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August 24, 2020

Administrator Seema Verma
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–1730-P
P.O. Box 8013
Baltimore, MD 21244–8013

RE: CMS–1730-P – Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements; published at Vol. 85, No. 126 Federal Register 39408-39453 on June 30, 2020.

Submitted electronically via http://www.regulations.gov

Dear Administrator Verma,

UnityPoint at Home is pleased to provide the following comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed Home Health rules for calendar year 2021. UnityPoint at Home is the Home Health Agency (HHA) 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, pharmacy, palliative care, hospice care, and (in certain locales) public health. In 2019, UnityPoint at Home provided more than 610,000 visits to consumers in lowa, Illinois and Wisconsin. 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 appreciates the time and effort spent by CMS in developing these proposed Home Health regulations. We respectfully offer the following comments to the proposed regulatory framework.

I. PERMANENCY OF COVID PANDEMIC FLEXIBLITIES FOR HOME HEALTH SERVICES

The Coronavirus Aid, Relief, and Economic Security Act or the "CARES Act" (H.R. 748) permanently authorized physician assistants (PAs) and nurse practitioners (NPs) to order home healthcare services for Medicare patients (in a manner consistent with state law). In terms of telehealth, CMS has indicated that the use of technology may not substitute for an in-person home visit that is ordered on the plan of care and cannot be considered a visit for the purpose of patient eligibility or payment; however, the use of technology may result in changes to the frequencies and types of in-person visits

as ordered on the plan of care. Additionally, CMS recognized that the homebound criteria for the Medicare home health benefit during this Public Health Emergency (PHE) have a wide application to vulnerable Medicare beneficiaries.

<u>Comment</u>: We applaud Congress for permanently authorizing PAs and NPs to issue home health orders for Medicare patients. Specifically, these advanced practice professionals may now sign the Home Health Certification and Care Plan — Form 485 and interim orders directly. It also permits advanced practice professionals to conduct and certify Medicare face-to-face encounters. For HHAs, and especially those in rural areas, this flexibility recognizes practice patterns and preferences of beneficiaries. It also promotes timely access to care. We would request that CMS use its authority to require similar flexibilities in state Medicaid programs. While CMS enables states to adopt this flexibility, we believe CMS should be more resolute, particularly where advanced practice professionals are authorized by scope of practice laws to practice independently.

The pandemic has also been the impetus to lift existing restrictions on Medicare coverage and payment for telehealth services furnished to Medicare beneficiaries. UnityPoint at Home has been an early adopter of telehealth infrastructure and supports the use of telehealth beyond the PHE, including remote patient monitoring, telephone calls (audio only and TTY); and 2-way audio-video technology. These are valuable tools not just for safely providing access to needed care during the pandemic but generally to manage the health of individuals with chronic conditions in the least restrictive and most convenient setting. As an example, during a significant COVID-19 surge in a rural part of Iowa, the hospital was overwhelmed by patient volume. Our HHA was able to increase census capacity via the use of remote patient monitoring. Generally, RN case managers are able to manage more patients when they are able to monitor and connect remotely. During the pandemic, remote monitoring was also crucial to our strategy to conserve Personal Protective Equipment (PPE). While CMS is proposing to permit telehealth service delivery as a home health benefit beyond the PHE, this proposal stops short of authorizing reimbursement and/or allowing for an audiovisual connection to count toward visit frequency, which improves the ability of HHAs to serve more patients, especially in rural areas. We urge CMS to expand this proposal. As CMS considers potential reimbursement framework for HHA telecommunication encounters, we would recommend reimbursement be tied to those identified within the Home Health plan of care and that the rate be commensurate with the various evaluation and management visit codes as set forth in the Medicare physician fee schedule.

We especially want to thank CMS for the broaden application of homebound criteria to vulnerable Medicaid beneficiaries during the PHE. The strategies needed to prevent transmission and protect beneficiaries from the spread of COVID-19 require many Medicare beneficiaries to receive necessary health care services in their homes. As an HHA affiliated with an integrated health care system, we support these strategies that maintain beneficiaries in their homes when possible and implore CMS to use similar rationale beyond this PHE to identify other situations or conditions where it is medically contraindicated for a beneficiary to leave the home to justify a categorical finding that an individual is homebound under existing law. In addition to stakeholder input, we encourage CMS to use data collected during this pandemic as well as quality outcomes to further support a re-envisioning of homebound status.

II. PAYMENT UNDER THE HOME HEALTH PROSPECTIVE PAYMENT SYSTEM (HH PPS)

Proposed Calendar Year (CY) 2021 HH PPS Payment Adjustment: Medicare payments to HHAs in CY 2021 are proposed to be increased by 2.7% or an estimated \$560 million. In addition, the wage index includes the adoption of the revised Office of Management and Budget statistical area delineations and a cap up to 5% on any decreases in a geographic area's wage index value in CY 2021.

<u>Comment</u>: **We appreciate the proposed rate increase**. Over time, payment adjustments have not kept pace with increased costs attributable to labor, technology and mileage. This increase will assist in maintaining health care access for Medicare beneficiaries that live in areas of the country where most HHAs are already experiencing very tight operating margins.

Rural Health Add-On Payments for CY2021: The Bipartisan Budget Act of 2018 imposed a -0.1% adjustment in payments, totaling an estimated -\$20 million.

<u>Comment</u>: We continue to be frustrated by the reduction in support for access to services for rural beneficiaries. In Iowa and central Illinois, we have a significant rural population. This add-on reduction negatively impacts access to care in low population density areas, where beneficiaries are older, have more chronic conditions, and face provider shortages. To compound matters, areas that receive rural add-on payments typically have much lower wage indices, and therefore are already faced with providing the same level of care as other HHAs but with less Medicare reimbursement.

<u>Payments for High-Cost Outliers</u>: For CY 2021, the Fixed Dollar Loss ratio for 30-day episodes is maintained at 0.63.

<u>Comment</u>: We support this methodology and agree that its "per unit" basis is appropriate to account for utilization and accompanying resource allocation by HHAs.

Transition of Requests for Anticipated Payment (RAPs) to Notice of Admission (NOA) process: In last year's final rule, CMS removed the upfront RAP payment for CY 2021; however, all HHAs must still submit a RAP at the beginning of each 30-day period to establish the home health period of care in the Common Working File and also to trigger the consolidated billing edits. In CY 2022, a one-time NOA is to be filed by all HHAs to alert the claims processing system that a beneficiary is under a home health episode of care. If the HHA does not submit the RAP for CY 2021 or NOA for CYs 2022 and beyond within 5 calendar days from the start of care, a payment reduction is instituted. The reduction in payment amount would be equal to a one-thirtieth reduction to the wage and case-mix adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submits the RAP or NOA.

<u>Comment</u>: UnityPoint Health is very concerned related to both the CY 2021 RAP changes given the pandemic as well as the NOA requirements starting in CY 2022.

When CMS finalized this provision in 2019, today's reality of a world-wide pandemic consuming our nation's health care system for the greater part of CY 2020 and likely beyond was inconceivable. The operational and financial strains faced by HHAs during the PHE have been great as care has shifted to an even greater extent to beneficiaries' homes. As a result, it have been difficult at best for many HHAs to operationalize the changes to effectuate the 5-day RAP submission time frame. With a looming payment reduction in 2021 related to this time frame, we fear these payment

reductions will be significantly more impactful than anticipated when CMS finalize the provision. UnityPoint Health implores CMS to delay the implementation of the payment penalty for a late RAP submission in 2021 until the greater of 6 months after the implementation date or three months after the PHE ends. We believe this request is consistent with other regulatory flexibilities granted by CMS during the PHE to ensure health care providers are adequately equipped and supported to respond to the pandemic and to be able to focus resources on providing patient care.

UnityPoint at Home wants to reiterate our concerns with the NOA requirement slated to begin in CY 2022. This is a major change that not only substantially reduces assessment time frames but also entails infrastructure costs, including EHR builds, HHA workflow changes and staffing reallocations and/or additions. The NOA requirements appear very similar to the Hospice Notice of Election (NOE), which itself is operationally cumbersome. As proposed, the one-time NOA requires a comprehensive assessment to be completed within 6 calendar days, including the admission day. This time frame is challenging, and it has not been piloted anywhere to demonstrate its effectiveness or underlying work effort. To implement, UnityPoint at Home will need to resource staff differently to assure timely submissions, including costly weekend coverage. As an aside, we are concerned that this short turn-around and quicker document production will potentially result in more documentation errors resulting from data entry missteps. In the hospice setting, many hospices failed to meet the NOE timely filing requirement because they submitted NOEs with systems-detectable billing errors. To correct these errors, hospices were required to wait for the NOE to be Returned to Provider (RTP), after which a new NOE could be submitted. In many instances, the system time required to process the RTP resulted in a failure to submit and accept a replacement NOE timely. Subsequently, CMS changed procedures to allow hospices to immediately submit corrected NOEs without waiting for the RTP process and likewise to immediately resubmit a corrected Notice of Termination/Revocation. Similar flexibility do not seem to be contemplated within the proposed NOA provisions. Beyond staffing, we will also need to realign communications / notifications between our back office and operations teams to sync time frames for the proposed NOA and updates to the Common Working File. Additionally, the NOA will require software changes to our EHR, which subsequently entails additional internal HHA testing and training. We strongly urge CMS to reconsider the proposed NOA requirement.

III. HOME HEALTH QUALITY REPORTING PROGRAM (HH QRP)

CY 2022 Proposed Measures: There are no proposals or updates for the CY 2022 program year.

<u>Comment</u>: **Thank you**. With the COVID pandemic, we appreciate the reprieve from HH QRP changes this year.

IV. CONDITIONS OF PARTICIPATION OASIS REQUIREMENTS:

New HHAs must successfully transmit test data to the Quality Improvement & Evaluation System (QIES) or CMS OASIS contractor as part of the initial process for becoming a Medicare-participating HHA.

Comment: We support this change.

V. HOME INFUSION THERAPY SERVICES

Home Infusion Therapy Services—Scope of Benefit and Condition for Payment: In last year's final rule, CMS finalized the provisions regarding payment for home infusion therapy services for CY 2021. Beginning January 1, 2021, HHAs will not be able to bill for the professional services associated with Part B home infusion drugs under the home health benefit. Rather, these services will need to be provided and billed by a home infusion therapy supplier under Medicare Part B, whether or not the home infusion therapy supplier is also the Medicare certified HHA. This proposed rule includes conforming changes to regulations excluding home infusion therapy services from coverage under the Medicare home health benefit as required by the 21st Century Cures Act.

<u>Comment</u>: We continue to be concerned with the overall approach to this benefit. As currently structured, we believe CMS has established a complex, costly and inefficient process for a very limited benefit. Instead, we would encourage CMS to pause this process and relaunch as a full comprehensive, all-inclusive home infusion therapy supplier benefit after seeking input from providers, beneficiaries and other stakeholders.

Beneficiary Impact: This benefit structure disadvantages beneficiaries in terms of cost-sharing implications, limiting entitled benefits and fragmenting care.

- <u>Cost-Sharing</u>: Currently under the home health benefit, eligible beneficiaries are able to receive the professional services associated with infusion without incurring out of pocket costs. The new Part B home infusion therapy benefit will require a 20% beneficiary co-pay for the professional services that are otherwise covered in full under the home health benefit.
- <u>Benefit Limitations</u>: Current eligible beneficiaries who qualify for the home health benefit due to the receipt of home infusion therapy services may also be entitled to receive dependent home health services, such as occupational therapy, home care aide, or social worker services. Under the new proposal, these beneficiaries will receive services under the home infusion therapy benefit, which includes skilled service but does not include other support services. As a result, these beneficiaries will not be covered under the home health benefit for these support services and will simply forego this care or be forced to seek private-pay arrangements for this care.
- <u>Fragmented, Inefficient Care</u>: Currently under the home health benefit, eligible beneficiaries receive coordinated care from HHAs for skilled services, including home infusion therapy services, and the responsibility for HHAs to coordinate this care remains unchanged in the HHA conditions of participation. Under the new proposal, the home infusion therapy benefit and the home health benefit operate concurrently and may require two distinct service providers in the home under separate plans of care during the same episode of care. For example, a beneficiary that requires skilled nursing for wound care and infusion services could potentially be required to receive skilled nursing for the wound care from the HHA and receive skilled nursing for the infusion from the home infusion therapy supplier. This fragmentation of care poses a clear risk to the quality of care

provided to the beneficiary. It also imposes additional time constraints on beneficiaries and caretakers due to multiple appointments.

<u>Scope</u>: In general, since most home infusion drugs are included under Part D, we believe the scope of this benefit (as evidenced by Table 12) will be very narrow in relation to this extensive new regulatory framework. We encourage CMS to include Part D under this new framework for consistency.

Technical clarifications: In addition, we request that CMS provide clarification on the following:

- Qualified Home Infusion Therapy Supplier Definition: This term is defined as a pharmacy, physician, or other provider of services or supplier licensed by the state in which supplies or services are furnished. We are concerned that "home health" is not specifically listed as a supplier as home health service times and billing are separate and distinguishable from that of a pharmacy. We urge CMS to include "home health" within this definition.
- Plan of Care Review: Home infusion therapy services are furnished in the individual's home to an individual who is under the care of an "applicable provider" and where there is a plan of care established and "periodically reviewed by a physician", prescribing the type, amount, and duration of infusion therapy services. We have two concerns with the plan of care review as described and seek clarification and flexibility from CMS. First, the term "periodically" is vague and open to interpretation. Instead, we would request that this "periodically" by replaced with "at least annually" to correspond with plan of care reviews. Second, since an "applicable provider" is defined to include a physician, NP or PA, we urge CMS to permit these plan reviews to be conducted by NPs and PAs to promote top of practice for these advanced practice professionals and prevent funneled workflows that require physician review.

We appreciate the opportunity to provide comments to the proposed Home Health rules and their impact on our HHA and beneficiaries. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

Margaret VanOosten, RN, BSN President & Chief Clinical Officer

UnityPoint at Home

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UnityPoint Health