



July 22, 2018

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Attn: CMS-10599
Hubert Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Submitted electronically to www.regulations.gov

**RE: Agency Information Collection Activities; Proposed Collection; Comment Request:
CMS-10599: Pre-Claim Review Demonstration for Home Health Services**

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), we are pleased to submit the following comments in response to CMS request for comments regarding “Pre-Claim Review Demonstration for Home Health Services”. The Alliance is a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose mission is to promote evidence-based quality care and access to products and services for people with chronic wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Many of our members provide wound care in the home health setting and therefore we have a vested interest in this demonstration. These comments were written with the advice and guidance of our clinical member associations and physician societies which are listed on our website: <http://www.woundcarestakeholders.org/about/members>

The Alliance has these significant concerns with the resurrection of the claim review for this home health service demonstration project:

1. CMS’s lack of transparency on this issue as well as the process by which the Agency will move forward with this demonstration.
2. This demonstration will create an administrative burden on home health agencies since they will need to hire additional staff in order to keep up with all the paperwork/documentation requirements.
3. It will have a tremendous negative impact on the access to care for beneficiaries in order for CMS to target a few bad apples.

Due to these concerns, we recommend that CMS withdraw this demonstration project altogether until more detailed information is provided.

SPECIFIC COMMENTS

While CMS indicates that the rationale for bringing this failed demonstration project back is to address issues of fraud and abuse, the Alliance highly recommends that CMS should utilize the data it already has on hand to target specific types of fraud and abuse as well as high risk providers. In addition, we recommend that the Agency allocate time and resources to target specific home health agencies whose behavior indicates that there may be fraudulent activity rather than overburdening and penalizing home health agencies that have no record of fraud and abuse and have established records of compliance with existing regulations.

CMS's lack of transparency on this issue is also quite alarming given the failed first attempt of this demonstration. This notice provides little detail regarding: how this demonstration will be rolled out; creation of an impact analysis regarding the administrative cost to providers; problems the demonstration project will create regarding access and disruption of care for patients, and CMS's timelines in processing the pre and post payment audits/review.

For example, while CMS notes in the proposal that a home health agency may be exempted from the review process after it attains a "target" pre-claim review affirmation or post-payment review claim approval rate, the Agency does not elaborate as to what this "target" number might be. CMS further does not provide any details regarding the timeliness of reimbursement for providers, the timeframe by which CMS will be required to issue a pre-review determination or the guidelines it will use to make the determinations. All of this information should have been provided in a proposed document affording the public the right to provide comments on these guidelines.

Furthermore, CMS has not been transparent in its policy-making efforts. Given the failed attempt with the original demonstration project, (which began in August 2016 but was paused in April 2017 after policymakers and industry groups decried the program, citing administrative burdens and patient access issues) stakeholders are justified being concerned with this demonstration as no additional information has been released to ensure that significant changes were made to the implementation and administration of the program. While we appreciate that the Agency would offer 100% post claim review as an "alternative" to 100% pre claim review, this still is not a significant change and CMS has not provided the clear and specific guidance necessary to roll out this demonstration project.

As such, we request that until more detailed information is provided, CMS withdraw this demonstration project altogether. CMS has not provided any additional detailed information

regarding how this demonstration will be rolled roll out causing significant concerns given the failed first attempt. The lack of transparency is alarming. The Alliance recommends that CMS reach out to stakeholders for some suggestions in how to address the perceived fraud and abuse issues as well as suggestions to roll out a limited demonstration project.

The Alliance appreciates the opportunity to provide CMS with our comments. We are hopeful that CMS will withdraw this demonstration and instead using the data it has to target the questionable home health agencies rather than subjecting all home health agencies to yet another burdensome process and impacting patient care and access along the way.

Sincerely,

A handwritten signature in black ink that reads "Marcia Nusgart R.Ph." in a cursive script.

Marcia Nusgart R.Ph.
Executive Director