July 30, 2018

Centers for Medicare & 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, MD 21244–1850


Submitted electronically via www.regulations.gov

Dear Mr. William Parham:

UnityPoint at Home appreciates the opportunity to provide comments on the proposed Pre-Claim Review Demonstration for Home Health Services. UnityPoint at Home is the Home Health Agency affiliated with UnityPoint Health, one of the nation’s most integrated healthcare systems. UnityPoint at Home offers a diverse set of programs: traditional home health, durable medical equipment (DME), pharmacy, palliative care, hospice care, and (in certain locales) public health. Among our achievements, we are early HIT adopters (telehealth, video, remote wound care, I-phones) and have been recognized for our progressive programming – our palliative care program started in 2005 and earned the American Hospital Association’s Circle of Life Award in 2013. Annually UnityPoint at Home provides more than 610,000 visits to consumers. All ten of our Home Health Agencies have a 3.0 or greater star rating in both Quality of Patient Care and Patient Satisfaction. Our readmission rates are lower than the national average – 11.5% for 30-day readmissions and 14.8% for 60-day readmissions. In addition, UnityPoint at Home is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. Among these initiatives, UnityPoint at Home is an ACO Participant in the CMMI Next Generation ACO Model, is participating in the Home Health Value-Based Purchasing (HHVBP) Model in Iowa, and is a CMMI Medicare Care Choices Model awardee in three Iowa regions.

UnityPoint at Home
In general, UPH is interested in assuring that our Home Health Agencies are enabled to continue efforts to provide timely services and support high quality outcomes, including the prevention of avoidable readmissions. When initially implemented in Illinois, our Home Health Agencies performed favorably. UPH is concerned that the Demonstration is overly broad in casting a net to include high-quality Home Health Agencies and that submission of all claims for review will divert direct care resources to administrative functions. This non-targeted approach (by state instead of by noncompliant agencies) to fraud and abuse seems at odds with the Administration’s push for the reduction in regulatory burdens. UnityPoint at Home respectfully offers the following comments on the proposed Demonstration.

CMS–10599: PRE-CLAIM REVIEW DEMONSTRATION FOR HOME HEALTH SERVICES

CMS is proposing to reinstate a revised version of CMS-10599 that was put on “pause” in Illinois on April 1, 2017, and was not expanded to other states. The stated purpose of the Demonstration is to develop “improved procedures for the identification, investigation, and prosecution of Medicare fraud occurring among Home Health Agencies (HHA) providing services to Medicare beneficiaries.” In particular, CMS is proposing either a voluntary pre-claim or post-payment review process to assure that payments for home health services are appropriate and Medicare appeals are reduced. Once a HHA achieves the target affirmation or approval rate, it may choose to be relieved from the claim reviews with the exception of continued spot checks. For HHAs choosing not to participate, they will receive a 25 percent payment reduction on all home health services claims and may be eligible for Recovery Audit Contractor review. Illinois is among the five states targeted for this Demonstration.

UnityPoint at Home urges CMS to further delay this Demonstration until a sufficient public notice and comment period is undertaken relative to the stakeholder obligations. In addition, UnityPoint at Home recommends that this Demonstration be restricted to those HHAs with a history of noncompliance that raise fraud and abuse concerns.

Regulatory Authority for Demonstration – We question the underlying sufficiency of the notice and comment process in support of this Demonstration. This Demonstration was not separately published for public comment outside the notices under the Paperwork Reduction Act of 1995. Specifically, this notice lacks full disclosure and rulemaking intent relating to background, legislative authority, and provisions of the notice. Without this detailed information, it is difficult for CMS to adequately solicit meaningful stakeholder input, particularly as it relates to alleged fraud and abuse concerns. We believe this notice falls short of the full public notice and comment process that are within the intent of the Administrative Procedures Act and the Medicare Act of 1965.
**Scope of Proposed Information Collection** – The broad statewide approach by CMS results in additional administrative burdens for compliant HHAs in targeted states and also requires Medicare Administrative Contractors (MACs) to employ additional and unnecessary staff to conduct these reviews. We believe HHAs would be better served by shifting these resourced to direct patient care and that MACs would be better served by focusing efforts on more timely reimbursement.

**Current Selection Criteria**: States selected for this Demonstration were selected as “known areas of fraudulent behavior and had either a high home health improper payment rate or a high denial rate during the Home Health Probe and Educate reviews.” CMS fails to define what constitutes “high” for improper rates and/or denial rates. In addition, state geographies encompass a large number of HHAs that vary in compliance rates. CMS appears to recognize that this Demonstration imposes an undue burden on compliant HHAs by indicating its intent to issue an escape hatch (allowing HHAs achieving the target rate to be relieved from the claim reviews). **At a minimum, we request that CMS publish payment rate and denial thresholds so that stakeholders can appropriately provide input on whether CMS is engaging in targeted fraud and abuse activities.**

**Opt-Out Criteria**: For the 24th week of initial pre-claim review in Illinois, 88.5 percent of pre-claim review requests received a fully affirmed decision. The vast majority of home health claims in Illinois were not fraudulent, and for the remaining claims, it is unclear whether documentation/submission was incomplete as opposed to fraudulent practices being the root cause. During our participation in the Illinois Demonstration, our HHAs posted affirmation rates in excess of the 24-week report (Moline 97.76% - 871 approved and 8 denied; Muscatine 95.58% - 108 approved and 2 denied; and Quincy 96.97% - 128 approved and 1 denied). **We urge CMS to detail the process by which HHAs with rates at or above the threshold may elect to opt out.** Given our past participation record, we are interested in commenting on the proposed opt-out process, including threshold levels, the minimum timeframe for participation, the opt-out application, any ability to publicize our affirmation rates, and CMS’ ongoing notice to the public regarding this program. We would also be supportive of a process whereby HHAs that opt-out would re-enter this Demonstration on an individualized basis if a spot check indicates poor compliance findings.

---


This support is contingent on learning more from CMS about how spot-check monitoring and demonstration re-entry would be operationalized.

**Targeted Participation Criteria:** As proposed, this Demonstration does not appear to be tailored to its purpose of identifying and investigating fraud – ALL HHAs within identified five states are required to submit documentation to CMS for home health services for ALL Medicare beneficiaries, unless they “choose” a 25% reduction in payment. We oppose the blanket approach that requires all HHAs practicing within the guidelines of the Medicare Benefit Policy Manual to heightened submission requirements. Instead, we firmly believe that the development of a program to identify fraud will be more effective if it is based on specific indicators of fraudulent billing practices. *We would suggest that CMS target its fraud activities to bad actors and consider exempting or excusing HHAs with a high compliance trend starting October 1, based on prior demonstration participation or data trends.* This can be accomplished by leveraging existing regulatory practices to identify high-risk agencies. Existing practices include:

- Current HH MACs structure to target home health fraud. HH MACs are conducting a Probe and Educate audit of all HHAs with follow-up auditing. On an individual basis, CMS could apply a more stringent fraud investigation to HHAs that continue to fail follow-up audits.
- Trend of indicators at risk for improper Medicare payments in the Program for Evaluating Payment Patterns Electronic Report (PEPPER). At-risk indicators include high case-mix scores, multiple 5-6 visit episodes, a large percentage of high therapy utilization episodes, a large number of 20-therapy visit episodes, high percentage of outlier payments, use of up-codes or down-codes, or any combination of the above. While PEPPER reports are evaluated annually, the frequency of this screening could be increased to identify potential high-risk agencies. Based on at-risk indicators, HHAs could be identified for fraud investigation.
- On-site reviews by state licensure and other accreditation agencies. Rather than performing what are often duplicative documents reviews, we would suggest that CMS consider deferring to findings from onsite audits from state regulatory agencies and private accreditation organizations to determine whether HHAs are high-risk agencies requiring special fraud monitoring/reporting. For instance, in Illinois, HHAs are required to be licensed with the public health department. The health department then works with CMS to perform onsite reviews every one to three years. Additionally, some HHAs are further accredited by private organizations. As an example, UnityPoint at Home is accredited by the Joint Commission that includes a periodic review of documents and site visits.

The above alternatives are existing methods that could be leveraged to target HHAs at-risk for fraud, but require CMS to flesh out with thresholds. Placing additional reporting burdens on at-risk HHAs relative to a heightened probability of identifying fraud, waste and abuse seems a reasonable trade-off as opposed to subjecting all HHAs regardless of history or risk factors.
Accuracy of Estimated Burden – CMS estimates that the proposed Demonstration burden is 30 minutes for the submission of each new Form CMS-10599 (OMB Control Number: 0938-NEW). It is unclear how this time and effort was calculated, but that the submission will now include a new form not required in the initial Demonstration. The inclusion of a new form is at odds with CMS’ statement that “Pre-claim review does not create new documentation requirements.” Also, while the submission requires HHAs will submit the same information they are currently required to maintain for payment, there is additional time and effort that results from submission versus maintenance requirements – just as there are additional resources required for audits as opposed to payment / reimbursement activities. For our HHA located in the Quad Cities, the initial Demonstration time and effort included the following:

- Each claim took our team an average of 90 -120 minutes to process (without the new proposed Form CMS-10599).
- We hired a full- time position for the Demonstration and still incurred overtime estimated at an average of 15 hours per week. The average hourly wage was $14-$16. Overtime was paid at time and a half. Benefits are roughly 27 percent.
- For infrastructure, a designated printer was used for printing and faxing at a rate of between $65 and $70 per month. These costs do not include costs associated with additional staffing such as computer equipment and maintenance fees and telephone costs.

This estimate does not include the 30 minutes for completing the new form.

Conclusion

We appreciate the opportunity to provide comments to the proposed Pre-Claim Review Demonstration for Home Health Services. We urge CMS to reconsider this proposal which strays outside of its stated purpose to prevent fraud and abuse. In particular, we request that this demonstration be tailored and exempt high-quality, compliant HHAs from participation. For Illinois HHAs that previously participated and achieved the targeted affirmation rate over the eight months of the 2016-17 Demonstration, they should be exempted or excused from participation. Given our concerns with the sufficiency of this public notice and CMS’ statement that “Additional details on the Demonstration and start dates will be published following PRA approval”4, we would encourage CMS to further delay Demonstration implementation until a sufficient public notice and comment process has occurred to enable stakeholders to determine impact and effectively comment to CMS. To discuss our comments or

---

3 CMS, Review Choice Demonstration, id.
for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Public Policy and Government Payors at Sabra.Rosener@unitypoint.org or 515-205-1206.

Sincerely,

Jennifer Ofelt, MHA, MSN, RN  
VP, Home Care  
UnityPoint at Home

Sabra Rosener, JD  
VP, Government and External Affairs  
UnityPoint Health