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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

Submitted via www.regulations.gov .

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

81 Fed. Reg. 6275 (Feb. 5, 2016).

To whom it may concern:

The National Association for Home Care & Hospice (NAHC) is the largest trade association in the country representing home health care agencies. NAHC members represent the entire

spectrum of home care agencies, including Visiting Nurse Associations, government-based agencies, multi-state corporate organizations, health system affiliated providers, and freestanding, proprietary home health agencies. NAHC members serve over several million Medicare home health care beneficiaries each year. NAHC members are significant stakeholders in Medicare and Medicaid, particularly Medicare home health services.

We appreciate the opportunity to submit comments regarding the above-entitled proposed rule. NAHC has spearheaded efforts to improve program integrity in the Medicare home health benefit for many years with innovative and successful policy and operations reforms. NAHC maintains a Code of Conduct as part of its membership standards that requires the highest level of compliance with program requirements. It is in this spirit that we offer the following comments on the proposal to institute a system of "prior authorization" on all home health services in five states.

A. Program Integrity Measures Should Meet Standards of Reasonableness

As part of our comments, we submit that any program integrity measure should be evaluated against a comprehensive set of guiding principles to ensure that the measure does not create more harm than good. Those evaluation principles should achieve effectiveness while avoiding unnecessary costs and burdens. Not all program integrity measures are effective or necessary, no matter how well intentioned. Also, while program integrity is a high priority in Medicare, some measures can bring significant adverse consequences to beneficiaries, compliant providers, and the Medicare program itself. To achieve the best results from program integrity efforts, any measure should be evaluated under the following principles:

1. The program integrity measure must be best targeted to the fraud, waste, and abuse of concern.

A random, untargeted program integrity measures can bring harm to Medicare beneficiaries and all other stakeholders. For example, a measure could raise barriers to access to timely care for beneficiaries duly entitled to coverage. Likewise, Medicare providers can be forced to incur unnecessary costs to comply with a new rule and respond to a new integrity effort when a broad-based action is taken to address the abusive, but isolated conduct of a few providers.

2. **Program integrity measures should be evidence-based with a demonstrated return on investment.**

Return on Investment (ROI) is at the core of any sensible action. For example, it is bad policy to spend a billion dollars to gain a return of a million dollars. An ROI should not be based in conjecture, but should be supported by concrete evidence.

3. **The most effective program integrity measures are those that avoid or prevent fraud, waste, and abuse.**

Abusers of the Medicare program generally do not evolve into abusers over time. Instead, it can be expected that they come into Medicare with original intent to commit fraud. As such, program integrity measures that prevent such providers from entering into Medicare should be considered and implemented as a priority approach.

4. **Stakeholder support is essential to achieving success in program integrity.**

It is axiomatic that the vast majority of Medicare providers and beneficiaries are honest and compliant with Medicare requirements. These stakeholders should be viewed as partners with Medicare on program integrity. The home health community's creation of program integrity measures to combat abusive providers is shown in two recent reforms: the 10% outlier cap and the targeted moratorium authority on new providers. Partnering with the provider community in the development and implementation of program integrity measures pays dividends for all.

5. **Program integrity measures should be developed in a transparent manner that assures the opportunity for public input.**

While on a real granular level, Medicare cannot disclose how it engages in program integrity oversight and enforcement. However, with broad-based policy changes, Medicare must utilize the longstanding public input process of formal rulemaking. Both the outlier cap and moratorium standards successfully followed that transparent path.

6. **There must be clear legal authority for any program integrity measure.**

The rules apply to all. Medicare should not move forward with a program integrity measure unless there is clear authority to employ that measure. Concerns regarding fraud do not supplant the requirement that the Medicare administration must maintain integrity too.

7. **A program integrity measure should not erect a barrier to appropriate care access.**

The underlying purpose in the establishment of Medicare is to provide access to care for Medicare enrollees. While program integrity is a crucial part of Medicare operations, it should not be done in a manner that subordinates that core goal.

8. **The least burdensome method of dealing with Medicare fraud and abuse is the best path to success.**

Efficiency is a hallmark of any process. Any program integrity measure proposed or in existence, should be evaluated relative to the burdens it creates for any and all stakeholders. While this is also part of the ROI evaluation, there can be situations where the nature of the burden created is of greater concern than the conduct intended to be addressed through the program integrity effort.

9. **Any reforms or remedies should properly distinguish fraud from unintentional noncompliance.**

Remedies to address unintended noncompliance are generally different than those needed to prevent or prosecute fraud. For example, if the core problem is the adequacy of the documentation, provider education, revised and clarified standards, and contractor guidance fit better than a broad-based rule that creates a new process to evaluate the same documentation.

10. **The outcome of the program integrity measures should be reliable with no "innocent victims" resulting**

There truly is no level of innocent victims that is acceptable when dealing with Medicare program integrity measures. It must be recognized that even the best "appeal system" is inadequate to fully remedy beneficiary harm. Likewise, upstanding providers should not be forced to apply limited financial resources to correct erroneous action operating in the name of program integrity. What harms providers of services harms Medicare beneficiaries.

Under these evaluation measures, the proposed prior authorization project should not be implemented. The proposal is untargeted, with high administrative costs and operational burdens, is likely to create improper barriers to access to timely care, would not be effective against the

fraud concerns in Medicare home health services, and would not aid in achieving a higher degree of compliance with the alleged claim documentation deficiencies. NAHC recommends that CMS withdraw the proposal and convene a stakeholder meeting aimed at evaluating alternative program integrity measures that may meet the guiding principles outlined above.

B. There is no legal authority for the proposed prior authorization demonstration program

1. The proposal does not comply with the congressionally expressed authority for a demonstration program of this nature

The expressed legal authority for the prior authorization project is 42 USC Section 1395b-1(a)(1)(J). That provision provides limited and qualified authority to CMS:

"to develop and engage in experiments and demonstration projects for the following purposes, …

(J) To develop or demonstrate improved methods of **investigation and prosecution of fraud**…" (emphasis added).

The proposed prior authorization project is outside that qualifying and limiting authority. The project focuses on five states because of findings of fraud in home health services in isolated parts of some of those states. The limited fraudulent conduct found in those states is a blatant and criminal act of billing for "phantom patents." In other words, fraudulent providers billed without rendering any services.

In discussions with CMS officials following the issuance of the instant proposal, those officials agreed that the project will not focus on areas known home health fraud such as billing for phantom patients as uncovered in Miami and elsewhere. The temporary success of such fraud is built on the fraudster's ability to manufacture high quality patient care documentation while not actually serving patients. With a prior authorization operation, those manufactured documents would be easily convincing the authorization agent to approve the request.

It is highly notable that the "Supporting Statement" accompanying the prior authorization Paperwork Reduction Act notice did not even attempt to define the nature of the fraud that the project would address. Instead, there is a broad-based reference to an old OIG report and CMS decision to impose moratoria on new home health agencies in limited areas of four of the five

states involved in the proposal. The OIG report does not indicate that there is widespread fraud in home health services in the states subject to the proposal or elsewhere.. Likewise, the moratoria in certain metropolitan areas do not support a statewide prior authorization project. In fact, the moratoria only indicate that there are concerns with new home health agencies in those areas, not fraud with existing, longstanding providers throughout the states.

Beyond the undefined fraud concerns, the Supporting Statement outlines "Tackling Improper Payments" with reference to the 2014 Comprehensive Error Rate Testing (CERT) results that report an improper payment rate of 51.4% compared to the FY 2013 report of 17.3%. Without commenting on the reliability of CERT, NAHC references CMS to qualifying and clarifying information regarding the nature of the alleged errors. First, FY 2014 was the year in which CMS expanded its claims reviews for compliance with the physician face-to-face encounter requirements. That led to an upsurge in claims denials. However, those denials, like the CERT results, were due to allegations of insufficient documentation, not fraud. The Supporting Statement verifies such in noting that 90% of the CERT reported errors were from "Insufficient Documentation."

It is also notable that CMS withdrew the requirement for a physician narrative as part of the documentation requirements as it was laden with confusion and was the core reason for claim denials on patients that otherwise met coverage standards. 79 Fed. Reg. 66032 (November 6, 2014)

Even if CMS were to try to bootstrap the documentation-related physician face-to-face encounter denials into a category of "fraud" for purposes of meeting the limitations of 42 USC Section 1395b-1(a)(1)(J), the prior authorization concept still does not fit as the physician encounter may not have even occurred at the time prior authorization is needed.. Under 42 CFR 424.22, the encounter can occur as late as 30 days after the admission of the patient to care.

Accordingly, the proposed program does not address any risk area for fraud in home health. Instead, the program would focus only on garden-variety disputes on claim documentation while not operating to address the now-rescinded face-to-face encounter documentation issues at the center of the CERT results.

2. Congress has limited the use of prior authorization to certain items of Durable Medical Equipment (DME)

Throughout the years, Congress has been very cautious about imposing any barriers to access to necessary care for Medicare beneficiaries. As such, it has only authorized the use of a prior authorization model with respect to certain items of medical equipment that have been susceptible to high levels of fraudulent claims. 42 U.S.C. Section 1395m(a)(15). Prior

authorization is an extraordinary measure. Absent express authority and/or mandate from Congress, CMS is not permitted to employ it.

The lack of authority is confirmed in the recent White House budget. https://www.govinfo.gov/features/featured-content/Budget-FY2017 That budget includes a proposal to gain the authority to do prior authorization in Medicare. While details of that budget proposal are lacking, it appears that the Administration has concluded that no authority currently exits, which is at odds with the CMS proposal for home health services.

3. Any proposal to implement a prior authorization system must be promulgated through formal rulemaking

Under 5 U.S.C. Section 553 and 42 U.S.C. Section 1395hh, CMS is required to establish Medicare program changes of the magnitude and impact of prior authorization only through the formal public notice and comment process of the Administrative Procedures Act (APA). Medicare changes have a fairly unique place in the realm of rulemaking as Congress had added a very specific compliance standard that amplifies the general rulemaking requirements of the APA.

Section 1395hh(a)(2) of Medicare law provides that:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that **establishes or changes a substantive legal standard governing** the scope of benefits, **the payment for service**s, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1). (emphasis added)

Implementation of a prior authorization project through a Paperwork Reduction Act notice process fails to comply with the requirements under the Administrative Procedures Act and the Medicare Act, both of which requires full public notice and comment rulemaking to institute this extraordinary process. It is indisputable that the prior authorization proposal "establishes or changes a substantive legal standard governing…the payment for services." As outlined in the Supporting Statement, claims for payment will be denied if the home health agency does not use the proposed prior authorization system. Also, a home health agency that does not use the prior authorization system with be subject to a 25% payment rate reduction in the event it is determined that the claim otherwise meets Medicare standards for coverage. As such, the proposed system substantively changes, in a significant manner, the claim submission and

determination process, the claim determination itself, and the payment rate. It is difficult to imagine a policy change of greater significance.

C. The proposed prior authorization project is overbroad, untargeted, administratively costly, and would be ineffective in curbing any fraud

CMS proposes to process 908,000 prior authorization requests involving every home health patient in the affected five states at a cost of nearly $300 million. In doing so, both the vast majority of home health agencies that have not operated fraudulently and the isolated few that have engaged in fraud will be subject to a burdensome process that is bound to create care barriers. To the extent that CMS has authority to establish a prior authorization program, the proposed program is overbroad and fails to provide a means to police or correct any known deficiencies in home health services claims.

The Medicare spending data over the last several years also clearly demonstrates that the Medicare home health services benefit is far from a program with "out of control" utilization. Further, state-specific data demonstrates that the states proposed to be included in the prior authorization do not show any broad-based concern in terms of spending growth or utilization increases. In fact, the data indicates that home health spending has declined both in terms of dollars and the percentage proportion of Medicare spending. Such is remarkable considering the widespread effort to rely on cost-effective community-based services as the alternative to inpatient and other institutional care.

Location	2011 HH Spending/% of Medicare spending	2012 HH Spending/% of Medicare spending	2013 HH Spending/% of Medicare spending	2014 HH Spending/% of Medicare spending
National	$17.48B/5.42%	$17.02B/5.25%	$16.88B/5.20%	$16.33B/5.04%
FL	$2.09B/8.49%	$2.00B/8.23%	$2.01B/8.32%	$1.87B/7.79%
IL	$1.08B/6.67%	$1.04B/6.42%	$1.04B/6.37%	$875M/6.06%
MA	$506M/5.75%	$511M/5.65%	$523M/5.76%	$514M/5.71%
MI	$747M/5.84%	$706M/5.51%	$688M/5.42%	$657M/5.28%

TX	$2.67B10.74%	$2.46B/9.98%	$2.27B/9.62%	$2.19B/9.10%
Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF.html				

This chart demonstrates that Medicare home health spending has declined overall nationally since 2011 (-$1.15B) and proportionately to all other Medicare spending (-0.38 points which equals a 7% proportionate decline). That trend is mirrored in each of the states subject to the proposal with the exception of Massachusetts which showed minor spending increase of $8 million over the period 2011-2014.

These data do not depict a Medicare sector in need of the extraordinary program integrity measure proposed here.

In addition, the alleged supportive CERT error rate in home health is predominately due to documentation disputes concerning the face-to-face physician narrative, a requirement no longer in effect. To the extent that there remain documentation issues with the face-to-face physician encounter requirements, prior authorization is untimely and unnecessary for the following reasons:

- Face-to-face encounters are not required until 30 days after the start of care. Prior authorization would precede the timing of the requirement.
- CMS is in the initial stages of the Probe and Educate audits. That translates to the reality that both Medicare and HHAs are yet to be in sync with what constitutes compliant documentation. A prior authorization contractor would operate in an environment where the standards for compliant documentation are fuzzy at best.
- The areas of fraud that have been uncovered in home health are highly limited and do not lend themselves to correction through prior authorization. For example, the vast majority of fraud convictions involve billings for phantom patients and referral kickbacks. Neither of these can be addressed through prior authorization. In fact, phantom patient billings should easily pass prior authorization, giving fraudsters an advantage over honest providers 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.

Further, it is impractical to expect that the volume of prior authorization requests can be processed on a timely basis. CMS proposes to model the home health prior authorization system after the one in use for Power Mobility Devices (PMD). However, in addition to having express statutory authorization (see above discussion), the PMD prior authorization involves a markedly smaller number of requests with a very generous allowance of 10-20 days for contractor decisions.

It is very apparent that patients and providers cannot wait 10-20 days for authorization. Home health services are life sustaining, curative, rehabilitative, and palliative care. A prospective home health patient's needs can not be suspended for 10-20 days without creating adverse risk to their health and well-being. Whether the prospective patient is in a hospital, skilled nursing facility, or community-based residence, when care is needed, it must be provided as soon as possible. Most home health agencies operate with a standard of admission and service within just hours of the referral to care in order to bring about a safe transfer to the home setting.

While delaying a discharge from an inpatient setting can give rise to unnecessary costs, it also brings increased risks for the patient in terms of infection, medication errors, and other factors that contribute to the mortality rates of the facilities. Patients are at higher risk in an inpatient setting because the bacteria is foreign to their bodily systems, while the colonized bacteria in their own homes are not of comparable risk

Beyond the health care risks with delayed admissions to home care, there is significant risk of dramatically increasing health care costs for providers and Medicare. For example, a one day delay in discharging a patient from a hospital setting brings an average cost increase of $1938 for Medicare. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2013.html. With the 10 day standard used in the PMD prior authorization project, that delay would mean nearly $20,000 in increased Medicare costs. If the patient develops an infection or other complication it can be expected that there would be further added costs.

Prior authorization is partly in use in Medicare Advantage plans and a few state Medicaid programs. NAHC members report one common consequence---delayed admission of the patients into home health services. It should also be noted that a home health agency would not even have the full assessment of a patient completed at the time of a prior Authorization request is due because that assessment occurs after admission.

Prior authorization creates barriers to care access, a highly negative consequence for all stakeholders. In discussions with CMS, the intention of the prior authorization project was described as "burden reducing." Home health agencies report the total opposite with their experiences with prior authorization with other payers. Overall, the agencies report high administrative costs accompanied by continual detours from providing care to undertaking efforts to convince a remote person with the payer to authorize care.

CMS (then HCFA) tried a form of prior authorization in home health services previously. The Omnibus Budget Reconciliation Act of 1986, Section 9305(k), mandated that Medicare develop and evaluate demonstrations of prior and concurrent authorization for coverage of home health and skilled nursing facility services. There were some differences between the current proposal and this demonstration. Most important of the differences was that home health agencies could select which cases went through concurrent authorization and which did not while the current proposal requires all cases to be managed though prior authorization. The outcomes of the demonstration were such that HCFA concluded that "legitimate questions about potential negative effects on appropriate service use remain." Report to Congress: Prior and Concurrent Authorization for Home Health and Skilled Nursing facility Services, U.S. Department of Health and Human Services, Health Care Financing Administration, HCFA Pub. No. 03310 (September 1990). Available in hard book form at selected libraries, http://www.worldcat.org/title/report-to-congress-prior-and-concurrent-authorization-for-home-health-and-skilled-nursing-facility-services/oclc/30147759

HCFA also noted that the lack of consistency among reviewers on the appropriate decision regarding CA [Concurrent Authorization] raise some additional concerns." The HCFA report offers the summary that the project produced marginal benefits and costs." While the evaluation authors recommended continuation of the project with work on refinements and improvements, HCFA did not continue the project.

With the proposed project, all of the burdens and costs outlined from the earlier trial would re-occur. However, with its design, the proposed project would add new burdens while not removing any existing burdens. NAHC understands that the project of prior authorization would not operate as "prior approval" program. In other words, the authorization given would merely authorize the provider to submit a claim in a manner consistent with current procedures, i.e. at the close of the episode. Medicare would retain the power to subject that claim to prepayment and/or post payment review as occurs today. As a result, the prior authorization program would add a significant burden.

Relative to the provider's burden, the Supporting Statement offers an estimate of 30 minutes of clerical time. It is unknown how CMS concluded that a process of getting Medicare coverage authorization involving highly clinical patient-specific factors could be handled by a non-clinical clerical person. With other payers using prior authorization processes, home health agencies rely on clinical professionals to manage the authorization request. That means that these clinical professionals are shifted away from patient care to paperwork. That is not a reasonable use of valuable resources, particularly when the alleged program integrity problems are not even slightly resolved with the proposed prior authorization project.

D. There are better tools to address Medicare home health risk areas:

The HHA industry has been a constructive and successful partner with CMS in developing the proper tools to address fraud, waste and abuse. Prime examples currently in use are the HHPPS outlier cap and the Medicare certification moratoria. These measures were created by and successfully advocated for by the home health services community. They have been the most successful program integrity measures in any health care sector. Each is not only effective, they also come at minimal administrative cost while being highly targeted. As such, the home health community is well positioned to play such a role presently as well. NAHC recommends that CMS convene a discussion with industry representatives to develop a consensus program integrity improvement plan.

CMS has the data capabilities to laser target program integrity measures to identified high risk situations rather than rely on broad-based, random, shotgun-like measures such as prior authorization. Accordingly, CMS should take advantage of this capability to the fullest extent.

E. Medicare beneficiaries and providers must be given full due process

As described above, NAHC views the proposed prior authorization proposal as costly and ineffective while also erecting barriers between physician-ordered care and the patient. In the event that CMS decides to move forward with consideration of prior authorization, it is essential that CMS provide an accelerated and robust appeal process for providers and beneficiaries. The absence of an authorization is a certain roadblock to care access. As such appeals must be processed immediately and with full reviews by a competent and objective decision-maker. This can take a variety of forms including a physician led peer review model of an evidentiary hearing with an Administrative Law Judge.

The process must be timely, 24 hours or less, as well as efficient. Care needs cannot wait for the burden of paperwork processing to dissipate.

F. The Proposed Prior Authorization Project Does Not Meet Program Integrity Standards Of Value

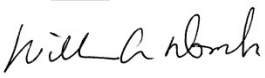
In evaluating the proposed prior authorization project under the guidelines set forth above, NAHC concludes that any upside benefits are far outweighed by downside consequences. The proposed project:

- is not sufficiently targeted to the fraud or abuse of concern
- is not evidence-based with demonstrated return on investment
- does not prevent fraud
- is absent adequate legal authority
- erects barriers to appropriate care access
- would be excessively burdensome
- fails to distinguish between fraud and unintentional noncompliance and
- would be highly likely to lead to a significant number of "innocent victims" through care delays, extended stays in high risk settings and wrongful rejections of authorization

G. Conclusion

NAHC is a leader in the development and implementation of program integrity innovations. NAHC has long partnered with Medicare and other payers in rooting out the fraud, waste, and abuse through creative policy changes. However, the proposed prior authorization project falls short of what it takes to be an effective program integrity tool sufficient to offset the down-side risks to Medicare beneficiaries and upstanding home health agencies. For the reasons stated above, NAHC respectfully recommends that CMS withdraw its proposal for prior authorization in home health services.

Very truly yours,



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