Supporting Statement Part A
Pre-Claim Review Demonstration for Home Health Services
CMS-10599/0938-NEW

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval for the Pre-Claim Review Demonstration for Home Health Services. This demonstration would test methods to help assure that payments for home health services are appropriate before the claims are paid, thereby preventing fraud, waste, and abuse, as well as helping to decrease improper payments.

As part of this demonstration, CMS proposes performing pre-claim review for all home health services within the designated demonstration states of Illinois, Florida, Texas, Michigan, and Massachusetts. Pre-claim review requests will be required for every new 60-day episode of Home Health services. Home Health Agencies (HHAs) or a beneficiary will need to submit a pre-claim review request any time after the referral for Home Health services is made, but before the final claim is submitted for payment. The pre-claim review demonstration does not create new clinical documentation requirements and there will be no required form to submit. HHAs will submit the same information they currently submit for payment, but will do so earlier in the process. They will still be able to submit their Request for Anticipated Payment (RAP) in the same manner and subject to the same rules as they would without the demonstration being in place. This will help assure that all relevant coverage and clinical documentation requirements are met before the claim is submitted for payment. This procedure is similar to the Prior Authorization of Power Mobility Devices, which was implemented by CMS in 2012, and would also follow and/or adopt prior authorization processes that currently exist in other health care programs such as TRICARE, certain state Medicaid programs, and in private insurance.

HHAs who choose to utilize the pre-claim review process may send to the Medicare Administrative Contractors (MACs) via regular mail, fax, or electronically (where available) 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 Medicare Administrative Contractor (MAC) with appropriate documentation and all relevant Medicare coverage and

documentation requirements are met for the home health service, then an affirmative pre-claim review 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 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 review 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. Alternatively, the submitter can fix the issues indicated in the decision and resubmit the pre-claim review request. Unlimited submissions are allowed prior to submitting the final claim for payment. Pre-claim review decisions cannot be appealed.

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 subject to pre-payment review. 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 apply starting three months after the demonstration begins in each state, is not subject to appeal. After a claim is submitted and processed, appeal rights are available as they normally are.

After the demonstration start date there will be a 3 month grace period in each of the demonstration states to allow HHAs to acclimate to the new process. After the grace period, the 25 percent payment reduction will be in effect for claims that are submitted without going through the pre-claim review process, and are found to be payable.

Targeting Fraud

Previous CMS experience, Office of Inspector General (OIG) reports[1], a Government Accountability Office Report[2], and Medicare Payment Advisory Commission reports[3] show there is extensive evidence of fraud and abuse in the Medicare home health benefit for treatment performed in the target states. Florida, Texas, Illinois, Michigan, and Massachusetts have been identified as high risk fraud states in the 2013 Affordable Care Act enrollment moratoria.[4]

---

[1] https://oig.hhs.gov/oei/reports/oei-04-11-00240.asp; https://oig.hhs.gov/oei/reports/oei-04-93-00260.pdf

[2] http://www.gao.gov/assets/290/286572.pdf

[3] www.medpac.gov/documents/reports/mar2015_entirereport_revised.pdf?sfvrsn=0; http://www.medpac.gov/documents/reports/mar14_ch09.pdf?sfvrsn=0

[4] https://www.federalregister.gov/articles/2015/07/28/2015-18327/medicare-medicaid-and-childrens-health-insurance-programs-announcement-of-the-extended-temporary#

Further, home health services have historically been vulnerable to fraud, waste, and abuse and as such been the subject of multiple fraud alerts since at least 1990. [5]

This proposed demonstration will help assist in developing improved methods to identify, investigate, and prosecute fraud in order to protect the Medicare Trust Fund from fraudulent actions and the resulting improper payments. In fact, 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.

Tackling Improper Payments

The improper payment rate for HHA claims has been increasing over the past several years. The fiscal year (FY) 2015 Department of Health and Human Services Agency Financial Report reported that the Comprehensive Error Rate Testing (CERT) program's improper payment rate for HHA claims increased to 59.0 percent. In comparison, the improper payment rate for HHA claims was 51.4 percent during the FY 2014 reporting period.

The Types of Errors included in the 59 percent error rate are:

Insufficient Documentation Errors (94.8%);
Medical Necessity Errors (4.1%);
No Documentation Errors (0.3%);
Incorrect Coding (0.3%); and
Other Errors (0.5%).

The increase in improper payments from 2014 to 2015 was primarily due to insufficient documentation errors, and specifically, insufficient documentation to support beneficiary eligibility for the home health benefit. The majority of home health payment errors occurred when the narrative portion of the face-to-face encounter document did not adequately describe how the clinical findings from the encounter supported the beneficiary's homebound status and the need for skilled services.[3] Other documentation errors included:

- Missing or deficient physician orders;
- Missing or inadequate physician certification/re-certification;
- Outcome and Assessment Information Set (OASIS) not in repository/medical record; and
- Progress notes did not support therapy services rendered on billed dates of service.

We believe this demonstration design will assist CMS in analyzing the effectiveness of a pre-claim review process in increasing the ability to identify, investigate, and prosecute fraud as well as reduce improper payments. CMS believes that this demonstration will provide a wealth of data to analyze, and through that data new avenues for identifying, investigating, and combating fraudulent behavior will be identified. CMS will share data developed from this demonstration within the agency and with our law enforcement partners for further investigation. This includes other components within Center for Program Integrity, Office of the Inspector General, Health

[5] https://oig.hhs.gov/oei/reports/oei-04-93-00260.pdf

Care Fraud Prevention and Enforcement Action Team (HEAT), Zone Program Integrity Contractors (ZPICs) and other types of CMS contractors. CMS believes that data evidencing changes in HHAs billing practices resulting from this demonstration could provide investigators and law enforcement with important information to determine how to focus their investigation activities to identify home health fraud. For instance, results from this demonstration could potentially identify HHAs that are bad actors, those that serve beneficiaries that are not homebound and those that serve an anomalous percentage of beneficiaries with no corresponding office visit. This, in turn, could assist investigators and law enforcement in modifying their investigation activities.

Additionally, such data may provide specific leads for investigators and law enforcement personnel to pursue. For instance, where a HHA provider that prior to the demonstration frequently submitted claims for home health services, stops submitting HHA claims during the demonstration, it may be evidence of home health fraud. Based on this information, law enforcement may determine it prudent to investigate that HHA provider further.

CMS will begin the demonstration in the state of Illinois, with a start date no earlier than August 1, 2016, Florida no earlier than October 1, 2016, Texas no earlier than December 1, 2016, and Michigan and Massachusetts no earlier than January 1, 2017. The goal of this three-year pre-claim review demonstration is to develop improved methods for the investigation and prosecution of home health fraud, as well as decrease the improper payment rate. This project is being proposed to, in the end, better enable CMS to detect and deter such conduct.

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 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

The information required under this collection is requested by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Medicare contractors will request the information from HHA providers submitting claims for payment from the Medicare program in advance to determine appropriate payment.

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. Requesting specific information from a

specific provider in some cases can be submitted through electronic means. CMS offers electronic submission of medical documentation (esMD) to providers who wish to explore this alternative for sending in medical documents.

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 a pre-claim review. 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. CMS welcomes comments from the public on ways to make the reviews conducted under the demonstration less burdensome while also accomplishing our other goals.

6. Less Frequent Collections

Pre-claim review requests are submitted during each 60-day episode. Since home health represents an area where a history of program vulnerabilities exist, less frequent collection of information on these items would be imprudent and undermine the demonstration.

7. Special Circumstances

More often than quarterly
Information will be requested frequently. The process will occur on a continual basis, and delaying the collection of the required information would undermine the demonstration.

More than original and one copy
There is no requirement to submit more than one copy of the requested documentation.

Retain records for more than three years
There are no new or additional record retention requirements beyond those requirements currently in place.

Conjunction with a statistical survey
Pre-claim review of medical records is not performed to create statistical pictures of Medicare utilization.

Use of statistical data classification
This collection does not require a statistical data classification.

Pledge of confidentiality
This collection does not require a pledge of confidentiality.

Confidential information
The Health Insurance Portability and Accountability Act Privacy Rule allows for the disclosure of health records for payment purposes. Medicare contractors have procedures in place to assure the protection of the health information provided.

8. Federal Register Notice

A 60-day Federal Register notice published on February 5, 2016 (81 FR 6275). Comments were submitted during the comment period and have been addressed. A 30-day comment published in the Federal Register on June 21, 2016 (81 FR 40308).

There was no addition outside consultation regarding the proposed information collection requirements.

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 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

The documentation submitted for the pre-claim review is the documentation from the medical record that that supports medical necessity and demonstrates that the Medicare home health coverage requirements are met. Home Health Agencies are required to have this information on file. The burden associated with this pre-claim review 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 Medicare contractor 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.

CMS anticipates clerical staff will collect the information from the medical record and prepare it to be submitted for review. CMS estimates 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 $15.89 with a loaded rate of $31.78. [6]

The bases of the pre-claim review is the documentation submissions to support medical review. CMS based the types of submission on the Home Health Probe & Education experience. Ninety-five percent of these submissions come through fax or electronic means (i.e., MAC portal or fax of a PDF document) with the vast majority (approximately 65-70 percent) submitted via fax. Only 5 percent is expected to be mailed in via USPS/FedEx. We calculated an additional cost of $5 for mailed submissions.

The burden estimate has been broken out into two tables below. The first table shows the estimated impact on Home Health Agencies in Illinois, Florida and Texas. The second table shows the estimated impact to Home Health Agencies in Michigan and Massachusetts. We broke out the states because the methodology is slightly different for the two groups. Based on claims data for calendar year 2013, the average number of episodes of care for Illinois, Florida and Texas is 3 episodes per beneficiary per year. In Michigan and Massachusetts, beneficiaries averages 2 episodes per year.

Based on calendar year 2013 data, CMS estimates that at a minimum there was 700,755 beneficiaries receiving home health services during a year in the states of Illinois, Florida, and Texas. In these states, each beneficiary receive an average of 3 eligible episodes per year. Since the pre-claim review is voluntary, we assume 10 percent of eligible episodes will not be submitted and later pulled for pre-claim review. Using 90 percent of the number of beneficiaries with 3 eligible episodes, CMS estimated that at least 1,892,039 initial requests will be reviewed each year in the three states. This demonstration will allow for an unlimited number of requests for pre-claim review after a non-affirmative decision. For budget estimation purposes, CMS calculated the number of resubmissions by assuming 25 percent of the initial submission for the

[6] http://www.bls.gov/oes/current/oes_nat.htm and the "May 2015 National Occupational Employment and Wage Estimates" report. Fringe benefit estimates were taken from the BLS March June 2015 Employer Costs for Employee Compensation report.

first resubmission (473,010), 25 percent of that number for the second resubmission (118,252) and 25 percent of that number for the third resubmission (29,563) for a total of 620,825 resubmission per year for Illinois, Florida, and Texas.

Based on calendar year 2013 data, CMS estimated at least 182,602 beneficiaries received home health services each year in Michigan and Massachusetts with each beneficiary receiving an average of 2 eligible episode per year. Since the pre-claim review is voluntary, we assume 10 percent of eligible episodes will not be submitted and later pulled for pre-claim review. Using 90 percent of the number of beneficiaries with 2 eligible episodes, CMS estimated that at least 328,684 initial requests will be reviewed each year in the two states. CMS calculated the number of resubmissions by assuming 25 percent of the initial submission for the first resubmission (82,171), 25 percent of that number for the second resubmission (20,543) and 25 percent of that number for the third resubmission (5,136) for a total of 107,850 resubmission per year for Michigan and Massachusetts.

Illinois, Florida, and Texas

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 1,797,437 Resubmissions 589,784	0.5 0.5	898,719 294,892	$28,561,290 $9,371,668
Home Health Demonstration Mailed in Requests	Submissions 94,602 Resubmissions 31,041	0.5 0.5	47,301 15,521	$1,503,226 $493,257
Mailing Costs	Total Submissions 125,643	$5		$628,215
Home Health Demonstration-Education	Home Health Agencies 5,208	3	15,624	$496,531
Home Health Demonstration Total				$41,054,187

Michigan and Massachusetts

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 312,250 Resubmissions 102,458[7]	0.5 0.5	156,125 51,229	$4,961,653 $1,628,058
Home Health Demonstration Mailed in Requests Mailing Costs	Submissions 16,434 Resubmissions 5,394 Total Submissions 21,828	0.5 0.5 $5	8,217 2,697	$261,136 $85,711 $109,140
Home Health Demonstration-Education	Home Health Agencies 795	3	2,385	$75,795
Home Health Demonstration Total				$7,121,493

13. Capital Costs

There are no capital cost associated with this collection.

14. Costs to Federal Government

CMS estimates that the costs associated with performing pre-claim review for home health services would be approximately $388.4 million for pre-claim review in IL, TX, and FL and $67.5 for MI and MA over the three years. Approximately $250,000 is estimated for the necessary system changes.

[7] Adding the resubmission numbers equals 107,851 which is one more than what is cited in the text. This is due to rounding.

15. Changes in Burden/Policy

This is a new collection.

16. Publication or Tabulation

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

17. Expiration Date

This is a three year demonstration that will end on June 30, 2019. CMS displayed the expiration date on the CMS website on the demonstration page that provides educational materials for providers such as power point slides and FAQs.