



April 5, 2016

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number CMS-10599
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS-10599, Medicare Prior Authorization of Home Health Services
Demonstration

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 prior authorization of home health services demonstration, 81 Fed. Reg. 6275 (Feb. 5, 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 appreciates the opportunity to provide comments in the following topic areas on the Federal Register notice and the related Supporting Statement proposed Medicare prior authorization for home health services demonstration: (I) barrier to access and quality of care; (II) barrier to achieving efficiency in alternative payment models; (III) burden for providers and the government; (IV) legal authority; and (V) using targeted means of addressing fraud, waste and abuse.

I. Barrier to Access and Quality of Care

The proposed prior authorization demonstration for home health services would present a barrier to access and quality of care for patients, and considerable delays as a result of administrative infeasibility.

First, if a prior authorization process were applied to home health services, the process and associated timeframe would be a barrier to achieving quality of care goals. CMS states that its prior authorization process for home health services would be modeled after the process for power mobility devices, which requires 10 days to process the prior authorization, and requires an additional 10 days to process any appeals. This timeline is unreasonable and inappropriate for home health services because the delay threatens to diminish the quality of care that is delivered, running counter to evidence-based practice standards. Particularly for Part A home health services, which are for post-acute care, the prompt delivery of care in the home is critical to avoid unnecessary rehospitalization. There is considerable peer-reviewed literature to support the need for a prompt home visit to support the patient's care transition from hospital to home.¹ It is a core tenet of the major care transitions and readmission reduction models to ensure that a home visit is provided within 24 to 72 hours of discharge from the hospital. Delaying the ability to deliver home health care within this timeframe will result in care that is inconsistent with well-recognized best practices that are essential to providing quality care.

Furthermore, delayed care will result in poor outcomes and unnecessary hospitalizations that will in turn drive overall health system costs up. Providers nationwide are pursuing the CMS-endorsed goal of achieving the Triple Aim of improved patient experience, improved population health and lower per capita cost of care. Delivering home health care promptly and consistent with the evidence-based models for care transitions can lower per capita cost of care by supporting avoidance of costly readmissions. Without the ability to deliver home health care promptly, efforts to achieve the Triple Aim are undermined and both quality and cost-related goals will be jeopardized.

Second, a prior authorization process for home health services would hinder the ability of home health providers to meet the timely initiation of care requirements in the Medicare program's home health conditions of participation, as well as CMS's performance measure for timely initiation of care. Medicare certified home health agencies are required in the conditions of participation to conduct the initial

¹ Naylor MD, and Sochalski JA. (2010). Scaling Up: Bringing the Transitional Care Model into the Mainstream. The Commonwealth Fund, Issue Brief, November 2010. PMID: 21053533, at 5 (http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2010/Nov/1453_Naylor_scaling_up_bringing_transitional_care_model_mainstream_ib_v2.pdf). See also <http://www.transitionalcare.info/publications>; and <http://caretransitions.org/evidence-and-adoption/>

assessment visit “either within 48 hours of referral, or within 48 hours of the patient’s return home, or on the physician-ordered start of care date.”² A prior authorization process modeled after the power mobility process would delay care for as long as 10 to 20 days, directly counter to CMS’s own regulation.

In addition, CMS created a home health performance measure for timely initiation of care that measures the “percentage of home health episodes of care in which the start or resumption of care date was either on the physician-specified date or within 2 days of the referral date or inpatient discharge date whichever is later.” This NQF endorsed measure has also been included on the Home Health Compare website. Thus, a prior authorization process for home health care would be inconsistent with CMS’s own measure of quality in home health care.

Third, home health care services are completely different in nature as compared to power mobility devices and 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.³ 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 prior authorization 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 prior authorization process for home health care, therefore, would be time-consuming for the Medicare program or its contractors to implement (even more lengthy than the one used for power mobility devices), and would lead to protracted delays in needed care. Prior authorization as applied to home health services is therefore not appropriate or feasible from a practical and administrative standpoint.

Finally, the proposed prior authorization process raises the question of how such a process would occur in relation to the face-to-face encounter requirement. Whereas the prior authorization process as envisioned would take place ideally before any services are rendered, the face-to-face encounter is not required to take place until 30 days after the start of care. To the extent that the CERT error rate is due to issues with documentation that stem from the face-to-face requirement, a prior authorization process would be an ineffective means of addressing such errors.

² Medicare home health condition of participation, 42 C.F.R. § 484.55(a)

³ 42 U.S.C. § 1395n(a)(2)(A)(ii).

II. Barrier to Achieving Efficiency in Alternative Payment Models

Prior authorization for home health services would also hinder the efforts of organizations seeking to achieve the Triple Aim and efficiencies in key models and programs that are being tested by the Center for Medicare and Medicaid Innovation (CMMI), such as bundled payment arrangements, accountable care organizations, and the Independence at Home demonstration. In many of the sites where such alternative payment models are being pursued, the participating organizations are leveraging home health care as a means of achieving success in these models.

To this point, the first year evaluation of the CMS Bundled Payments for Care Improvement (BPCI) Initiative by The Lewin Group specifically identified use of home health care as a key strategy to lower the overall cost of care in BPCI episodes. The evaluation report states that “[l]owering the cost of care may involve substituting more intensive with less intensive services (for example, using home health care rather than skilled nursing care).”⁴ As a reflection of this strategy, in BPCI SNF initiated episodes, overall unadjusted average Medicare payments were lower compared to comparison groups (\$11,311 vs. \$16,896), but “[a]verage Part A payments for home health agency services increased significantly more from baseline to intervention for BPCI patients relative to comparison group patients during the 90-day post-discharge period.”⁵ In other words, BPCI participants are using more home health services because home health services are a less intensive, lower cost alternative to facility-based Part A services in post-acute care. At end of the first year of BPCI, these aspects were translating into overall episode cost reduction. CMMI officials also recently published a viewpoint in the *Journal of the American Medical Association (JAMA)* on “Medicare’s New Bundled Payments: Design, Strategy, and Evolution” and pointed to the use of home health care in this manner, stating that:

Preliminary evidence from the earliest participants in the [BPCI] model encompassing the hospitalization and postacute period suggests that more costly institutional postacute care was substituted with less costly home health care and that hospital length of stay and 30-day readmission rates decreased.⁶

In practice, a delay of 10 days to await prior authorization for home health services would either require the patient to stay in the short-term acute care hospital for 10-20 days (pending prior authorization approval) or to send the patient instead to a facility-based setting that would be more costly. Sending patients who could be sent home with

⁴ The Lewin Group, “CMS Bundled Payments for Care Improvement (BPCI) Initiative Models 2-4: Year 1 Evaluation & Monitoring Annual Report,” Prepared for CMS (February 2015) (<https://innovation.cms.gov/Files/reports/BPCI-EvalRpt1.pdf>), at 17.

⁵ *Id.* at 8.

⁶ M.J. Press, R. Rajkumar, P.H. Conway, “Medicare’s New Bundled Payments: Design, Strategy and Evolution,” Vol. 315 no. 2 *Journal of the American Medical Association* at 131 (Jan. 12, 2016).

home health care to a facility based setting runs contrary to the goals of the Triple Aim and overall need to shift more care, as clinically appropriate, towards the community and the home as they are less restrictive and more cost effective settings.

III. Considerable Burden for Providers and the Government

The estimated burden on home health providers of a prior authorization 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 prior authorization process given that most agencies will need to hire additional administrative staff to submit and manage prior authorizations. The work associated with the prior authorization 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 prior authorization 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 four or five times CMS's estimate for provider burden.

Moreover, CMS estimates that Medicare contractors will spend approximately \$294.4 million to implement a prior authorization demonstration for home health services in the five states, with an addition \$267,000 in cost to make systems changes. The government cost associated with implementing a prior authorization demonstration is high given that it is unclear what kind of savings will be gleaned. Better estimates of the costs that would be avoided, taking into consideration overall system cost that would be incurred due to delays in needed treatment, must be analyzed to assess whether the high administrative cost associated with the prior authorization program can be justified.⁷

⁷ To that end, CMS cited in the supporting statement FY 2014 data on CERT reported improper payment rates, stating that 90% of these improper payments relate to insufficient documentation errors. In FY 2014, such improper payments largely involved issues with documentation of the face-to-face encounter requirement. As stated in these comments in Section I *supra*, the face-to-face encounter can occur as late as 30 days after the start of care, and thus the timing of a prior authorization process will not address issues with the face-to-face requirement. Moreover, CMS in 2015 resolved key issues with the face-to-face requirement through elimination of the narrative requirement in its annual HHPPS rulemaking.

IV. Legal Authority

The Paperwork Reduction Act notice and the accompanying Supporting Statement describe CMS' plans to pursue a demonstration project that would require prior authorization 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 prior authorization 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 prior authorization in advance of Medicare home health services.⁸ There is also no specific statutory provision to authorize conduct of a demonstration project on prior authorization 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 prior authorization 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 prior authorization 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 prior authorization 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 prior authorization as a means to "identify" those who may have been submitting fraudulent claims before implementing the prior authorization 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.

⁸ See 42 U.S.C. § 1395f(a)(2)(C).

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 prior authorization 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 prior authorization 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.

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

Rather than developing a prior authorization 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,

/s/
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Executive Director

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