

OMB Control Number: 0938-NEW
Response to the Paperwork Reduction Act Comments
07/27/2016

Twenty-nine commenters responded to the notice entitled, Agency Information Collection Activities: Submission for OMB Review; Comment Request published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on June 21, 2016, regarding the Pre-Claim Review Demonstration (PCRD) For Home Health Services (Form Number: CMS-10599 (OMB Control Number: 0938-NEW). The vast majority of the comments were repeats of previously submitted comments or were issues addresses by CMS in roll-out activities including open door forum calls and frequently asked question that are posted on our website. Below is a summary of the comments and CMS' response.

Five commenters stated they had concerns the demonstration will result in delay of care and could cause adverse consequences to the beneficiaries. In particular commentators were concerned that the beneficiaries they serve would be at risk for longer lengths of hospital stays, and readmissions. One reviewer felt hospitalization rates would spike due to unqualified reviews of the requests.

Response: CMS does not believe this demonstration will result in delay of care to the beneficiaries. Under this demonstration, a home health agency may submit the request at any time prior to the final claim being submitted for payment. A beneficiary does not have to wait to receive home health services before the request submission is made as services can begin immediately. The beneficiaries can then continue to receive those services while the review process is in progress. Home health services following an inpatient stay will not be delayed and beneficiaries can receive the medically necessary care needed for their condition; therefore, CMS does not anticipate there would not be an increase in hospitalization stays or longer lengths of stays. The pre-claim review is administered by the Medicare Administrative Contractors (MACs), the same contractors that currently process claims and conduct medical review on home health services. Nurses are trained in conducting these reviews and are qualified to review the documentation.

Several commenters felt patients requiring high levels of care may be declined by home care agencies due to the financial risk of a non-affirmed PCR decision.

Response: The demonstration will help Home Health Agencies with their cash flow as they will know that before they submit a final claim that the claim is likely to be paid. Without the demonstration, the agency would have to submit a final claim, and if that claim got denied, have to go through the appeals process. Through this demonstration, the agency will be able to submit all the documentation and get a provisionally affirm decision telling them that this claim looks like it will be paid if almost all the other coverage requirements and claims processing requirements are met. Ultimately, having an affirmed decision will help the cash flow for the provider as payment can be anticipated as long as other payment

requirements are met. In addition, the Request for Anticipated Payment (RAP) will be submitted according to the same rules and procedures as are currently in place. Therefore, the Home Health Agencies would receive their RAP payment as they normally would. This would allow for cash flow to the home health agency while they are waiting for the decision on their request. In addition, the Home Health Agencies would know that in this demonstration if they receive a non-affirmed decision, they are allowed an unlimited number of opportunities to fix the issues indicated in their decision letter and resubmit their request. Therefore, the risk of taking on patients requiring higher levels of care is reduced since the Home Health Agencies that receive a provisionally affirmed decision will know their claim will be paid as long as all other Medicare requirements are met. Outside the demonstration, the Home Health Agency would provide the care, risk having the claim denied and the only remedy would be to appeal which is a costly and timely process for the provider.

A few commenters stated that home care agencies may elect to discharge Medicare beneficiaries from skilled services when a request is returned non-affirmed.

Response: The decision letter will specify the reasons the pre-claim review request was non-affirmed. Home Health Agencies can correct the deficiencies and resubmit the request with additional documentation that supports medical necessity. Home Health Agencies will have unlimited opportunities to correct and resubmit their requests for review. Medicare contractors will work closely with the home health agency during the pre-claim review process to explain what documentation is needed and why a prior submission was insufficient. We believe most of the improper payment rate for home health services is due to poor or missing documentation, so with the help of the Medicare contractors, patients who qualify for the Medicare home health benefit will receive care while the Home Health Agency corrects the documentation issues. Therefore, we do not believe there will be a risk of Home Health Agencies discharging patients following a non-affirmed decision. All claim appeal rights also will remain in place for any claims that are denied.

One commenter believes there may be a delay in needed services if a beneficiary is admitted for nursing but has a change in medical condition during an episode and the agency must submit another pre-claim review with all of the same information submitted the first time asking for the additional HCPCS codes.

Response: This is incorrect and on July 27th, CMS updated the Frequently Asked Questions on our website to clarify this point. The response on the website include, in part, “The pre-claim review initial request should be submitted after you have had enough time to evaluate the beneficiary’s condition to determine the services (HCPCS) that will be required for the episode. However, if later in the episode the beneficiary’s condition supports additional services that were not on the initial provisionally affirmed pre-claim review request, you would not need to submit an additional pre-claim review request for that episode.”

Four commenters stated concerns that the demonstration will increase the administrative burden and/or costs for the providers. Commenters stated that the demonstration would add an increased operational burden and overhead costs for the Home Health Agencies. One commenter states they are concerned the reviews will not be timely and will delay reimbursement of claims. One commentator is concerned that staff will need to be shifted from providing care to compile the necessary documents or that new staff will need to be hired.

Response: CMS does not believe this demonstration will greatly increase the administrative burden or costs for the providers. The process does not create any new documents or administrative requirements. Instead, it just requires the currently needed documents to be submitted earlier in the process. As the request may be submitted at any time prior to the final claim being submitted, the Home Health Agencies would have time to pull together the needed documentation. They would not have to pull their staff away from providing care. Ultimately, having an affirmed decision will help the cash flow for the provider as payment can be anticipated as long as other payment requirements are met. In addition, the Request for Anticipated Payment (RAP) will be submitted according to the same rules and procedures as are currently in place. Therefore, the Home Health Agencies would receive their RAP payment as they normally would. This would allow for cash flow to the home health agency while they are waiting for the decision on their request.

Five commenters stated that the demonstration will not effectively target fraud and will unfairly burden providers who are not engaging in fraudulent activity. In particular two commenters stated that the demonstration does not distinguish between fraud and unintentional noncompliance with documentation requirements. Other commenters suggested that CMS only conduct the prior authorization demonstration in selected areas of the states that have historically demonstrated high incidences of fraud related to home health care or focus more on certain providers.

Response: Previous CMS experience, Office of Inspection General reports, Government Accountability Office reports, and Medicare Payment Advisory Commission reports show extensive evidence of fraud and abuse in the Medicare home health benefit for treatment performed in these demonstration states. Most of the demonstration states have also been identified as high-risk states that have select cities and counties under the temporary moratoria on home health provider enrollment authorized under the Affordable Care Act. Additionally, the Medicare improper payment rate for home health services increased from 17.3 percent in 2013 to 51.4 percent in 2014. The Fiscal Year 2015 HHS Agency Financial Report reported a further increase to 59 percent in 2015. We acknowledge that poor or missing documentation accounts for a large part of the improper payment rate. Due to the depth of the problem, a broad approach is needed.

One commenter suggested limiting submission of documents to what can reasonably be obtained by the Home Health Agency in the short amount of time that will show the beneficiary eligible for the home health benefit.

Response: This demonstration makes no changes to beneficiary eligibility for home health services under Medicare and does create any new documentation requirements. It will help CMS make sure that all relevant clinical and/or medical documentation requirements for home health services are met before claims are submitted for payment. It is reasonable that a home health agency can obtain all needed documentation since the pre-claim review request may be submitted any time before the final claim is submitted.

One commenter stated that the demonstration will interfere with the goals of CMS's alternative payment models (APM). They were concerned this demonstration would be placing all agencies on 100% pre-claim Additional Documentation Request (ADR) review without cause.

Response: This demonstration affirms or non-affirms the service before the final claim is submitted. APM would only apply to claims that are submitted, medically necessary and approved for payment. This demonstration will not interfere with the bundled payments or quality measure models. This demonstration does not put all Home Health Agencies on 100% pre-payment ADR review. For those Home Health Agencies who utilize the request process and receive a non-affirmed decision, they will have unlimited chances to fix the issues with their request and resubmit their request prior to submitting the final claim for payment. With pre-payment review through an ADR, there is no opportunity to fix any issues and resubmit. The home health agency would be required to use the appeal process if they feel the claim should have been paid.

One commenter stated that the demonstration has no authority to be implemented. The commenter also states that the provision CMS cites does not give legal authority because the demonstration is not a means of either investigating or prosecuting fraud since the demonstration will screen every home health service claim in the states. The commenter believes that any proposal to implement a pre-claim review system, would need to occur through rulemaking because it would be a major change in that it results in an automatic claim denial if there is not an affirmative decision. Also, the commenter felt the demonstration was violating various statutes by implementing the prior authorization demonstration through the PRA Notice.

Response: CMS is testing this demonstration under section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1(a)(1)(J)) which authorizes the Secretary to “develop or demonstrate improved methods for the identification, investigation, and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act (the Act).” This demonstration will help with fraud prevention as it will non-affirm any services that are not medically necessary and lack proper documentation. Also, the demonstration does not create any new coverage or documentation requirements. It simply asks for it earlier in the process. Therefore, CMS does not believe the demonstration would result in a change that alters the operation of the home health benefit. Home Health Agencies are given multiple opportunities to fix any issues that resulted in them receiving a non-affirmed decision and are afforded all appeal

rights for any denied claims. The PRA Notice was not an announcement of a demonstration for home health services, and as such, lacked detailed information about the demonstration. The Federal Register Notice¹ announcing the home health demonstration as well as information on the demonstration and Medicare Administrative Contractor websites provide more detail.

There were some comments about the Medicare Administrative Contractors (MACs), specifically three comments concerned that the MACs would be unable to process the volume of prior authorization requests and claims in a timely manner. One commenter felt that without the development of specific guidelines, the decision would be subject to the reviewer's interpretation.

Response: CMS is confident the MACs will be able to handle the volume of claims. The MACs have hired and trained staff in order to handle the volume of requests that may come in for each state. The reviewers will use the all current standards and coverage guidelines to make their decision on the review. The standards and guidelines are not changing and are the same for every reviewer.

Some commenters were concerned with the backlog of appeals. There was concern the demonstration may result in many additional requests for administrative appeals and increase the backlog.

Response: This demonstration allows for an unlimited number of resubmissions for requests that receive a non-affirmed decision. This allows the Home Health Agencies time to fix any issues with their documentation to meet all requirements and resubmit the request. The home health agency may continue to do so until they submit the final claim for payment. This in turn would reduce the number of potential appeals as the home health agency would not need to wait for a denial on their claim to see what the issues are and would not need to appeal in order to fix those issues.

Three commenters expressed concern that they would have to request additional information from physicians to meet the specific requirements. They believe there could be confusion by the physician on what is needed and external issues beyond a Home Health Agencies control. Another concern is that the timeframe to get the physician signature is reduced under the demonstration.

Response: This prior authorization demonstration requires the currently mandated documentation just earlier in the claims payment process which should not be a burden for providers complying with the Medicare rules. The physician signature on the plan of care is needed for submission with request. However, as the request may be submitted at any time prior to the submission of the final claim, the Home Health Agencies do have time to

¹ CMS-6069-N; FR Doc. 2016-13755

get the physician signature. Therefore, there would be no delay in services. Since a request may be submitted at any time prior to the final claim being submitted for payment, there is time for the home health agency to collect the needed information (e.g. physician signatures) and documentation. In addition, education will be provided to the physician community to make sure they know about the demonstration and the importance of getting the documentation to the Home Health Agencies in a timely manner.

Four commenters expressed concern that the demonstration requirements would result in confusion as there is still confusion over the documentation needed for the Face-to-Face encounter. A commenter felt education should be provided to help providers understand the Face-to-Face encounter requirement and other home health requirements rather than conduct the demonstration.

Response: CMS has published numerous educational materials to inform Home Health Agencies and Medicare beneficiaries of the policies and documentation requirements for home health services. The Medicare Administrative Contractors (MACs) conducted Probe and Educate on the issue of the Face-to-Face Encounter in the targeted states prior to the start of the demonstration. Additionally, CMS has submitted the Home Health Face-to-Face Encounter Progress Note Template through the PRA process and hopes this will be another tool to help providers document Medicare home health criteria. CMS and the MACs will continue to educate providers as needed throughout the demonstration.

One commenter was concerned with Low-Utilization Payment Adjustment (LUPA) cases. The commenter was concerned that the LUPA case may turn into a full episode.

Response: LUPA claims with four or fewer visits are excluded from the Pre-Claim Review Demonstration for Home Health Services; however, all other episodes home health care that include five or more visits must submit a pre-claim review request. In the case of a LUPA turning into a full episode, the full episode would now be subject to the demonstration and require submission of a request for review. The request may be submitted at any time prior to submitting the final claim, there would be time for the home health agency to prepare the request and send in the submission.