurisdiction, CMS estimates that at a minimum there will be 578,803 initial pre-claim review requests and responses to ADRs mailed during a year. CMS also estimates there will be 151,936 resubmissions of a request mailed following a non-affirmed decision. The total mailing cost is estimated to be $3.7 million

13. Capital Costs

There are no capital cost associated with this collection.

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

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 $392.9 million over the 5-year demonstration period.

15. Changes in Burden

The overall burden has decreased as a result of the proposed new review options that will allow for greater flexibility for the providers and different states being included (from 1,492,170 to 680,145). This is a revised collection. Due to the change in the states included in the demonstration and the additional review choice options, the burden estimate has decreased from $49.5 million to $24 million. This is due to the decrease in the number of providers estimated to be included and the revised assumption that beneficiaries in the Palmetto/JM jurisdiction will receive an average of 1.12 episodes of care per year, rather than 3.

16. Publication or Tabulation

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

17. Expiration Date

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

[i] www.cms.gov/esMD