July 21, 2016

Attention: CMS Desk Officer
Office of Management and Budget (OMB)
Office of Information and Regulatory Affairs
725 17th Street, NW
Washington, DC 20503
SUBMITTED VIA E-MAIL: OIRA_submission@omb.eop.gov

RE: Agency Information Collection Activities: Submission for OMB Review; Comment Request (OMB Control Number: 0938-NEW)

To whom it may concern:

I am writing on behalf of the Alliance for Home Health Quality and Innovation (the "Alliance") in response to the Centers for Medicare and Medicaid Services' request for comments on the Paperwork Reduction Act (PRA) notice in the *Federal Register* announcing CMS' intention to collect information pertaining to a Medicare pre-claim review demonstration for home health services, 81 Fed. Reg. 40308 (June 21, 2016). The Alliance appreciates the opportunity to provide comments.

About the Alliance for Home Health Quality and Innovation

The Alliance is a non-profit 501(c)(3) organization with the mission to lead and support research and education on the value of home health care to patients and the U.S. health care system. Working with researchers, key experts and thought leaders, and providers across the spectrum of care, we strive to foster solutions that will improve health care in America. The Alliance is a membership-based organization comprised of not-for-profit and proprietary home health care providers and other organizations dedicated to improving patient care and the nation's healthcare system. For more information about our organization, please visit: http://ahhqi.org/.

The Alliance supports, and is aligned with, the comments on this PRA notice submitted by the Visiting Nurse Associations of America, the Partnership for Quality Home Healthcare, and the National Association for Home Care and Hospice. In addition to supporting these organizations' comments, the Alliance appreciates the opportunity to provide comments in the following topic areas on the Federal Register notice and the related Supporting Statement proposed Medicare pre-claim review demonstration for home health services: (I) process considerations and burden estimate; (II) legal authority; and (III) using targeted means of addressing fraud, waste and abuse.

I. Process Considerations and Burden Estimate

The proposed pre-claim review demonstration for home health services would present considerable delays as a result of administrative infeasibility. The Alliance is concerned that CMS continues to analogize home health services to power mobility devices in pursuing a pre-claim review process. Home health care services are completely different in nature as compared to power mobility devices and a process modeled after the prior authorization process for power mobility devices cannot be similarly applied to home health care. Whereas there is consistency and uniformity as to what constitutes a power mobility device, home health services vary based on the patient's needs and this tailored approach is required by statute. Because of the way the Medicare home health benefit is structured in legislation, home health services are tailored to each specific patient's needs through a physician-established plan of care.[1] As a result, each beneficiary's home health services will differ based on the beneficiary's unique needs. The tailored nature of home health services will make pre-claim review impossible to process promptly because each patient would need to be individually evaluated and matched to each specific plan of care. In other words, there is no simple algorithm possible for home health services, with easy inputs that lead to standardized items or services. A pre-claim review process for home health care therefore will be time-consuming for the Medicare contractors to implement (much more lengthy than the one used for power mobility devices). Pre-claim review as applied to home health services is therefore not feasible from a practical and administrative standpoint.

Moreover, CMS and its contractors are seeking to begin the pre-claim review demonstration in Illinois on August 1, but to date have struggled with providing consistent guidance to home health agencies in Illinois (and future states) on implementation. CMS and Palmetto have provided directly contradictory information that has been confusing for home health agencies seeking to prepare for the pre-claim review demonstration. There has been no specific guidance provided as to what the documentation should look like to meet the pre-claim review request elements. As a result, the MAC process for reviewing these requests will likely be lengthy (because of vast amounts of information provided unnecessarily) or result in unnecessary denials (because insufficient documentation is provided in the absence of adequate guidance).

Furthermore, the estimated burden on home health providers of a pre-claim review demonstration in five states has been grossly underestimated by CMS. CMS's estimate in the supporting statement for the PRA notice is that home health agencies will spend 30 minutes per reviewed claim; using a low hourly rate estimate of $15.89 per hour, CMS estimates that agencies will incur about $21.6 million in cost over three years.

Thirty minutes is an underestimate of the time that home health agencies would likely spend on a pre-claim review process given that most agencies will need to hire

[1] 42 U.S.C. § 1395n(a)(2)(A)(ii).

additional administrative staff to submit and manage pre-claim reviews. The work associated with the pre-claim review process would go well beyond only locating and obtaining information to submit and then submitting the materials for review; agencies will need to engage in further application activities on appeals if applications are denied, and to communicate with Medicare contractors both on applications and appeals. Moreover, the hourly rate for agency staff who are capable of managing the pre-claim review process is easily the "loaded rate of $31.78", which CMS references in the supporting statement. Thus, the cost to agencies is likely to be at least twice CMS's estimate for provider burden.

In addition, critical to this effort is physician education and engagement, but the burden borne by physicians in such efforts and the related cost to physicians have not been taken into consideration in terms of burden estimates. Recently, Palmetto (one of the MACs in the affected states) has been trying to launch physician education efforts, but such trainings seemingly highlight the considerable burden that is being imposed on physicians that are partnering with home health agencies. The complexity of the guidance thus far suggests that the cost estimates are extremely inaccurate because the physician's perspective was not taken into consideration.

II. Legal Authority

The Paperwork Reduction Act notice and the accompanying Supporting Statement describe CMS' plans to pursue a demonstration project that would require pre-claim review for all home health agency services in five states: Florida, Texas, Illinois, Michigan and Massachusetts. CMS states that the legal basis for the demonstration is in statute at 42 U.S.C. § 1395b-1(a)(1)(J), which gives the Secretary authority "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 this chapter." (emphasis added)

First, CMS does not have express legal authority in statute to pursue a pre-claim review demonstration for home health care. The Medicare home health benefit is prescribed in statute and there is no express statutory language that enables CMS to require pre-claim review in advance of Medicare home health services.[2] There is also no specific statutory provision to authorize conduct of a demonstration project on pre-claim review for home health services, consistent with the description in the PRA notice and supporting statement.

Second, CMS does not have legal authority to pursue a pre-claim review demonstration for home health services pursuant to 42 U.S.C. § 1395b-1(a)(1)(J), the provision CMS cites as the legal basis of the demonstration, because the proposed pre-claim review

[2] *See* 42 U.S.C. § 1395f(a)(2)(C).

demonstration is not a means of either "investigation or prosecution of fraud." What is proposed in the notice and the Supporting Statement is a program to screen every home health service through a pre-claim review process for the five identified states. The proposed demonstration tests a method of screening and utilization management, not a method for investigation and prosecution of fraud. CMS states that "the 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." (emphasis added). CMS goes on to explain in the supporting statement that it plans to use pre-claim review as a means to "identify" those who may have been submitting fraudulent claims before implementing the pre-claim review demonstration; CMS would identify these parties because agencies that stopped submitting claims may have been submitting fraudulent claims before. The law at 42 U.S.C. § 1395b-1(a)(1)(J), however, does not authorize Secretarial authority to test methods to identify fraud in this manner. 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.

Moreover, the demonstration as proposed is not a method of fraud investigation because there is no indicia or evidence used as a basis of investigation. Using pre-claim review as a means of investigation is the equivalent of creating a program to search every household in Florida for illicit drugs because Florida as a state has been known to have drug traffickers in the state. To constitute "investigation," there must be some evidence or indicia of fraud. The demonstration as proposed does not use any evidence of indicia of fraud to pursue investigation of the same. The proposed method of screening and utilization management applied across the board to all home health agency services in the identified states is simply not a method of investigation of prosecution of fraud and therefore as proposed is not authorized by 42 U.S.C. § 1395b-1(a)(1)(J).

Notwithstanding, even if the Secretary had legal authority to pursue pre-claim review for home health care, such a demonstration program would require notice and comment rulemaking because it would be a major, mandatory administrative change that alters the operation of the Medicare home health benefit (in contravention of the benefit as specifically and expressly prescribed in the Social Security Act) with a very significant impact on patient access, health system efficiency, and increased burden on providers of all sizes, including small businesses. Changes of this magnitude that are mandatory in nature are required to go through notice and comment rulemaking consistent with the Administrative Procedure Act (APA). CMS has recognized the need for notice and comment rulemaking in other demonstration project contexts that are mandatory in nature. Most recently, CMS used notice and comment rulemaking prior to beginning the home health value based purchasing model and the comprehensive care for joint replacement model. In both cases, CMS recognized that for a program that is being tested in select areas of the country where participation is

mandatory for providers, full notice and comment rulemaking consistent with the APA should be used to implement such programs.

III. Importance of Pursuing Targeted Means of Addressing Fraud, Waste and Abuse

Rather than developing a pre-claim review program to screen all home health services, the Alliance recommends that CMS use targeted means to identify fraud, waste and abuse in home health care. CMS has numerous appropriate tools in its armamentarium to identify fraud, waste and abuse. By identifying aberrant billing practices through claims data, CMS has the ability to identify providers who may be engaged in suspect behavior that may constitute fraud. With that information in hand, CMS could then use a variety of methods of investigate whether fraud is actually being committed. In some cases, there may be legitimate reasons for unusual patterns in billing. For example, some home health providers may serve a disproportionate share of patients that require higher intensity utilization of services. In other cases, however, providers may be committing fraud. CMS and the HHS Office of Inspector General (OIG) can use its investigations and audit apparatus to distinguish legitimate and appropriate utilization and billing practices from fraud and abuse.

The Alliance supports efforts to target fraud and abuse investigation and prosecution efforts by identifying providers with aberrant billing practices in claims data, and following up with its many tools for appropriate investigation and prosecution. CMS and OIG have the ability to do so while protecting and supporting the critical policy goals of patient access, quality of care, and efficient health care delivery, while using a least burdensome administrative approach for providers, patients and the Medicare program. Alliance members are committed to helping CMS and OIG to develop appropriate methods to investigate and prosecute fraud in home health care. The Alliance recommends development of a public-private partnership or working group that would support CMS and OIG's efforts in this area and would welcome the opportunity to engage in such an endeavor.

* * *

Thank you for the opportunity to comment on this notice. Should you have any questions, please contact me at 571-527-1530 or tlee@ahhqi.org.

Sincerely,

Teresa L. Lee, JD, MPH
Executive Director

From: Amy Jezek
To: OS OIRA (HHS/OS)
Subject: Pre-Claim Review Demonstration Project Comments
Date: Wednesday, July 20, 2016 11:19:20 PM

Dear CMS Desk Officer:

Thank you for allowing an opportunity to submit comments on the proposed home health Pre-Claim Review Demonstration project (PCR). I have worked in home care for the past 20 years and know first hand how this will negatively impact agencies and ultimately patients needing skilled care in their homes.

Our industry is fraught with fraud and abuse, so I emphatically support efforts to prevent this; however, I fail to see how PCR will benefit the reduction and hopeful elimination of fraud and abuse. I would prefer tax dollars go toward punitive measures targeted toward known abusive providers and toward heightened prevention in areas known for fraud and abuse. This project unjustly targets agencies with proven compliance and commitment to integrity of the industry.

I appreciate the aspect of no delay in providing medically necessary care for Medicare beneficiaries; however, PCR poses undue financial burden on agencies that will not receive reimbursement for a non-affirmed PCR. Even with an appeals process for non-affirmed PCR, the backlog would become exponential, requiring more resources to process them.

I foresee other costs associated with this project to be excessive. Agencies will be forced to discharge some patients for non-affirmed PCRs. The home care demographic includes a majority of patients with chronic illness, having frequent exacerbations and these patients will be at greater risk for hospital stays and subsequent re-hospitalizations without skilled home care providers. This cycle causes more money to be spent than would have without this project.

I fear software and staffing issues within agencies will be additional pitfalls if PCR is implemented. Many agency employees already fill multiple roles and additional processes required for this would be counter-productive and minimize crucial time needed for patient care. Many home care patients are rural and the skilled care they receive from staff who spend a great deal of time driving to see them is imperative. Every second counts for these beneficiaries.

PCR will adversely affect Medicare beneficiaries in need of skilled home care and will place undue burden on the agencies trying to serve them. I urge development of a less burdensome approach to address fraud and abuse in our industry. The focus should be on high risk agencies and areas as this project is a blanket approach and unjustly punishes compliant agencies.

Thank you for considering my comments in determining further action on PCR.

Sincerely,

Amy Jezek, HCS-D
332 W. Hinton St.
Tioga, TX 76271
940-293-3471

PRE-CLAIM REVIEW DEMONSTRATION PROJECT

Dear CMS Desk Officer,

Thank you for the opportunity to submit comments regarding the home health Pre-Claim Review Demonstration project.

I am a Clinical Software Specialist in the Home Health and Hospice industry. I have served this industry for 22 years in multiple roles. I have many friends and relatives that have benefited from Home Health and Hospice services. Because of the amount of time I have been around the industry, I have seen a lot of changes as should be expected in any industry. The problem with most of the changes in this industry (in particular home health) is that the patient is rarely thought of. I do understand that any business must be able to provide a financially viable service so there is always a delicate balance between the best interest of the customer being served and the cost of the service itself. One of the major problems in home health I have seen over the years is over regulation without proper justification paired with decreased payment. These two factors threatens the survival of this vital service. Not only to the patients we serve but to the healthcare system as a whole. Home Health, Hospice along with preventative care programs are the final link in the continuum of care. Without these services, there will be more hospital visits, more re-hospitalizations, more physician visits and more emergency care required. Not to mention a decrease in quality of life for a population we owe our lives to…literally.

With all that said, this particular demonstration is another example of the government not listening to the home health and hospice industry and **its patient population** in regards to what will and will not work. There are so many regulations that in this case, many are overlapping and contradicting each other making it seem that the end goal is not to remove fraud but to simply put agencies across the board out of business.

Below is a list of statements that point out some of the contradictions and realities of implementing this "demonstration." I appreciate your consideration in repealing any proposed or current laws that put the pre-claim review process into effect based on the following points.

- While I support all efforts to prevent fraud and abuse in the home care industry, such efforts should target abusive providers and not decrease access to care for our most vulnerable population at home.
- Our taxpayer dollars could be better served with targeted fraud and abuse rather than sweeping burdens placed on all agencies.
- While home care reimbursement is proposed to decrease next year, agencies will incur additional costs to implement this project.
- This project results in additional administrative costs and operational burdens on home care agencies.
- While agencies strive to achieve higher quality care with increased efficiencies and less reimbursement, the added administrative costs of the pre-claim review process are an additional financial burden on home care agencies.

- This demonstration project unduly targets compliant agencies instead of targeting cities where known fraud exists.
- While I appreciate no delay in the provision of medically necessary care for Medicare beneficiaries, this project poses an undue financial burden on an agency who will not receive reimbursement for a non-affirmed PCR.
- Medicare Administrative Contractors (MACs) are not ready for implementation of this project.
- While a non-affirmed PCR allows the opportunity for appeal, such appeals will further increase the catastrophic backlog of Medicare appeals pending review by an Administrative Law Judge (ALJ.)
- As currently proposed, this project conflicts with existing CMS regulation. Examples:
    - F2F documentation is not required until 30 days after the start of care. Because F2F is now required to be submitted with the PCR, the allowed 30-day timeframe will be effectively reduced.
    - Physician orders, including the Plan of Care, are currently required to be signed by the physician prior to the agency's submission of the End of Episode (EOE) claim. Because the POC must be signed prior to submitting a PCR, the timeline for obtaining physician signatures has significantly decreased.
- The proposed submission of a subsequent PCR for changes in plans of care during an episode effectively changes the PCR project to a prior authorization process. The only difference is the PCR process places financial liability on the home care agency while the prior authorization process delays and limits access to medically necessary home care services.
- The cost to the federal government to reimburse MACs for this project is excessive. These same funds could be used more effectively in targeted review.
- MACs' pre-claim review of all episodes results in excessive volume with doubt that PCR requests will be processed on a timely basis.
- CMS currently performs targeted edits of home care agencies through Additional Documentation Requests (ADRs.) However, this project essentially places all agencies on 100% pre-claim ADR review without proper cause.
- Despite an agency's best efforts to prepare for a PCR submission, external issues beyond their control (e.g. timely receipt of physician signatures) will further delay agency submission and subsequent response of an affirmed/non-affirmed decision.
- One of the basis for this demonstration project is an increasing improper payment rate for home health claims. The 90% of errors due to insufficient documentation is evidence of unclear F2F documentation requirements. Despite CMS education while the F2F requirements evolved, undue confusion resulted for home care agencies.
- Without the development and distribution of clear guidelines for this project, the PCR affirmation is subject to the reviewer and/or the MAC's interpretation. We have learned from our experience with the F2F requirement, how easily misinterpretation results in denial.

Suggestions:

- Rather than create this broad-spectrum project, I recommend CMS utilize data to identify high risk situations and target program integrity measures.
- I suggest CMS, in conjunction with the home care community, develop a less burdensome approach to fraud and abuse.
- Rather than using this project to remedy non-compliance with documentation requirements, I recommend CMS provide clarified and consistent standards with education to the home care community and MACs. (e.g. F2F)
- Rather than create this broad-spectrum project, I recommend CMS to utilize data to identify high risk situations and target program integrity measures.
- Because the home care agency provides medically necessary services in good faith of receiving reimbursement, I recommend CMS provide reimbursement for services provided until the date of the non-affirmed PCR decision.

Thank you again for your consideration.
Annie Cardona

Cypress Home Care
"Bringing Healthcare Home"

Administration Office
P.O. Box 2284 ♦ 303 W. First St.
Mt. Pleasant, TX 75456
(903) 575-9506 ♦ fax (903) 575-9508

July 20, 2016

Attention: CMS Desk Officer via email: *OIRA_submission@omb.eop.gov*

To the OMB, Office of Information Regulatory Affairs:

CMS is requiring impossible tasks by requiring home health agencies to have all physicians' orders signed and dated for the pre-claim review demonstration. Under current regulations, the home health agency has 60-75 days to obtain the signed and dated order(s) when submitting the End of Episode claim (Compliance Program). Until the physician has returned the signed and dated order, nurses are working and carrying out the **physicians' VERBAL order(s).**

CMS is also requiring the Face to Face Encounter form be signed and dated for the pre-claim review. Under current regulations the agency has 30 days to receive the signed and dated face to face encounter form back from the physician. **To change this requirement mid-stream with little time for education is certainly unfair to home health agencies and beneficiaries.**

Home Health agencies have been under reimbursement cuts for years now. In 2017, we will receive more reimbursement cuts of the fourth year phase cuts. Home health agencies will have to hire an additional 1-2 person(s) to begin uploading medical records to eServices as CMS is requiring under this pre-claim review demonstration. Due to cuts, agencies **do not have the cash flow** to hire additional man power.

Since CMS is requiring PGBA receive the electronic health record on **EVERY HOME HEALTH CLAIM, APPROVING OR DENYING SERVICES TO THE BENEFICIARY AFTER THE SERVICES HAVE ALREADY BEEN PROVIDED it is <u>of grave concern</u> that PGBA can process 18,000 plus claims EVERYDAY <u>MANUALLY</u> BY <u>NEWLY HIRED STAFF</u> THAT HAVE LITTLE TO NO EXPERIENCE ABOUT HOME HEALTH SERVICES AND THE NEEDS OF BENEFICIARIES. PGBA stated on an open door forum call that LPN'S will be reviewing these claims. It is illegal and against the nurse practice act for a LPN to review and supervise a patients plan of care. It is certainly illegal for the LPN to deny or approve patient's services. LPN's do not have the expertise needed to develop and/or supervise a plan of care in any area of nursing.**

CMS is implementing the pre-claim review under the **paper work reduction act**. However, the new requirements are placing a greater demand on physician's paper work by requiring the physician's signature and date in an undoable time frame.

IF the OMB, Office of Information Regulatory Affairs allows CMS to implement this pre-claim review demonstration with the rules that CMS has come up with, **MANY OR ALL home health agencies will be forced out of business.** And, having been a Registered Nurse for 21 years and having practiced in skilled and certified home health services for 17 years, I foresee **<u>hospitalization rates spiking due to unqualified reviewers denying beneficiaries home health services.</u>** With the baby boom generation turning 65 years old, home health is needed now more than ever! It is cheaper for CMS to care for these beneficiaries in their own home. Without home

health agencies, the beneficiary will end up in the hospital or emergency room time and time again driving Medicare costs through the roof.

Thank you,

Lance Cornell
CEO
Cypress Home Care

PRE-CLAIM REVIEW DEMONSTRATION PROJECT

Dear CMS Desk Officer,

Thank you for the opportunity to submit comments regarding the Home Health Pre-Claim Review Demonstration Project. I am an RN in the Home Health Industry and have been for the past 26 years. I have served hundreds of patients and families over this time period that have benefited immensely from our Home Health services. Because of this time that I have spent in this industry, I have seen many changes occur – which is to be expected. However—what saddens me most, is that the patients are rarely though of when these changes are made and carried out. I certainly understand that businesses must be able to provide a financially viable service so there is that delicate balance between the patient being served adequately and the cost of that said service. One of the MAJOR problems I have witnessed in Home Health is over regulation without proper justification paired with decreased payment. This combination threatens the survival of this VITAL service. Not only to the patients and families that I have served but to the healthcare system as a whole. Home Health & Hospice, along with preventative care programs are the final link in the continuum of care. Without these services, the hospital visits, re-hospitalizations, Dr's visits and ER visits will continue to climb. Not to mention a decrease in quality of life for a population we owe our lives to…LITERALLY!!!

With all this said, this certain demonstration is yet another example of the government not listening to the Home Health & Hospice industry and its patient population in regards to what will and what will NOT work. There are so many regulations that in this case, many are overlapping and contradicting each other, making it seem that the end goal is not to remove fraud but to simply put Agencies across the board, out of business.

Below is a list of statements that point out some of the contradictions and realities of implementing this "demonstration". I appreciate your consideration in repealing any proposed or current laws that put the pre-claim review process into effect based on the following points.

- While I support all efforts to prevent fraud and abuse in the home care industry, such efforts should target abusive providers and not decrease access to care for our most vulnerable population at home.
- Developing another layer of government bureaucracy is not an efficient or effective use of taxpayer dollars. This PCR project requires CMS to invest substantial resources into the procedures and personnel.
- Our taxpayer dollars could be better served with targeted fraud and abuse rather than sweeping burdens placed on all agencies.

- This PCR project is not sufficiently targeted to the fraud or abuse of concern. It fails to distinguish between fraud and unintentional noncompliance with documentation requirements.
- Current state and federal anti-fraud enforcement agencies have the resources and have been successful in targeting fraud and abuse among specific home care agencies.
- While home care reimbursement is proposed to decrease next year, agencies will incur additional costs to implement this project.
- This project results in additional administrative costs and operational burdens on home care agencies.
- While agencies strive to achieve higher quality care with increased efficiencies and less reimbursement, the added administrative costs of the pre-claim review process are an additional financial burden on home care agencies.
- Rather than targeting all agencies within the demonstration states, CMS should target specific agencies and/or cities where known fraud and abuse occur.
- This demonstration project unduly targets compliant agencies instead of targeting cities where known fraud exists.
- While I appreciate no delay in the provision of medically necessary care for Medicare beneficiaries, this project poses an undue financial burden on an agency who will not receive reimbursement for a non-affirmed PCR.
- Agencies will incur the cost for skilled services provided in the event a pre-claim review is non-affirmed.
- Agency requirements for this project are evolving and not fully defined.
- Medicare Administrative Contractors (MACs) are not ready for implementation of this project.
- While a non-affirmed PCR allows the opportunity for appeal, such appeals will further increase the catastrophic backlog of Medicare appeals pending review by an Administrative Law Judge (ALJ.)
- Although this is a demonstration project, Medicare Administrative Contractors (MACs) have not been allowed sufficient time to test the process. Similarly, home care vendors have not had time to update their software.
- This project causes potential for adverse consequences to Medicare beneficiaries.
- This project is a potential for barrier to home care. Patients requiring high levels of care may be declined by home care agencies due to the financial risk of a non-affirmed PCR decision. Further, home care agencies will discharge Medicare beneficiaries from skilled services when a PCR is returned non-affirmed. Such barriers may result in increased hospital stays and increased re-hospitalizations.
- The cost to the federal government to reimburse MACs for this project is excessive. These same funds could be used more effectively in targeted review.
- MACs' pre-claim review of all episodes results in excessive volume with doubt that PCR requests will be processed on a timely basis.

- Without the development and distribution of clear guidelines for this project, the PCR affirmation is subject to the reviewer and/or the MAC's interpretation. We have learned from our experience with the F2F requirement, how easily misinterpretation results in denial.
- CMS currently performs targeted edits of home care agencies through Additional Documentation Requests (ADRs.) However, this project essentially places all agencies on 100% pre-claim ADR review without proper cause.
- One of the basis for this demonstration project is an increasing improper payment rate for home health claims. The 90% of errors due to insufficient documentation is evidence of unclear F2F documentation requirements. Despite CMS education while the F2F requirements evolved, undue confusion resulted for home care agencies.
- As currently proposed, this project conflicts with existing CMS regulation. Examples:
    - F2F documentation is not required until 30 days after the start of care. Because F2F is now required to be submitted with the PCR, the allowed 30-day timeframe will be effectively reduced.
    - Physician orders, including the Plan of Care, are currently required to be signed by the physician prior to the agency's submission of the End of Episode (EOE) claim. Because the POC must be signed prior to submitting a PCR, the timeline for obtaining physician signatures has significantly decreased.
- Despite an agency's best efforts to prepare for a PCR submission, external issues beyond their control (e.g. timely receipt of physician signatures) will further delay agency submission and subsequent response of an affirmed/non-affirmed decision.
- The proposed submission of a subsequent PCR for changes in plans of care during an episode effectively changes the PCR project to a prior authorization process. The only difference is the PCR process places financial liability on the home care agency while the prior authorization process delays and limits access to medically necessary home care services.

Suggestions:

- I suggest CMS, in conjunction with the home care community, develop a less burdensome approach to fraud and abuse.
- Rather than using this project to remedy non-compliance with documentation requirements, I recommend CMS provide clarified and consistent standards with education to the home care community and MACs. (e.g. F2F)
- Because the home care agency provides medically necessary services in good faith of receiving reimbursement, I recommend CMS provide reimbursement for services provided until the date of the non-affirmed PCR decision.
- Rather than create this broad-spectrum project, I recommend CMS utilize data to identify high risk situations and target program integrity measures.

- Rather than targeting all agencies within demonstration states, CMS should target specific agencies and/or cities where known fraud and abuse occur.

Thank you again for your consideration,
Alicia Anne Anderson BSN, RN

From:	Michelle Mongogna
To:	OS OIRA (HHS/OS)
Cc:	Michelle Mongogna
Subject:	Pre-Claim Review Demonstration Project
Date:	Wednesday, July 20, 2016 5:52:09 PM

Attention: OMB
Office of Information and Regulatory Affairs
Re: **PRE-CLAIM REVIEW DEMONSTRATION PROJECT**
VIA Email

July 20, 2016

Dear CMS Desk Officer,

Thank you so much for opening up the lines of communication for home health providers. We appreciate the opportunity to submit comments regarding the **home health Pre-Claim Review Demonstration** project.

We agree with you and stand beside you to support efforts to prevent fraud and abuse in the home care industry, however, we believe that such efforts should target those providers who are abusing the system rather than blanketing entire states where many elderly rural patients already lack access to care. I work for a home health provider that sees rural home health patients who live many miles from hospitals. If home health care is restricted, my opinion is that these patients will end up sicker and in hospitals, SNFs or other facilities and resulting in more costs to the Medicare program.

Because we know that the actual process requires hand keying of fields, we are confused as to why more time could not be given to software vendors time to update their systems so this could be done more efficiently. For example, the system does not save any previous entries so the agency must retype any resubmission again. And if the same document is required in two sections then it must be saved twice in the MACs' same system. It seems that if more time and consideration went into which providers needed to participate in the project, then the work would be done in a more effective and less costly manner. Agency requirements for this project are not fully defined. Home health agencies are being held accountable for documentation out of their control. Physicians have no incentive and see no reason to document to satisfy an auditor. PCR will not change this problem. In my opinion, it will only serve to deprive patients of much needed care.

Another concern is that this project will place an undue financial burden on agencies who will not receive reimbursement for a non-affirmed PCR. If agencies do not get their PCR approved the first time, they will have provided the care so all their dollars will have been spent, and the PCR may or may not be approved the second time. Additionally the concern is that if the RAP gets cancelled, then the cash flow will stop. If enough of this type of thing happens then care will be greatly compromised, thereby increasing costs overall. Signed physician orders should not be required before PCR is submitted. This is a burdensome and additional required step that has been added prior to the EOE. This will substantially delay the submission of the PCR.

Please consider developing a less burdensome approach to preventing fraud and abuse or utilize this as a targeted approach to a smaller area. If home care providers are expected to comply in a specific manner, equally specific education to the providers should be offered. We look forward to a positive

response as a result of sincere consideration of our concerns. Our first priority is for the beneficiaries to have access to quality home health care.

Sincerely,
Michelle Mongogna
Foundation Management Services

From:	Brandy Ash
To:	OS OIRA (HHS/OS)
Cc:	Brenda Beggs; Marcylle Combs
Subject:	Pre-Claim Review Demonstration Project
Date:	Wednesday, July 20, 2016 5:26:42 PM

To whom it may concern,

I am extremely concerned about this new CMS project. I fully agree that the fraud within our industry needs to be held in check, but this approach is going to have an adverse effect on all agencies and many patients. It feels more like a shotgun affect as opposed to a focused approach, causing unnecessary collateral damage. Good quality patient care is your objective as well as mine, …however, this demonstration project has a high potential of compromising that. As homecare continues to be burdened with much paperwork (a good portion of it we have to rely on physicians that we have no control over) this is one more thing we will have to push the physicians even harder for. As I lead a sizable sales force for a large regional provider, I know firsthand how difficult it is to get timely signatures from physicians based on CMS current requirements. In addition, we serve a large rural area where many of the patients are seen by Nurse Practitioners or Physician Assistants and the physicians are at a totally different location making timely signatures even more challenging in the current environment.
I realize, on the calls, we have been reassured that the physicians and hospitals will be educated, however, that will not change their own personal workload and the priorities they must make in daily activities. So as we will have to push even harder, irritating the physician offices even more, I believe we will have physicians say to us, as some did when Face to Face was implemented, "I do not want to deal with all of the paperwork homecare requires for my patients". We saw an overall drop in admissions the year F2F was implemented due to the frustrations of physicians and their offices. I am confident that it wasn't the fact that the number of patients in need of homecare services suddenly dropped that year…physicians most likely chose other more costly and less desirable solutions: admitted to facilities unnecessarily, longer stays in the hospital or re-admission to the hospital…or even worse, perhaps sent them home with no help. I believe this demonstration project is positioned to have the same result as physicians tire of our "nagging".

In addition, there will be additional costs incurred, not only on homecare agencies, but to the MACs and CMS as well. These additional costs will do nothing to improve the patient care we deliver and the end result will be reduced resources for patients on services. That being said, I must say again, I believe something needs to be done to stop the fraud. CMS sites 59% of home health claims have an improper payment rate. Surely there is a way CMS can target the ones with the highest instance of fraudulent claims and/or use data sets they should have that can indicate red flags among the agencies that are causing the problem. Why make the whole industry suffer for the few bad apples…at the end of the day the real loser is the patient!

Respectively,

Brandy Ash¦ Vice President of Sales
Foundation Management Services, Inc.
2800 Shoreline Dr. Suite 300 ¦ Denton, TX 76210
O: (940) 220-2105¦C: 940-231-0801
>www.askFMS.com<
It's an honor to serve you.

PRE-CLAIM REVIEW DEMONSTRATION PROJECT

Dear CMS Desk Officer,

Thank you for the opportunity to submit comments regarding the home health Pre-Claim Review Demonstration project. I am an IT Professional in the Home Health and Hospice industry. I have served this industry for 21 years. One of the major problems in home health over the years I have served is over regulation without proper justification paired with decreased payment as this threatens the survival of these vital services. Not only to the patients we serve but to the healthcare system as a whole. Home Health, Hospice along with preventative care programs are the final link in the continuum of care. Without these services, there will be more hospital visits, more re-hospitalizations, more physician visits and more emergency care required.

With that said, this particular demonstration is another example of the government not listening to the home health and hospice industry and its patient population in regards to what will and will not work. There are so many regulations that in this case, many are overlapping and contradicting each other making it seem that the end goal is not to remove fraud but to simply put agencies across the board out of business.

Below is a list of statements that point out some of the contradictions and realities of implementing this "demonstration." I appreciate your consideration in repealing any proposed or current laws that put the pre-claim review process into effect based on the following points.

- While I support all efforts to prevent fraud and abuse in the home care industry, such efforts should target abusive providers and not decrease access to care for our most vulnerable population at home.
- One of the basis for this demonstration project is an increasing improper payment rate for home health claims. The 90% of errors due to insufficient documentation is evidence of unclear F2F documentation requirements. Despite CMS education while the F2F requirements evolved, undue confusion resulted for home care agencies.
- As currently proposed, this project conflicts with existing CMS regulation. Examples:
    - F2F documentation is not required until 30 days after the start of care. Because F2F is now required to be submitted with the PCR, the allowed 30-day timeframe will be effectively reduced.
    - Physician orders, including the Plan of Care, are currently required to be signed by the physician prior to the agency's submission of the End of Episode (EOE) claim. Because the POC must be signed prior to submitting a PCR, the timeline for obtaining physician signatures has significantly decreased.
- Despite an agency's best efforts to prepare for a PCR submission, external issues beyond their control (e.g. timely receipt of physician signatures) will further delay agency submission and subsequent response of an affirmed/non-affirmed decision.
- The proposed submission of a subsequent PCR for changes in plans of care during an episode effectively changes the PCR project to a prior authorization process. The only difference is the PCR process places financial liability on the home care agency while the prior authorization process delays and limits access to medically necessary home care services.

- This PCR project requires CMS to invest substantial resources into the procedures and personnel that is not an efficient or effective use of taxpayer dollars. This PCR project is not sufficiently targeted to the fraud or abuse of concern. It fails to distinguish between fraud and unintentional noncompliance with documentation requirements.
- Current state and federal anti-fraud enforcement agencies have the resources and have been successful in targeting fraud and abuse among specific home care agencies.
- While home care reimbursement is proposed to decrease yet again next year, agencies will incur additional costs to implement this project.
- This project results in additional administrative costs and operational burdens on home care agencies.
- While agencies strive to achieve higher quality care with increased efficiencies and less reimbursement, the added administrative costs of the pre-claim review process are an additional financial burden on home care agencies.
- This demonstration project unduly targets compliant agencies instead of targeting cities where known fraud exists.
- While I appreciate no delay in the provision of medically necessary care for Medicare beneficiaries, this project poses an undue financial burden on an agency who will not receive reimbursement for a non-affirmed PCR.
- Agencies will incur the cost for skilled services provided in the event a pre-claim review is non-affirmed.
- Agency requirements for this project are evolving and not fully defined.
- Medicare Administrative Contractors (MACs) are not ready for implementation of this project.
- While a non-affirmed PCR allows the opportunity for appeal, such appeals will further increase the catastrophic backlog of Medicare appeals pending review by an Administrative Law Judge (ALJ.)
- Although this is a demonstration project, Medicare Administrative Contractors (MACs) have not been allowed sufficient time to test the process. Similarly, home care vendors have not had time to update their software.
- This project causes potential for adverse consequences to Medicare beneficiaries due to the financial and administrative burden placed on the provider.
- This project is a potential for barrier to home care. Patients requiring high levels of care may be declined by home care agencies due to the financial risk of a non-affirmed PCR decision. Further, home care agencies will discharge Medicare beneficiaries from skilled services when a PCR is returned non-affirmed. Such barriers may result in increased hospital stays and increased re-hospitalizations.
- The cost to the federal government to reimburse MACs for this project is excessive. These same funds could be used more effectively in targeted review.
- MACs' pre-claim review of all episodes results in excessive volume with doubt that PCR requests will be processed on a timely basis.
- Without the development and distribution of clear guidelines for this project, the PCR affirmation is subject to the reviewer and/or the MAC's interpretation. We have learned from our experience with the F2F requirement, how easily misinterpretation results in denial.

- CMS currently performs targeted edits of home care agencies through Additional Documentation Requests (ADRs.) However, the PCR project essentially places all agencies on 100% pre-claim ADR review without proper cause.

Suggestions:

- I suggest CMS, in conjunction with the home care community, develop a less burdensome approach to fraud and abuse.
- Rather than using this project to remedy non-compliance with documentation requirements, I recommend CMS provide clarified and consistent standards with education to the home care community and MACs. (e.g. F2F)
- Because the home care agency provides medically necessary services in good faith of receiving reimbursement, I recommend CMS provide reimbursement for services provided until the date of the non-affirmed PCR decision. □ Rather than create this broad-spectrum project, I recommend CMS utilize data to identify high risk situations and target program integrity measures.
- Rather than targeting all agencies within the demonstration states, CMS should target specific agencies and/or cities where known fraud and abuse occur.

Thank you again for your consideration.

Thomas Rich

Parham, William N. (CMS/OSORA)

From: Keith Warren <warrenk1966@gmail.com>
Sent: Wednesday, July 20, 2016 5:17 PM
To: OS OIRA (HHS/OS); Keith Warren
Subject: Pre Claim Review Demo

Dear CMS Desk Officer,

Thank you for the opportunity to comment on the Pre-Claim Review Demonstration project.

I have grave concerns over this proposed legislation. It is one more major burden placed on the Home Health industry that will clearly reduce the number of agencies as they will have to close their businesses. I understand the need to eliminate the fraud taking place in home health and hospice but the increased scrutiny and red tape has impacted every agency, great or crooked. CMS should target those agencies suspected to be fraudulent or those with compliance issues rather than the entire industry.

Year after year, the industry has been hit with major changes affecting reimbursement for home health services and this is probably the final straw as the potential slowdown of cash payments will have dire consequences as agencies simply try to make payroll every week.

Home health is the answer to rising health care costs because it is simply the most inexpensive remedy to health problems facing this country much less the best option for the patient wanting to be seen at home and not in the hospital setting. Penalizing every agency in this way is just too much; the lives of some really great people from the patients to the field staff to the owners of small businesses will be jeopardized at the expense of those truly responsible for these type actions from CMS.

Thank you

Parham, William N. (CMS/OSORA)

From: Ryan Locklear <rymilo@gmail.com>
Sent: Thursday, July 21, 2016 4:48 PM
To: OS OIRA (HHS/OS)
Subject: Pre-Claim Review

Please don't do Pre-Claim review. It just adds expense to Home Health and slows done patient care. The industry is already hurting with the cut backs. As an employee at a Home Health I have not had a raise in years, and this might force my company to lay off workers or even me.
Thanks,
Ryan Locklear

Parham, William N. (CMS/OSORA)

From: Janice Douglas <janice@sanangelohomehealth.com>
Sent: Wednesday, July 20, 2016 10:21 AM
To: OS OIRA (HHS/OS)
Subject: Pre-claim review in Texas

I want to offer my opinion with 21 yrs experience in home care as my basis.

I oppose the proposed demonstration program entitled Medicare Program: Pre-Claim Review demonstration for Home Health Services.

We are an improved industry. Focusing on outcomes has transformed the care most agencies provide to be about results.
I know that we have raised the bar for our clinicians to not only improve their skills of identifying the hurdles that prevent the patient from being successful in the home, but also having them challenge patients to "get in the driver seat of their care". We have also focused on finding solutions when there are gaps in patient care. Sometimes it may be identifying that someone else needs to be setting up the patient's medications and/or administering their medications all the way to recommending that the patient needs to move to a higher level of care.
These are tough decisions for patient's and their families and many times it is stressful to be the messenger in these situations. But I have seen some tremendous success stories, success when the majority of seasoned clinicians thought it wasn't possible.

What an exciting time to be in this industry. We support CMS' mission to fight fraud and abuse. We are tired of competing for referrals with agencies that continually recertify patient's for their home health benefit under questionable grounds. I applaud CMS efforts to curb this mis-use of medicare dollars.

My concern is that CMS is not fully prepared to do a pre-claim review for every home health patient claim. There is no doubt that this process will add to our overhead cost. But my biggest concern is that the reviews will not be timely and the backlog will bring valid claim reimbursement to a stand still which would be the death of our agency.

I strongly urge you to reconsider this demonstration and take into account the many state and national association recommendations to improve this process while also protecting the patient's access to critically needed care.

--
Janice Douglas, RN
Director
>www.sanangelohomehealth.com<
423 South Irving, San Angelo, Texas 76903
(325) 655-6600 phone / (325) 655-6602 fax

Parham, William N. (CMS/OSORA)

From: Sharon Klimski <sklimski@yahoo.com>
Sent: Tuesday, July 19, 2016 1:40 PM
To: OS OIRA (HHS/OS)

Dear CMS Desk Officer,
Thank you for the opportunity to submit comments regarding the **home health Pre-Claim Review Demonstration** project. …

- While I support all efforts to prevent fraud and abuse in the home care industry, such efforts should target abusive providers and not decrease access to care for our most vulnerable population at home.
- Developing another layer of government bureaucracy is not an efficient or effective use of taxpayer dollars. This PCR project requires CMS to invest substantial resources into the procedures and personnel.

- Our taxpayer dollars could be better served with targeted fraud and abuse rather than sweeping burdens placed on all agencies.
- This PCR project is not sufficiently targeted to the fraud or abuse of concern. It fails to distinguish between fraud and unintentional noncompliance with documentation requirements.

- Current state and federal anti-fraud enforcement agencies have the resources and have been successful in targeting fraud and abuse among specific home care agencies.

- While home care reimbursement is proposed to decrease next year, agencies will incur additional costs to implement this project.
- This project results in additional administrative costs and operational burdens on home care agencies.
- While agencies strive to achieve higher quality care with increased efficiencies and less reimbursement, the added administrative costs of the pre-claim review process are an additional financial burden on home care agencies.
- Rather than targeting all agencies within the demonstration states, CMS should target specific agencies and/or cities where known fraud and abuse occur.

- This demonstration project unduly targets compliant agencies instead of targeting cities where known fraud exists.
- While I appreciate no delay in the provision of medically necessary care for Medicare beneficiaries, this project poses an undue financial burden on an agency who will not receive reimbursement for a non-affirmed PCR.
- Agencies will incur the cost for skilled services provided in the event a pre-claim review is non-affirmed.
- Agency requirements for this project are evolving and not fully defined.
- Medicare Administrative Contractors (MACs) are not ready for implementation of this project.
- While a non-affirmed PCR allows the opportunity for appeal, such appeals will further increase the catastrophic backlog of Medicare appeals pending review by an Administrative Law Judge (ALJ.)
- Although this is a demonstration project, Medicare Administrative Contractors (MACs) have not been allowed sufficient time to test the process. Similarly, home care vendors have not had time to update their software.
- This project causes potential for adverse consequences to Medicare beneficiaries.
- This project is a potential for barrier to home care. Patients requiring high levels of care may be declined by home care agencies due to the financial risk of a non-affirmed PCR decision. Further, home care agencies will discharge Medicare beneficiaries from skilled services when a PCR is returned non-affirmed. Such barriers may result in increased hospital stays and increased re-hospitalizations.
- The cost to the federal government to reimburse MACs for this project is excessive. These same funds could be used more effectively in targeted review.
- MACs' pre-claim review of all episodes results in excessive volume with doubt that PCR requests will be processed on a timely basis.
- Without the development and distribution of clear guidelines for this project, the PCR affirmation is subject to the reviewer and/or the MAC's interpretation. We have learned from our experience with the F2F requirement, how easily misinterpretation results in denial.
- CMS currently performs targeted edits of home care agencies through Additional Documentation Requests (ADRs.) However, this project essentially places all agencies on 100% pre-claim ADR review without proper cause.
- One of the basis for this demonstration project is an increasing improper payment rate for home health claims. The 90% of errors due to insufficient documentation is evidence of unclear F2F documentation requirements. Despite CMS education while the F2F requirements evolved, undue confusion resulted for home care agencies.
- As currently proposed, this project conflicts with existing CMS regulation. Examples:
    - F2F documentation is not required until 30 days after the start of care. Because F2F is now required to be submitted with the PCR, the allowed 30-day timeframe will be effectively reduced.
    - Physician orders, including the Plan of Care, are currently required to be signed by the physician prior to the agency's submission of the End of Episode (EOE) claim. Because the POC must be signed prior to submitting a PCR, the timeline for obtaining physician signatures has significantly decreased.

- Despite an agency's best efforts to prepare for a PCR submission, external issues beyond their control (e.g. timely receipt of physician signatures) will further delay agency submission and subsequent response of an affirmed/non-affirmed decision.

- The proposed submission of a subsequent PCR for changes in plans of care during an episode effectively changes the PCR project to a prior authorization process. The only difference is the PCR

process places financial liability on the home care agency while the prior authorization process delays and limits access to medically necessary home care services.

Suggestions:

- I suggest CMS, in conjunction with the home care community, develop a less burdensome approach to fraud and abuse.
- Rather than using this project to remedy non-compliance with documentation requirements, I recommend CMS provide clarified and consistent standards with education to the home care community and MACs. (e.g. F2F)
- Because the home care agency provides medically necessary services in good faith of receiving reimbursement, I recommend CMS provide reimbursement for services provided until the date of the non-affirmed PCR decision.

Rather than create this broad-spectrum project, I recommend CMS utilize data to identify high risk situations and target program integrity measures.

Thank you,
Sharon Klimski

Texas Association for Home Care & Hospice
Leading ★ Advancing ★ Advocating

CMS-6069-N Medicare Program
81 FR 37598
Document # 2016-13755
Pre-Claim Review Demonstration

Medicare Program: FY 2017 Hospice Wage Index and Payment Rate Update and Hospice Quality Report Requirements

Comments submitted by Molly Tomlin, Director of Clinical Practice and Regulatory Affairs
Texas Association for Home Care and Hospice

July 21, 2016

The Texas Association for Home Care and Hospice ("TAHC&H") represents over 1300 licensed home and community support services agencies across the state of Texas and appreciates the opportunity to submit comments on the proposed demonstration program entitled Medicare Program: Pre-Claim Review demonstration for Home Health Services.

We are writing as the provider association for one of the five states chosen for this demonstration that combined represents almost one million Medicare beneficiary claims. Please also note the attached letter from those five states that seeks additional clarity for several outstanding issues. We would appreciate Centers for Medicare and Medicaid's ("CMS") input and response to that letter as well (*see attached*).

We urge CMS to halt the demonstration in Illinois and delay it in Florida, Texas, Michigan, and Massachusetts, until CMS provides appropriate clarity on the documentation requirements and stakeholders have sufficient time to prepare for this additional administrative burden **in order to avoid any disruptions to patients attempting to access home health services.**

We have participated in all of the Open Door Forums on this demonstration and since the announcement the regulatory requirements and responsibilities for stakeholders continue to change.

For example when the demonstration was first introduced, agencies were told the Pre-Claim Review (PCR) could be submitted prior to receiving the physician's signature on the Face-to-Face Document and the Plan of Care, however agencies are now being told that the signature will be required. Currently the signature of the physician is only required on these documents prior to the final claim billing. This places an undue burden on the agencies to secure the physician's signature quickly enough to send in the PCR, get it approved, and then submit the billing. In order to minimize their financial risk, providers will be forced to

discharge patients early, or delay care until such time that they receive the paperwork needed to obtain an affirmation.

In addition, the contractors and CMS continue to offer conflicting information as to what paperwork is necessary to determine a patient's eligibility and have not offered clarification to the many provider questions that are essential to successful completion of the pre-claim review process.

We are most concerned about the potential impact of this demonstration on **access to critically needed care**. Requiring a PCR for every home health patient claim across our five states for vital clinical services that keep people in their homes rather than costly institutions, often when they are at their most medically vulnerable state, is a fundamental shift in care and needs to be fully developed and thought out. From the information provided to-date, we are not confident that CMS, our providers or the Medicare beneficiaries are prepared for such a demonstration. As CMS is aware, under this demonstration project CMS would have to review more than 900,000 claims each year. Furthermore, the revisions to the demonstrations that change it to pre-claim review, would allow for "unlimited re-submissions" by providers. This could potentially increase the number of claim reviews to well over 1.5 to 2 million claims once the program is fully implemented.

Currently CMS and CMS staff review approximately 25,000 claims annually. We have still been offered no clarity on how CMS has the resources or capacity to accomplish this task and simply cannot afford the continuing burden of delayed and unpaid claims that were properly submitted to Medicare contractors, but were denied for trivial matters.

The home health industry has a responsibility to be a good steward of the Medicare program and collectively, we support CMS' mission to fight fraud and abuse within our sector. The demonstration as proposed would add an increased administrative burden **(which the industry believes is grossly underestimated by CMS)** on both physicians and home health agencies, while likely adding little value for identifying and preventing fraud. **The proposal, ostensibly designed to curb waste, fraud and abuse, punishes home health agencies that do not have a history of fraud because it fails to differentiate between agencies with a questionable record and those that show a long history of compliance.**

The CERT error rate is cited as the basis for this demonstration. The CERT error rate in home health is predominately due to documentation disputes concerning the F2F narrative requirement that existed prior to 2015. To the extent that there remain documentation issues with F2F, PCR will not address any perceived deficiencies for the following reasons:

i. CMS is in the initial stages of the Probe and Educate audits that continues to show a high rate of error primarily related to the F2F documentation. That translates to the reality that both Medicare and HHAs are yet to be in sync with what constitutes compliant documentation.

The areas of actual fraud that have been uncovered in home health are highly limited and do not lend themselves to correction through PCR. For example, the vast majority of fraud convictions involve billings for phantom patients and referral kickbacks. Neither of these can be addressed through PCR. In fact, phantom patient billings could easily pass PCR as the fraudsters can perfect the documentation to succeed since they are not bound by real facts.

With claim documentation as the key area of alleged noncompliance, education, clear compliance standards, and provider support are better tools to employ as the vast majority of HHAs are bona fide Medicare providers.

Another equally concerning issue that will involve the Pre-Claim Reviews is the agencies that are affected by the Comprehensive Care for Joint Replacement demo. The whole premise of this demo is to get these patients out of the hospital quicker, into home health and then discharged independent in their home environment. With the Pre-Claim Reviews pending, agencies will be reluctant to accept these patients until which time they can be assured that they will be reimbursed for the care they deliver. Once home there must be some assurance that the Pre-Claim Reviews on these patients will be approved quickly or the patients will likely end up back in the hospital, as the home health agencies will have little recourse if they cannot get paid for the care they are to deliver. The program is designed around efficiencies which will likely be impeded by the PCR demo. Agencies deserve to receive direction on this issue before the PCR demo is allowed to progress further.

Finally, an across-the-board pre-claim review program is an additional procedural step that will raise administrative cost with little or no proven return. From our interactions with stakeholders and CMS the demonstration in its current form is not manageable or realistic and we respectfully request that CMS halt the demonstration in Illinois and postpone the others until there are appropriate assurances that the demonstration effectively targets fraud and avoids risks to patients needing access to home health services.

To the extent that PCR moves forward for home health it must:

- Be limited only to the documentation that is truly needed to determine eligibility and capable of a very quick turnaround. Continued back and forth between the contractor and the provider in attempts to obtain a pre-claim affirmation will result in early discharges of patients, increased re-hospitalizations and unsustainable financial losses for providers.

- Be targeted and time limited. Targeted toward providers that have high indicators of Fraud and Abuse and time limited when providers demonstrate consistent compliance with pre-claim review requirements.

Thank you again for providing us the opportunity to provide our Association's comments on the Pre-Claim Review demonstration. If you have any questions feel free to contact me at 512-338-9293.

Sincerely,

Molly Tomlin RN CLNC

Molly Tomlin, RN, CLNC
Director of Clinical Practice and Regulatory Affairs
Texas Association for Homecare & Hospice

June 28, 2016

Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
Room 120F
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Room 310G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Pre-Claim Review Demonstration of Home Health Services (CMS-6069-N)

Dear Secretary Burwell and Acting Administrator Slavitt:

We are writing as representatives of the almost one million Medicare beneficiary claims and Medicare providers in the states affected by the Centers for Medicare and Medicaid Services (CMS) mandatory pre-claim review demonstration for home health services. Our organizations provided stakeholder input when the demonstration was first announced as a "prior authorization

demonstration" and participated in the recent open door forum hosted by CMS. We appreciate the agency's willingness to take the time to answer questions from the home health sector; however there were many questions left unanswered and there is still significant concern by our collective membership on the effects this could have on continuity of care for the Medicare beneficiaries we serve. Waiting until the program rolls out to see what happens is just not an appropriate approach when Medicare Beneficiary's care is at stake.

We urge CMS to delay the demonstration until CMS provides appropriate clarity on the documentation requirements and stakeholders have sufficient time to prepare for this additional administrative burden in order to avoid any disruptions to patients attempting to access home health services. For instance, CMS states the "operational instructions will be available in a few weeks." The first roll out is in less than six weeks. That gives agencies and the MAC barely three weeks to implement an entirely new program.

As your agency correctly stated "Home Health Agency (HHA) services are a critical part of the health care continuum and are instrumental in helping a patient with Medicare benefits recover after an illness or injury. The Medicare home health benefit allows beneficiaries who are deemed homebound to receive certain medically necessary services in their homes, which is a preferred setting for many beneficiaries." We agree and could not have stated it better.

We are most concerned about the potential impact of this demonstration on access to that critically needed care. Requiring pre-claim review for every home health patient claim across our five states for vital clinical services that keep people in their homes rather than costly institutions, often when they are at their most medically vulnerable, is a fundamental shift in care and needs to be fully developed and thought out. From the information provided to-date, we are not confident that CMS, our providers or the Medicare beneficiaries are prepared for such demonstration. As CMS is aware, under this demonstration project CMS would have to review more than 900,000 claims each year. Furthermore, the revisions to the demonstration that change it to pre-claim review, would allow for "unlimited re-submissions" by providers. This could potentially increase the number of claim reviews to well over 1.5 to 2 million once the program is fully implemented.

Currently CMS and CMS staff review approximately 25,000 (need footnote here). We have still been offered no clarity on how CMS has the resources or capacity and we simply cannot afford the continuing burden of delayed and unpaid claims that were properly submitted to Medicare contractors, but were denied for trivial matters.

The home health industry has a responsibility to be a good steward of the Medicare program and collectively, we support CMS' mission to fight fraud and abuse within our sector. The demonstration as proposed would add an increased administrative burden on both physicians and home health agencies, while likely adding little value for identifying and preventing fraud. The proposal, ostensibly designed to curb waste fraud and abuse, punishes home health agencies that do not have a history of fraud because it fails to differentiate between agencies with a questionable record and those that show a long history of compliance.

Additionally, we are concerned about the authority CMS is using to pursue the demonstration. The pre-claim review demonstration will affect every Medicare claim in our states, yet home

health agencies have not been granted the privilege of providing feedback on such a fundamental change. We believe the Paperwork Reduction Act Notice is an insufficient basis for promulgating such a wide-reaching program. A full notice and comment rulemaking process, allowing stakeholders to comment with specificity on the details of a proposed demonstration project should be required.

Because the agency failed to undertake a formal rulemaking process in announcing this initiative we perceive that our provider Members, Members of Congress and other stakeholders did not have an adequate opportunity to provide CMS with information on how this would affect home health services for Medicare beneficiaries. While we do recognize and appreciate some accommodations have been made since the agency's first announcement, we still believe CMS should review and consider comments on this newest proposal from the interested and affected stakeholders (*see attached*).

Finally, an across-the-board pre-claim review program is an additional procedural step that will raise administrative costs with little or no proven return. From our interactions with stakeholders and CMS the demonstration in its current form is not manageable or realistic and we respectfully request that CMS delay any implementation until there is adequate and the appropriate assurances that the demonstration effectively targets fraud and avoids risks to patients needing access to home health services.

Sincerely,

Texas Association for Home Care & Hospice

Home Care Alliance of Massachusetts

Home Care Association of Florida

Michigan HomeCare & Hospice Association

Illinois HomeCare & Hospice Council

VNAA
Visiting Nurse Associations of America

VIA E-MAIL: OIRA_submission@omb.eop.gov

July 21, 2016

Attention: CMS Desk Officer
Office of Management and Budget (OMB)
Office of Information and Regulatory Affairs
725 17th Street, NW
Washington, DC 20503

RE: Agency Information Collection Activities: Submission for OMB Review; Comment Request (OMB Control Number: 0938-NEW)

To Whom It May Concern:

Visiting Nurse Associations of America (VNAA) appreciates the opportunity to comment on the Notice entitled *Agency Information Collection Activities: Submission for OMB Review; Comment Request* (the "Notice") 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)).[1] VNAA advances quality, value and innovation in home-based care and represents mission-driven providers of home and community-based health care, including hospice, across the United States.

VNAA continues to be greatly concerned and frustrated with the impending Pre-Claim Review Demonstration for Home Health Services. The changes from the Prior Authorization Demonstration for Home Health Services and the newly dubbed Pre-Claim Review Demonstration for Home Health Services are cosmetic, at best, and not of true substantive value. At its core, these changes grant ability for home health agencies to comply with the Conditions of Participation and begin care prior to Pre-Claim approval while remaining at risk of being denied payment as a result of poorly-implemented and inconsistently applied documentation requirements.

The Paperwork Reduction Act (PRA) notice used to implement the Pre-Claim Review demonstration notes as the justification for the demonstration "extensive evidence of fraud and abuse in the Medicare home health program, in particular, in the chosen demonstration states." VNAA supports a wide range of policies to combat waste, fraud and abuse, and our members are committed to improving the integrity of the Medicare home health program. VNAA has strongly endorsed home health moratoriums, outlier caps and other data-driven tools that are effective at stemming fraud in a targeted and direct

[1] CMS, *Agency Information Collection Activities: Submission for OMB Review; Comment Request*, 81 Fed. Reg. 40308 (June 21, 2016).

manner. The HHS Office of the Inspector General recently identified five key characteristics for home health fraud[2]:

- High percentage of episodes for which the beneficiary had no recent visits with the supervising physician
- High percentage of episodes that were not preceded by a hospital or nursing home stay
- High percentage of episodes with a primary diagnosis of diabetes or hypertension
- High percentage of beneficiaries with claims from multiple home health agencies (HHAs)
- High percentage of beneficiaries with multiple home health readmissions in a short period of time

Despite these clear and appropriate characteristics of fraudulent activity, Dr. Shantanu Agrawal, Deputy Administrator and Director of the CMS' Medicare Integrity Program Office, stated in his May 24, 2016 testimony before the U.S. House of Representatives Committee on Energy and Commerce that the majority of the 59 percent of improper payments were because of *poor or incomplete documentation*[3]. In the year prior to the start of Face-to-Face, the improper payment rate for home health care was about 17.3 percent for 2013 and following the implementation of Face-to-Face; 51.4 percent in 2014 and 59 percent in 2015.[4].

The Pre-Claim Review Demonstration is a blunt policy instrument that targets all providers and puts a disproportionate burden on good actors. At the same time, nothing in the Pre-Claim process will stop bad actors from submitting falsified claims; Pre-Claim programs have no mechanism to identify these bad actors. Ultimately, this demonstration will add little additional value in preventing fraud but will certainly result in improperly delayed or denied payments to agencies while giving CMS the ability to claim even higher numbers of "improper payments" due to "incomplete documentation."

The Pre-Claim Review Demonstration is slated to begin in Illinois on August 1, 2016. As a result of this tight timeline for implementation, , VNAA urgently requests that CMS quickly develop, clarify, implement and oversee responses to the following in the form of publicly posted Frequently Asked Questions and official guidance documents to providers, physicians and, most importantly, Medicare Administrative Contractors.

- Will there be opportunities for adjustments to the Pre-Claim review and documentation process, and if so, when?
- How will CMS ensure general accountability of the Medicare Administrative Contractors (MACs) and provide satisfactory oversight to ensure consistency in application of requirements?
- When a MAC reviews a pre-claim submission, will it indicate all areas from the submission that do not meet "acceptance" or will there be multiple submissions for each pre-claim?

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[2] Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases, 6/21/16, https://oig.hhs.gov/oei/reports/oei-05-16-00031.asp

[3] Dr. Shantanu Agrawal 5/24/2016 U.S. House Energy and Commerce testimony quote "One area in Medicare fee-for-service on which we are focusing our efforts is in home health services, which have had particularly high improper payment rates in recent years, mainly due to documentation errors."

[4] Health and Human Services Supplementary Appendices for the Medicare Fee-for-Service Improper Payment Rate Report (2013, 2014 and 2015 editions)

- What level of re-education will be conducted for the MACs? When will this education commence?
- What level of education will be done for physicians? When will this education commence?
- Will MACs have required response times to home health agencies that will vary by method of submission (e.g., on-line portal, fax, electronic submission of medical documentation (esMD), etc?)
- Will CMS provide electronic forms for use by referring physicians and receiving home health agencies to simplify the Pre-claim documentation process?
- Will home health agencies have the opportunity to be "whitelisted" or "provisionally approved" when they show compliance with Pre-claim documentation for a consistent and defined time period?"

VNAA will continue to offer to its support and expertise in developing processes and procedures that will reduce the documentation errors that are at the heart of improper payments, as well as, ways to combat waste, fraud and abuse while protecting patient access to quality home health care. Please contact Joy Cameron, Vice President of Policy and Innovation at jcameron@vnaa.org or 571-527-7536 with any questions or concerns.

Sincerely,

Joy Cameron
Vice President, Policy and Innovation