COALITION OF

Wound Care Manufacturers

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:

The Coalition of Wound Care Manufacturers ("Coalition") is submitting the following comments in response to the CY 2019 Interim Final Rule regarding DME. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including but not limited to Negative Pressure Wound Therapy and surgical dressings.

The Coalition urges CMS to withdraw this policy. As you may recall, Congress urged CMS to suspend the original demonstration citing administrative burdens and patient access issues. In the letter to CMS, Congress stated, "This demonstration project imposes costs on patients, providers, and taxpayers. Delaying patient care while waiting for CMS to approve home health services may put patient health in jeopardy and cause patients to stay in the hospital longer than necessary." CMS has done little to allay industry concerns as there are few details surrounding the operations of this demonstration project. Moreover, we have grave concerns regarding the lack of transparency that CMS has exhibited regarding this project.

This notice provides little detail regarding:

- Timeline for implementation of this demonstration
- Creation of an impact analysis regarding the administrative costs to providers

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- Problems the demonstration project will create regarding access and disruption of care for patients

- CMS's timelines in processing the pre and post payment audits/review

- Details regarding the timeliness of reimbursement for providers

- 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 meaningful comments.

While it appears that CMS is trying to curb what it perceives is fraud and abuse in the home health sector, CMS should simply utilize data and resources it already has on hand to target specific types home health agencies whose behavior indicates that there may be fraudulent activity rather than implement a wide spread demonstration project which will overburden and penalize home health agencies that have no record or patterns of fraud and abuse.

While we appreciate that the Agency will 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 implemented causing significant concerns given the failed first attempt. The Coalition recommends that CMS reach out to stakeholders with vested interest in this issues such as home health agency associations (e.g., Elevating HOME, NAHC) as well as ourselves for some suggestions in how to address the perceived fraud and abuse issues as well as recommendations on how to implement a limited demonstration project.

The Coalition appreciates the opportunity to provide CMS with our comments. We recommend that CMS will withdraw this demonstration and instead use the data it has to target 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,

Karen Ravitz, JD
Health Care Policy Advisor