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.

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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