Appendix 1 – Response to 60-day comments

CMS Responses to Public Comments Received for CMS-10599: Prior Authorization Demonstration For Home Health Services

***Important Note:** Due to the addition of other review options beyond pre-claim review, this demonstration has been renamed from the "Home Health Pre- Claim Review Demonstration," to the "Review Choice Demonstration for Home Health Services (RCD)".*

Responses for the HH PRA comments
CMS received comments in response to the 60-Day FR Notice, many of which expressed the same concerns.

Many commenters expressed concern that the demonstration would create delays in care or lack of access for Medicare beneficiaries. Commenters stated that this would leave beneficiaries in their state (Ohio) vulnerable. The commenters stated RCD will delay care for seniors in their state, especially in rural areas. Other commenters said that programs like prior authorization weigh heavily on HHAs' budgeting for staff, which directly effects the quality of care provided.

Response:
CMS disagrees that this demonstration will result in delays in care or result in a lack of access to care for beneficiaries. HHAs that choose the pre-claim review option will conduct all necessary intake procedures and evaluations, submit a Request for Anticipated Payment (RAP), and begin services as they currently do. The pre-claim review request may be completed and submitted for review at any time prior to the submission of the final claim for payment. A beneficiary does not have to wait for the pre-claim review request decision to begin receiving home health services. Beneficiaries can then continue to receive those services while the pre-claim review process is in progress.

Under the other review options, the providers will conduct all necessary intake procedures and evaluations, submit a Request for Anticipated Payment (RAP), and begin services just as they do currently. The Medicare Administrative Contractor (MAC) would then send the provider an Additional Documentation Request (ADR) for claims eligible for review (depending on the option chosen) following receipt of the final claim for payment. Home health services will not be delayed and beneficiaries can receive the care and instruction needed for their condition. Documentation requirements are not changing under any of the review options. HHAs will collect the same information and documentation as they currently are required to under the home health benefit. Depending on the review option chosen, the documentation may just be looked at earlier in the claim process. HHAs who do not wish to participate in either the pre-claim or postpayment review options 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.

Within this demonstration, the process for providing care remains the same. In addition, the additional review options allow a provider the flexibility to decide which option would work best for their staff and patients. Therefore, CMS does not believe this demonstration would affect the quality of care or limit access.

Many commenters stated concerns that the demonstration and return of pre-claim review will increase the administrative burden and/or costs for providers. Commenters stated that the demonstration would add an increased paperwork burden on the home health agencies. Commenters were also concerned that the process would be too complex and time consuming. They stated that it would require a full time staff member to complete and monitor the PA process. This would take away resources from providing patient care, which could lead to a financial strain. One commenter stated that participation in the original PCR demonstration took one hour per claim and they will get behind in their revenue cycle. Other commenters were concerned that the initial demonstration caused the closure of many of the Illinois home health agencies, especially smaller ones. The commenters were concerned that cash flow issues would cause providers to close or move away from Medicare.

Response:
In an effort to create a process that balances provider burden while continuing our fiduciary responsibility to lower the home health improper payment rate and prevent fraud, waste and abuse, CMS restructured the demonstration services based on input from the provider community and other stakeholders. The revised Review Choice Demonstration offers increased flexibility, provider choice, as well as additional risk-based changes.

The pre-claim review option 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. Resources should not need to be diverted from patient care. Ultimately, having an affirmed pre-claim review decision will help the cash flow for the provider as an affirmative decision shows that a claim likely meets Medicare's coverage and payment rules. Absent evidence of fraud or gaming a provider can anticipate payment as long as other payment requirements are met. HHAs have the flexibility and choice to participate in other options if they don't want to participate in pre-claim review. Under the postpayment review option, the provider will follow all of the standard procedures they currently do and submit the claim for payment. As the provider would already have received payment for the claim, this would not cause a financial hardship for the providers.

In addition, HHAs that choose the pre-claim or postpayment review options and reach a pre-claim review affirmation or postpayment review approval rate of 90% or greater after 6 months, will have the additional option of a spot-check review of only 5% of claims, to ensure continued compliance. Providers that demonstrate continued compliance with Medicare rules and regulations may remain in that option for the duration of the demonstration if they choose.

Providers also have the option to not to participate in one of the 100% review options by selecting the third option. These providers 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.

CMS believes that the additional review options, along with the ability to opt out of reviews once a provider demonstrations compliance with Medicare offers providers the flexibility to choose a review option that will work for them based on their resources and financial needs no matter the size of the agency. In addition, with the pre-claim review option and 100% postpayment option, providers who have not met the threshold will be given the opportunity to change options if they believe another option will work better for their resources. Therefore, CMS does not believe the

demonstration will cause providers to close or move away from Medicare.

Commenters stated changes in healthcare policy and the beneficiary communities result in shorter hospital stays, which increase the need for home health services. Commenters were concerned that this demonstration will increase hospitalization rates, lead to long term healthcare consequences, and associated costs. Another commenter stated that RCD will handicap licensed professionals in their goals to decrease reliance on opioid medications, hospital and Emergency Department utilization, and impact change in poor lifestyle choices and home safety. In addition, one commenter said that HHAs will be more focused on financial matters and less focused on clinical outcomes. Smaller agencies will continue to push patients to higher cost care in SNFs and LTCHs.

Response:
CMS disagrees that this demonstration will increase hospitalization rates and associated costs. The demonstration will not restrict access to home health services that are medically necessary and meet all the coverage requirements. Discharge from an institution to home will not be delayed, as the same process for initiating home health services (i.e., order, HHA visit and initiation of the RAP) has not changed. As home health services for beneficiaries is not being restricted under this demonstration, the beneficiaries will not have additional hospitalization services they would not have normally needed or be pushed into a higher cost care in SNFs or LTCHs. Likewise, the demonstration should not affect work to decrease reliance on opioid medications, ED utilization, or change poor lifestyle choices. As part of the demonstration, CMS will contract with an independent evaluator to fully analyze the impacts of the demonstration, including effects on patient care and access to covered services.

Commenters stated that the initial demonstration was ineffective at identifying fraud. Commenters also stated that the proposed demonstration will not effectively target fraud and will unfairly burden providers who are not engaging in fraudulent activity. Commenters stated that most errors found in the initial demonstration were human or clerical errors. Another commenter stated the high affirmation rate seen in the initial demonstration established that the central issue was not fraud or medically unnecessary claims, but was improper payments. Several commenters stated that the proposed program is one size-fits all solution and not an appropriate way to address the problem. A few commenters felt that CMS should utilize other resources such as data analytics or the PEPPER to assist in identifying patterns that appear out of the norm and target those agencies to use fraudulent tactics. Some commenters said that larger agencies with a larger patient census will reach the affirmation/approval threshold sooner than smaller agencies.

Response:
As home health services continue to be subject to increasing potential fraudulent behavior, CMS continues to look for new ways to combat fraud, and lower the payment error rate while maintaining or improving the quality of patient care, and decreasing provider burden. CMS disagrees that the demonstration is a one-size-fits-all solution to fraud and improper payment in the home health benefit. By offering several review options and rewarding providers who demonstrate compliance with Medicare home health policies the demonstration will not unfairly burden providers who are not committing fraudulent behavior or submitting incorrect claims.

Under this demonstration CMS will determine whether applicable Medicare coverage and clinical documentation requirements are met. The demonstration targets fraud by identifying and either non-affirming pre-claim review requests or denying claims that are not medically

necessary, not covered under the Medicare benefit, or should not be paid due to other reasons. If a pre-claim review request or claim is submitted for medically necessary, properly documented services, the request will be affirmed or the claim approved. By reviewing each episode of care, CMS will be able to determine if providers have a pattern of submitting medically unnecessary services, if the documentation is insufficient to support the services, or if there are other compliance concerns. Under the pre-claim review option, if the documentation is incorrect or insufficient on the initial submission of the pre-claim review request, the provider will have unlimited opportunities to resubmit the request with the correct documentation. Under other review options the providers will submit the claims and receive an ADR for claims subject to review (depending on the option chosen), and claims will be denied or adjusted as needed.

While the demonstration did non-affirm medically unnecessary and insufficiently documented requests that may have reduced improper payments, it also had a deterrent effect. The increasingly high affirmation rate under the initial demonstration only reflects requests that were submitted. Knowing that their documentation and claims would be scrutinized, a number of providers did not submit pre-claim review requests during the demonstration, and did not submit claims for payment. When the demonstration was paused, some of these providers submitted claims for payment that had not gone through the pre-claim review process, or that had been non-affirmed during pre-claim review. Although CMS does not provide details on UPIC and law enforcement activities, CMS did make a number of referrals based on provider behavior during the initial demonstration.

CMS does not believe this demonstration will unfairly burden home health providers who are not engaging in fraudulent behavior. The providers must remain in a review option until they meet a 90% pre-claim review full affirmation or claim approval threshold. This threshold is based on a minimum of ten submissions and is calculated every six months. Those providers who are submitting fraudulent and unnecessary claims will not reach the threshold and will remain subject to review. In addition, if a provider shows a continued pattern of submitting non-medically necessary claims, they may be referred to the UPIC for additional review. However, the providers who show compliance with Medicare rules and met the threshold will have the chance to choose a subsequent review options which includes an option to opt of reviews except for a spot check of a small percentage of their claims.

Commenters thought that Illinois providers should be handled differently or excluded because they participated in the initial demonstration. Similarly, another commenter felt that HHAs that participate in Probe and Educate and/or provided themselves trustworthy should not subject to pre-claim review.

Response:
CMS agrees that Illinois providers who participated in the initial PCR demonstration and demonstrated compliance with Medicare home health policies should be handled differently. Those providers in Illinois who participated in the initial demonstration and met the pre-claim review affirmation rate threshold, based on a minimum of ten PCR submissions may begin with one of the subsequent review options, including the spot check option.

Some commenters stated that CMS has already implemented extensive regulatory requirements, safeguards, criteria and accountability mechanisms in the industry, including requirement for a face to face visit, episode payments, value-based purchasing, PEPPER, and mandatory performance reporting. Commenters felt CMS already has capability in place to deny inappropriate admissions. Another commenter felt the

demonstration will only add to the access to care issues and burden brought on through these other programs and changes.

Response:
The services provided by home health providers is valued by CMS. Based on previous CMS experience, Office of Inspector General's reports, Government Accountability Office's reports, and Medicare Payment Advisory Commission findings, there is extensive evidence of fraud and abuse in the Medicare home health program. Data collected from this demonstration will be carefully analyzed. Such analytics will include the number of claims submitted, the referral of potential fraud cases to investigators, and the development of fraud cases, as necessary. The data will be used for the purpose of making comparisons between the demonstration and non-demonstration states. CMS will monitor the rates of pre-claim review requests that are provisionally affirmed and non-affirmed, along with the overturn rate and adjudication status of appealed claims. For the other review choices, CMS will monitor the rates of claim approvals and denials as well the adjudication status of appeals. CMS will collect qualitative information to help determine whether or not, and to what extent the review choice process has improved upon existing methods for investigating and prosecuting fraud, as well as reducing the improper payment rate for home health services. CMS continues to look for new ways to combat fraud, and lower the payment error rate while maintaining or improving the quality of patient care, and decreasing provider burden.

Commenters expressed concern that the demonstration essentially gives MACs the opportunity to make medical decisions. Commenters felt it is the professional judgment of the clinician to decide the combination of home health services appropriate for the beneficiary. Another commenter stated that CMS should be doing the reviews, not the MACs. Another commenter also stated the reviews would not be consistent amongst reviewers and there was a lack of inter-rate reliability. A commenter felt that there was little oversight of the auditors and that their decisions were not made objectively. The providers should be made privy to the same information as the auditors/reviewers. In addition, a commenter stated that the reviewers did not offer good customer service and there was no direct line to discuss discrepancies.

Response:
The MACs regularly perform Medicare reviews on behalf of CMS and will be following the same review guidelines as they currently do for postpayment review as no new documentation will be required under the demonstration. The MAC is not substituting their judgment for the physician's, but ensuring that the documentation meets Medicare rules and clearly demonstrates the physician's reasons for ordering services. The MAC who will review the pre-claim review requests is the same contractor who currently reviews and processes home health claims in the selected demonstration states. CMS has published numerous educational materials to inform HHAs and Medicare beneficiaries of the policies and documentation requirements for home health services. In addition, CMS has made available to the public, clinical templates for providers to use. To ensure consistency in operations and to eliminate potential contractor variation in medical review, CMS restructured the demonstration to include states in only one MAC jurisdiction – specifically Palmetto Jurisdiction M.

CMS will ensure there is continued oversight of all MAC activities under this demonstration. The MAC reviewers will undergo training to ensure consistency prior to beginning the reviews. Both the MAC and CMS will monitor the reviewers' accuracy throughout the demonstration. In

addition, CMS staff will conduct reviews on a selection of requests/claims to ensure the MAC decisions are accurate and consistent across reviewers.

The MAC will have a dedicated customer service line for the demonstration that providers can contact to speak to knowledgeable customer service representatives about the demonstration. Both Palmetto and CMS have gained experience from the initial demonstration when it was active in Illinois and have applied lessons learned to the revised demonstration. For example, the MAC has made a number of improvements to increase the efficiency of its online provider portal and will have resources dedicated to helping providers navigate the portal and making their review choice. Another example is a process CMS put in place during the latter half of the initial demonstration that will continue with the revised demonstration. If a pre-claim review request is non-affirmed due to a documentation issue, the MAC will proactively reach out to the provider to discuss the issue and encourage the provider to resubmit the request. In addition, under the pre-claim review option, CMS will allow providers to submit a request for more than one episode of care for a beneficiary at a time.

Several commenters expressed concern that payment would be/was denied based upon minor infractions made by the prescribing physician and authorization was denied because of lack of information providers and/or incorrect wording used in the script.

Response:
Since this demonstration does not create or require any additional documentation to what Home Health Providers are already required to maintain, they should need to gather the same information they currently do. Under the pre-claim review option, if the documentation is insufficient for the services requested or incorrect, in addition to receiving a decision letter, the MAC will proactively reach out to the provider to discuss the documentation issues. The provider will then have an unlimited number of resubmissions prior to submitting the final claim for payment in order to correct the issue.

Commenters expressed concern that there was not enough explanation of what the review choices were. They were concerned that it was hard to anticipate staffing without detailed information. Another commenter was concerned that no additional information had been released to ensure that significant changes were made to the implementation and administration of the program. One commenter stated that there was little detail about the review rate threshold that was needed to move to the subsequent choices. Another commenter requested that CMS publically share PCR affirmation rates, data related to fraud found by PCR, and additional data on changes in patient, episode, and agency characteristics during PCR.

Response:
CMS worked deliberately over the last year to carefully assess all options and to incorporate provider feedback such as flexibility and risk-based options into the revised demonstration. This first announcement of the revised demonstration was to let the public know the demonstration had been modified and would be implemented in the future. CMS is publishing additional information in the Federal Register, as well as both the CMS demonstration website and the MAC website. In addition, CMS will publish an Operational Guide with details on the demonstration and the process. A flow chart with the demonstration process will be released as well. CMS will also hold at least one open door forum (ODF) on the process and requirements for the home health services demonstration and the MAC will begin providing additional education soon.

CMS regularly shared data from the initial demonstration on the demonstration website, including [1]regular updates of the pre-claim review affirmation rate. As the demonstration was paused before CMS could acquire an evaluation contractor and perform additional data analysis, the available data is limited at this time. In addition, while CMS may not share the details of active fraud cases, there were referrals made to the UPIC and law enforcement about potentially fraudulent providers.

One commenter wanted clarification on CMS' average episodes of care per year for a beneficiary in the revised demonstration.

Response:
CMS used Medicare claims data and billing data from the demonstration states to determine the average number of episodes of care per year. The average was reduced from the estimate used in the original demonstration as more updated data was available and several of the demonstration states were changed. CMS calculated the change in burden by estimating the number of reviews. This number included initial pre-claim review requests, potential resubmissions following a non-affirmative decision, and claim reviews following receipt of an ADR.

Some commenters expressed concern about the cost of implementing the demonstration. They stated that PCR was costly and showed no fraudulent findings. The commenter believed that the initial demonstration was costly, had served its purpose, and did not need to be reinstated in this format.

Response:
CMS has taken great care with the research and development of the demonstration, and has made safety and continuity of care for beneficiaries a top priority. While the initial demonstration did help to give CMS valuable information on a pre-claim review option, CMS believes the revised demonstration with more review options will provide even more valuable information on how a review choice program can reduce fraud. CMS estimates that this demonstration will bring a sufficient Return on Investment (ROI) to offset the cost of implementation in the demonstration states. In addition, while CMS may not share details of ongoing cases, there were referrals made to the UPIC about potentially fraudulent providers.

Several commenters stated that CMS should meet with home health leaders and other stakeholders to find other ways to identify and stop fraud and abuse.

Response:
CMS based the revisions in the review choice demonstration on stakeholder feedback, including offering flexible options for provider participation and rewarding those providers who demonstrate compliance with Medicare home health policies. Other stakeholder feedback led to a process where the MAC proactively reaches out to the provider following a non-affirmative decision to educate them on documentation issues. Another revision CMS is implementing due to stakeholder feedback is the ability to request more than one episode of care for a beneficiary on one pre-claim review request.

CMS believes close communication is vital to ensuring the demonstration's success. CMS will

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Choice-Demonstration/Review-Choice-Demonstration-for-Home-Health-Services.html

conduct Open Door Forum calls where all stakeholders can learn more about the demonstration, ask questions, and provide comments. In addition to this, CMS will create an email address where stakeholders can send questions and comments as well. CMS welcomes input and suggestions from the Home Health community and other stakeholders as we continue to look for new ways to combat fraud and lower the payment error rate while maintaining or improving the quality of patient care.