UnityPoint at Home

Administration
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December 11, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1689–FC
P.O. Box 8013
Baltimore, MD 21244–8013

RE: **CMS–1689–FC** – Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and Proposed CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations; published at Federal Register, Vol. 83, No. 219, November 13, 2018.

Submitted electronically via www.regulations.gov

Dear Administrator Verma,

UnityPoint at Home is pleased to provide the following comments related to the definition of "infusion drug administration calendar day" for the home infusion therapy services temporary transitional payment. 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. In 2017, UnityPoint at Home provided more than 610,000 visits to consumers in Iowa and Illinois.

CMS has proposed regulations in support of the new home infusion therapy benefit that was established in section 5012 of the 21st Century Cures Act. The rulemaking comment period has been reopened to address a specific definitional issue. We respectfully offer the following comments.

DEFINTION OF "INFUSION DRUG ADMINISTRATION CALENDAR DAY"

CMS is proposing to finalize this definition of mean the "day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration."

CMS further states that "[t]he skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel." CMS proposes to monitor the effects of access to care based on this definition, and if warranted, may engage in additional rulemaking and seeks comment on this interpretation.

Comment: We reiterate and expound upon our concerns with the proposed interpretation and, instead of monitoring a flawed definition, **we urge CMS to revise this definition to adhere to legislative intent and support home infusion best practices.**

The proposed definition triggers when a supplier can bill for home infusion therapy services. While we agree that the 21st Century Cures Act limits payment to dates on which professional services are furnished, the 21st Century Cures Act does not generally require that skilled professionals (i.e. nurses) be physically present in an individual's home on the day the infusion drug is administered for payment to occur, nor does it specifically require that nursing services exclusively trigger payment.[1] We believe it would be more appropriate for CMS to apply the National Home Infusion Association's (NHIA) "per diem" definition and associated payment methodology to define home infusion administration calendar day for purposes of triggering Medicare payment. According to NHIA, "per diem" represents each day that a given patient is provided access to a prescribed therapy, beginning with the day the therapy is initiated and ending with the day the therapy is permanently discontinued.[2]

We opine that the CMS proposed interpretation is flawed in several respects.

- Interpretation should rely on home infusion industry standards. CMS incorrectly equates professional services to skilled services as set forth in 42 CFR 409.32. We are uncertain why CMS would reference regulations related to the coverage of posthospital skilled nursing facility (SNF) care as the equivalent of care in the home setting. Again, we would suggest that the NHIA "per diem" definition represents home infusion industry practices and is the more appropriate standard.
- Interpretation should use the statute's plain language: Limiting reimbursement for professional services to those instances when a nurse has a physical presence in the home appears contrary to the statute's plain language, which authorizes "*professional services, including nursing services, furnished in accordance with the plan*." It is clear from this language that nursing services are a subset of professional services. The NHIA definition references the skilled role of pharmacists, nurses and other medical professionals and does not prioritize one role over the other. Further, while the 21st Century Cures Act states that the "Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type," this again does not limit rate development to only those situations in which nursing services are furnished generally or more specifically at the home of the consumer.
- Interpretation should not supersede plans of care: The CMS requirement of in-person nursing services seems to overstep the Congressional intent that professional services are furnished according to the provider's plan of care. We do not believe that Congress intended CMS to offer

[1] Public Law 114–255, Section 5012, ". . . Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type."

[2] NHIA, *National Home Infusion Association National Definition of Per Diem—January 2018*, accessed at http://www.nhia.org/resource/hiec/per_diem.cfm

clinical judgment related to how home infusion drugs are furnished. In many instances, the plans of care for home infusion therapy have goals of promoting and teaching patients to be independent.

- Interpretation should rely on successful commercial insurance practices. For decades, private insurances have required patients to perform their own administration of their IV medications without the physical presence of a nurse.
- Interpretation should promote access to care. This exacerbates a nursing shortage, particularly in rural areas. To make matter worse, this shortage is predicted to worsen as the baby boomers retire.

We are also concerned that, despite reopening this definition for further comment, CMS continues to believe that the "best course of action is to monitor the effects on access to care of finalizing this definition." Given that this is a temporary transitional payment, **we believe that the better course of action under this shortened timeframe would be to implement industry standards as set forth by NHIA.** This approach gives deference to empowering consumers to self-administer these drugs when accompanied by professional services furnished by any skilled interdisciplinary team member whether in home or remotely.

We appreciate the opportunity to provide comments to this Home Health rule and its impact on our home health agency and beneficiaries. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government & External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,

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