CMS Responses to Public Comments Received for CMS-10599: Pre-Claim Review Demonstration For Home Health Services

***Important Note:** Due to the title of "Prior Authorization" implying that services will be withheld from the beneficiary until an affirmed decision is achieved, this demonstration has been renamed from the "Home Health Prior Authorization Demonstration" to the "Home Health Pre-Claim Review Demonstration," as home health services are already being provided to the beneficiary when the pre-claim review process begins.**

Responses for the HH PRA comments

Fifty-four commenters stated that the demonstration will result in delay of care to the beneficiaries. In particular several commentators stated that the beneficiaries they serve would be at risk for a compromise in their medical recovery, an increase in clinically risky and costly outcomes, longer lengths of hospital stays, and readmissions while waiting for services. It may also increase emergency room use. Commenters stated that the beneficiary would have a delay in receiving time-sensitive needed care and would not have any one to explain their disease process, how to manage it, or get help with medications following a discharge from an inpatient facility. Another commenter stated that is it's a core tenet of the major care transitions and readmission reduction models to ensure that a home visit is provided within 24 to 72 hours of discharge from a hospital and that home health providers must conduct an assessment visit within 48 hours of referral and sometimes within 24 hours. Another commenter feels that the use of prior authorization for time-sensitive, hands-on nursing and therapy services furnished by home care providers unnecessarily risks the safety and well-being of patients being discharged to home from hospitals. A commenter stated that when spontaneous changes in beneficiary conditions arise, the most cost effective intervention available will be delayed due to the imposition of awaiting prior approval for treatment plans. One commenter asks about the mechanics of the prior authorization process and if it is the role of the hospital discharge planner to obtain prior authorization or if the patient would remain in the hospital until the authorization was obtained. Two commenters believe that home health services following an inpatient stay should be exempt from any prior authorization policy or process. Several commenters stated that they have experience with patients who need pre-authorization from Medicare advantage plans and feel it delays access to care. Another believes this demonstration will take nurses away from providing care as they must spend time putting the prior authorization request together. The commenter feels this is a duplication as the MD has already assessed the patient and signed up for the SNV or HHA hours and having to repeat the process every 30 days also makes the process more burdensome. A commenter also stated that this would be inconsistent with the CMS home health performance measure for timely initiation of care that measures the "percentage of home health episodes of care in which the state or resumption of care date was either on the physician-specified date or within 2 days of the referral date or inpatient discharge date whichever is later."

Response: CMS does not believe this demonstration will result in delay of care to the beneficiaries. Under this demonstration, a home health agency will conduct all necessary intake procedures and evaluations, submit a Request for Anticipated Payment (RAP), and begin services. The prior authorization request will then be completed and submitted for review. A beneficiary does not have to wait to receive home health services before the prior authorization request decision is made as services can begin after the RAP is submitted as they do prior to the demonstration being implemented. The beneficiaries can then continue to receive those services while the prior authorization review process is in progress. Therefore, home health services following an inpatient stay will not be delayed and beneficiaries can receive the care and instruction needed for their condition.

Thirty-two commenters stated concerns that the demonstration will increase the administrative burden and/or costs for the providers. Three commenter stated they were unsure how CMS estimated there would be 30 minutes of clerical time would be needed as stated in the Supporting Statement and believe the time would be much greater and could be as much as one to two business days. Another commenter stated that the demonstration would add an increased paperwork burden on both the physician and home health agency while adding little additional value for identifying and preventing fraud. The commenter states that the home health agencies are currently implementing the Face-to-Face encounter which was supposed to reduce fraud and the demonstration is an additional layer of administrative burden that is untenable for home health agencies that will only lead to delaying the implementation of home health services. A commenter from Massachusetts asked that an accounting of costs be put into perspective of the costs that all home health providers are already incurring to be in the mandatory Home health Values Based Purchasing program and that many are incurring for the One Care (dual eligible) demonstration. Another commenter stated that the smaller home health agencies will have so much overhead costs associated with the new demonstration that financial hardships will prevail, and the agencies will have no choice but to close.

Response: CMS does not believe this demonstration will increase the administrative burden or costs for the providers. The prior authorization 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. Ultimately, having an affirmed prior authorization decision will help the cash flow for the provider as payment can be anticipated as long as other payment requirements are met.

Twenty-seven commenters stated that this demonstration will increase hospitalization rates and associated costs. One commenter stated that the prior authorization demonstration would run counter to the Maryland all-payer model goals which encourage hospitals to find more cost-effective, high-quality discharge destinations for their patients and would delay cost effective care at the risk of unnecessary hospitals stays. Another commenter stated that reduced or delayed access to home health services would compromise patient outcome and lead to additional utilization of services, including hospital readmissions. A commenter also stated that the demonstration could result in an increase of placements of beneficiaries in Skilled Nursing

Facilities (SNF) which may increase Medicare Spending per Beneficiary. Another commenter stated that the demonstration may lead to acute-care facilities being forced to maintain Medicare beneficiaries on their census for longer periods of time, resulting in higher costs or risk re-hospitalization rates and financial penalties. It may also lead to beneficiaries assuming a greater finical responsibility for the cost of their care if the SNF benefit is not approved.

Response: CMS does not believe 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. Access to care and services should not be delayed for people with Medicare's home health benefit. 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.

Twenty-seven 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 proposed program is too broad, failing to police or correct any known deficiencies in home health claims. Three 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. Another commenter felt that the broad-based reference made to an OIG report and CMS decision to impose moratoria on new home health agencies in limited areas was the only definition of fraud in the PRA notice and that these do not support a statewide demonstration. One commenter felt CMS should identify aberrant billing practices through claims data to find providers who may be engaged in suspect behavior that could constitute fraud and then investigate whether the providers are actually committing fraud or have high utilization for other legitimate reasons. Another commenter felt that half of the providers in the selected states have a Quality of Patient Care stat rating of 3.5 of better and that the CMS approach is too broad. The commenter felt this may be the last "regulatory straw" for some providers and cause them to leave Medicare which would reduce access to care. We received six comments that stated fraudulent home health agencies will continue their fraudulent practices by submitting fraudulent paperwork or changing their behavior to continue to avoid getting caught. Another commenter stated that many agencies do not send documentation requested by third parties or the FI and it is those agencies who should require more scrutiny. Another commenter stated that CMS officials in congressional testimony have noted that the majority of denied payments for home health services is the result of documentation issues and not the result of weeding out fraud. A commenter stated that this demonstration will be a duplication of existing fraud prevention measures such as a signed physician certification, Face-to-Face requirements, ADR requests and RAC and ZPIC audits. Another commenter felt that CMS should have program integrity measureless that prevent providers from enrolling who come into Medicare with the intent of committing fraud. A commenter states that state-specific data demonstrates that the states proposed to be included in the prior authorization do not show any broad-based concern in terms

of spending growth or utilization increases and that home health spending has declined both in terms of dollars and percentage proportion on Medicare spending. A commenter states that CMS is in the initial stages of the Probe and Educate audits and that Medicare and home health providers are yet to be in sync with what constitutes compliant documentation. The commenter also believes that the areas of fraud that have been uncovered in home health are highly limited and do not lend themselves to correction through prior authorization. A commenter stated that CMS (then HCFA) tried a form of prior authorization for home health services previously. The providers were then able to select which case went through concurrent authorization and which did not. The commenter stated that CMS (then HCFA) concluded that "legitimate questions about potential negative effects on appropriate serve use remain." It was also noted that lack consistency among reviews on the appropriate decision raised some additional concerns.

Response: CMS does not believe this demonstration will unfairly burden home health providers. PA does not create any new documentation requirements for the Medicare Home Health benefit, and only asks for the documents earlier in the process. The demonstration targets fraud by identifying non-affirming non-medically necessary services. If a prior authorization request is submitted for medically necessary, properly documented services, the request will be affirmed. Ultimately, having an affirmed PA decision helps ensure cash flow for the provider as payment can be anticipated as long as other payment requirement are met. Per the Appendices for the 2015 Medicare Fee-for-Service Improper Payment Report, the error rate for Home Health services has increased to 59%, consequently, 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.

Three commenters stated concerns about whether this initiative would help with decreasing improper payments error rates as two commenters stated that the high improper payment rate was related to disputes over the Face-to-Face narrative requirement and one commenter stated that many errors were related to insufficient documentation often associated with clerical errors. One commenter stated that there remain documentation issues with the face-to-face physician encounter requirements and prior authorization is untimely and unnecessary. Commenters also had concerns due to the fact that Face-to-Face encounters are not required until 30 days after the state of care and prior authorization would precede the timing of the requirement.

Response: This demonstration will enable CMS to determine whether applicable Medicare coverage and clinical documentation requirements are met before the claim is submitted for payment. If the documentation is incorrect or insufficient on first submission of the prior authorization request the provider will have unlimited opportunities to resubmit the PA request with the correct documentation. Thereby, reducing the error rate. With regard to concerns about the Face-to-Face encounter not being required until 30 days after the start of care, and Prior Authorization preceding the timing of the requirement. Please be aware, once the Request for Anticipated Payment (RAP) has been submitted and

processed, Home Health providers may submit their Prior Authorization request anytime thereafter up until or even with their final claim for the 60 day episode of care.

Five commenters stated that CMS is only providing another regulation in an already over-regulated industry thereby creating administrative jobs and reducing direct care resources. Five comments stated that there were already numerous initiatives in place to decrease fraud and abuse in home health such as PEPPER Reports, Face-to-Face encounters, value-based purchasing pilots, etc. One commenter stated that as a provider who follows the rules, sends in clinical records, and spends funding on education and mitigation of potential fraud, this was another indication that their professional services are not valued and is concerned that CMS is going to take statistical data and determine a "probable fraud percentage." Another commenter added that home health agencies have experienced three consecutive years of rebasing mandated by the Affordable Care Act and continued rate reduction through the annual Prospective Payment System. The commenter feels prior authorization will only add to the access to care issues and burden brought on through these other programs and changes. One commenter feels that the demonstration is not necessary as there is already a thorough authorization process in place that stems from the signed plan of care the physician's signature on the plan of care signifying that the patient meets the Medicare certification requirements.

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. The rates of prior authorization requests that are provisionally affirmed and non-affirmed will also be collected, along with the rate and adjudication status of appealed claims. CMS will collect qualitative information to help determine whether or not, and to what extent the prior authorization process has improved upon existing methods for investigating and prosecuting fraud as well as reducing the improper payment rate for home health services. Per the Appendices for the 2015 Medicare Fee-for-Service Improper Payment Report, the error rate for Home Health services has increased to 59%, consequently, 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.

Five commenters stated that the demonstration will interfere with the goals of CMS's alternative payment models. One commenter stated that the demonstration may interfere with the Center for Medicare and Medicaid Innovation models to test bundled payments and quality measures.

Response: Prior authorization 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 quaintly measure models. Prior authorization affirms or non-affirms the service before the final claims is submitted. The models would only apply to claims that are submitted, medically necessary and approved for payment.

Commenters stated that the demonstration has no authority to be implemented. One commenter stated that CMS does not have express legal authority in statute to pursue a prior authorization demonstration and that there is no express statutory language that enables CMS to require prior authorization in advance of home health services. 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 demonstration tests a method of screening and utilization management, not a fraud investigation and prosecution method. The commenter believes the Secretary's legal authority would permit investigation and prosecution of fraud, not universally pre-screening all home health services through a broad utilization management program. In addition, the commenter says that to constitute "investigation" there must be some evidence or indication of fraud and the demonstration does not use any evidence or indication of fraud to pursue investigation. Finally, commenters believe that even if the Secretary had the legal authority to pursue prior authorization, the demonstration would require notice and comment rulemaking because it would be a major, mandatory administrative change that alters the operation of the home health benefit. One commenter states that the demonstration is a thinly veiled utilization management told masquerading as a fraud prevention program. Another commenter comments on the CERT results and that the demonstration would not address any risk area for fraud in home health, but instead focus only on garden-variety disputes on claim documentation while not operating to address the now-rescinded face-to-face encounter documentation issues at the center of the CERT results.

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.

Four commenters shared concerns that CMS was violating various statutes by implementing the prior authorization demonstration through the PRA Notice. Two commenters stated that this notice has left unanswered in particular how the process would work and what specifically would be prior authorized. An additional commenter stated that CMS should set clear standards and timeframes for the prior authorization process.

Response: The PRA Notice was not an announcement of a prior authorization program for home health services, and as such, lacked detailed information about the demonstration. Federal Register Notice, CMS 60-69-N, displayed 06-08-16 and published 06-10-16, announced the home health prior authorization demonstration program in further detail.

Seven commenters expressed concern about the cost of implementing the PA model to providers and CMS, and whether the cost supports sufficient return on investment. Two commenters were concerned that these funds would be allocated to increase staff at CMS and the MACs to implement the demonstration and decreasing funds to pay for services for beneficiaries. One commenter was concerned that this is a cost cutting proposal under the guise of combating fraud and abuse. Another commenter stated that return on investment should be based on concrete evidence.

Response: CMS has taken great care with the research and development of the Home Health Prior Authorization demonstration, and has made safety, and continuity of care for beneficiaries, a top priority. Be assured that all of the necessary requirements to make this demonstration a success have been well planned, and thought out, and in no way are funds that were meant for a beneficiary's care being used to hire more staff for CMS, or the Medicare Administrative Contractors (MACs). CMS estimates that this demonstration will bring a sufficient Return on Investment (ROI) to offset the cost of implementation in the demonstration states.

There were some comments about the MACs, specifically 6 comments concerned that the MACs would be unable to process the volume of prior authorization requests and claims in a timely manner. One commenter stated that Massachusetts recently implemented an emergency regulation requiring prior authorization for the home health benefit under the MassHealth Medicare program. The program is only triggered once certain thresholds of services have been met, however Mass Health has been overwhelmed with more than 10,000 prior authorization requests in the first three weeks according to the commenter. The commenter is concerned that given that outcome, the volume for the MACs will be much larger. Another commenter stated that contractors should be required to provide a response to a prior authorization request within 4 hours of the request, seven days a week. Additionally, a second commenter feels CMS should require the MAC to review the request within 24 hours. One commenter felt that prior authorization could not be processed promptly because each home health service is tailored differently based on the patients' needs and would need to be individually assessed and matched to an unquiet plan of care.

Response: The design of the demonstration will require the MAC to make all reasonable efforts to make and postmark the notification of their decision within 10 business days for the initial prior authorization request. If a subsequent prior authorization request is resubmitted after a non-affirmative decision, then CMS or its agents will have 20 business

days in which to conduct a complex medical review and postmark the notification of their decision to the HHA and the beneficiary. These timeframes are consistent with the PMD prior authorization demonstration model and meeting these timeframes will become part of the MACs' performance metric. As services may begin following the submission of the RAP and prior to the submission of the prior authorization request, these timeframes will not delay the beneficiary in receiving home health services.

Two commenters expressed concern that the very nature of the prior authorization demonstration essentially gives MACs the opportunity to make medical decisions. Specifically, one commenter stated "This essentially equates to Medicare contractors practicing medicine," and the other commenter stated "This is another example of bureaucrats involving themselves in the medical decisions that should be between a physician and their patient." Another commenter stated that CMS should make sure that the MACs have a high degree of expertise in patient care and are able to make reasonable decision s on the applicability of home case. A commenter also stated that program integrity measures should be evaluated against a comprehensive set of guiding principles to make sure the measure does not create more harm than good.

Response: The operational process of the physician providing services to the patient and ordering home health services will remain the same. Prior authorization is a process through which a request for provisional affirmation of coverage, payment and coding rules are met before claims are submitted. A beneficiary who requires one or more home health services in the treatment of his/her illness or injury and otherwise qualifies for home health benefits is eligible to have payment made on his/her behalf for the skilled nursing, physical therapy, occupational therapy, or speech-language pathology services he/she needs, as well as for any of the other home health services specified in the law. The MACs who will review the prior authorization requests are the contractors who currently handle the home health claims. In addition, no new coverage or documentation requirements will be created.

Six commenters had comments related to concerns of the Medicare Home Health Compare performance measure for timely initiation of care, and how non-compliance with this measure would affect their STAR ratings for their home health agency.

Response: The prior authorization process will occur in the first 30 days of treatment and beneficiary access to treatment will not be delayed. This prior authorization demonstration will not interfere with the Medicare Home Health Compare performance measure for timely initiation of care, nor will it affect Home Health Agencies STAR ratings.

The comparison of the home health prior authorization demonstration to the power motorized devices (PMD) prior authorization demonstration caused concerns to be raised by 6 commenters. Three commenters pointed out that the needs of beneficiaries for PMD and HH services are quite different and that a beneficiary could wait for a Preauth to be affirmed for the PMD while HH

services should begin right away. One commenter stated that while the PMD PA demo decreased costs that may not translate to appropriate care. Another commenter felt that the prior authorization request volume would be much greater for home health than with the PMDs. A commenter also stated that if the demonstration was similar to the Repetitive Scheduled Non-Emergent Ambulance and Hyperbaric Oxygen Therapy models, the timeframes would result in delays to access to care.

Response: CMS used the example of the PMD Prior Authorization demonstration model to illustrate that there was another prior authorization demonstration initiated and the process for home health Prior Authorization demonstration would be similar. The difference is that the services in the home health demonstration can be started before the prior authorization is requested.

Provider risk was a concern that commenters raised. One commenter stated that some providers may be unwilling to "assume financial risk of starting care prior to authorization." Another commenter stated "…the question of whether or not prior authorization will result in payment of claims or implementation of yet another appeals process and the financial risks face(ed) by my agency …..is overwhelming." Two commenters were concerned about the Medicare Conditions of Payment and whether potential harm to a patient could result in a provider's termination for the Medicare program. The commenter also sought guidance on where the liability for patient safety would lie if a prior authorization request was denied. A commenter also stated that the 25 percent payment reduction may reduce access to care as some providers may be unwilling to accept any patient whose case did not receive prior approval for fear of this penalty. One commenter asked that CMS provide additional details on the appeals options. Another commenter stated that an accelerated and robust appeal process for providers and beneficiaries must be put in place to avoid delays in access to care. A commenter states that any reforms or remedies should properly distinguish fraud from unintentional noncompliance.

Response: While this demonstration does not include a separate appeals process for a non-affirmative prior authorization decision, there are an unlimited number of prior authorization requests that may be submitted to meet all requirements. Further, a non-affirmative prior authorization decision does not prevent the submission of a claim. If such a claim is submitted and subsequently denied, the denial would constitute an initial determination that would make the appeals process available for beneficiaries and HHAs.

Two commenters expressed concern that they would have to request additional information from physicians on top of completing the 483, verbal orders, medication orders, and to produce a Face to Face document with sufficient narrative to meet the specific requirements. They point out that this would put an added stress on the relationship between the home health agency and physicians, and control over the agencies' payment to the physician.

Response: With the promulgation of the Home Health Prospective Payment System (HH PPS) Final Rule which was put into effect January 1, 2015, the narrative for the Home

Health Face-to-Face encounter is no longer required. Since this demonstration does not create or require any additional documentation to what Home Health Providers are already submitting to along with their claims, and only requires the documentation earlier in the process, CMS believes this should not increase provider burden.

Three commenters from one of the demonstration states expressed concern that Medicare beneficiaries in their state would have less access to the Medicare home health benefits than beneficiaries in non-demonstration states.

Response: The Medicare home health benefit is not changed for any state. A beneficiary who requires intermittent skilled nursing, occupational therapy, physical therapy, or speech-language pathology services will qualify for the home health benefit.

Three commenters expressed concern that the pre-authorization requirement would result in a massive amount of confusion as there is still confusion over the documentation needed for the Face-to-Face encounter and how the MAC and the audit contractors review them. Another commenter had concerns on how the Face-to-Face encounter would work with the prior authorization request timing wise. One commenter feels education should be provided to help providers understand the Face-to-Face encounter requirement which insufficient documentation errors may actually be attributed to rather than implement the demonstration.

Response: This demonstration does not create any new clinical documentation requirements. HHA's will submit the same information they currently submit for payment. **CMS has published numerous educational materials to inform HHAs and Medicare beneficiaries of the policies and documentation requirements for home health services. CMS will also conduct several open door forums (ODF) on these policies as well as the process and requirements for the home health services demonstration.**

Two commenters expressed concern that the prior authorization demonstration may expand to other states in the future and could have unintended and negative ramifications on their patients.

Response: At this time, CMS has no plans to expand the demonstration to additional states. The demonstration will be implemented in five states- Florida, Illinois, Massachusetts, Michigan, and Texas. Prior to any possible expansion in the future data will be collected from this demonstration and 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. The rates of prior authorization requests that are provisionally affirmed and non-affirmed will also be collected, along with the rate and adjudication status of appealed claims. CMS will use this information to help determine whether and to what extent the prior authorization process improved upon existing methods for investigating and prosecuting fraud and reducing improper payments for home health services.

Several commenters' state that CMS should work with stakeholders to make sure the demonstration is successful or find other ways to identify and stop fraud and abuse.

Response: CMS would very much like to work with the Home Health community, and other stakeholders as this demonstration moves forward, and believes that this will help ensure its success. CMS will conduct Open Door Forum calls where all stakeholders can learn more about the demonstration, and will be able to ask questions and provide comments. In addition to this, CMS has created an email address where stakeholders can send questions and comments as well. Per the Appendices for the 2015 Medicare Fee-for-Service Improper Payment Report, the error rate for Home Health services has increased to 59%, consequently, CMS has and will continue to look for new ways to combat fraud, and lower the payment error rate while maintaining or improving the quality of patient care.