September 9, 2019

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1711–P
P.O. Box 8013

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

Re: Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements (CMS–1711–P)

Dear Administrator Verma:

Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Innovatix, which is part of Premier, is one of the nation's largest, non-acute care group purchasing organizations that delivers savings and value to infusion and other provider organizations. Together, Premier and Innovatix serve more than 4,800 home infusion locations and approximately 165,000 other providers.

Premier appreciates the opportunity to comment on the recently issued Centers for Medicare & Medicaid Services (CMS) proposed home health rule on the "*CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements*" which was published in the July 18, 2019 *Federal Register*. Our comments focus on the following sections of the proposed rule:

- Medicare Coverage of Home Infusion Therapy Services
- Home Health Value Based Purchasing Model
- Home Health Quality Reporting Program

MEDICARE COVERAGE OF HOME INFUSION THERAPY SERVICES

CMS Should Amend its Definition of "Infusion Administration Calendar Day"

As noted in comments Premier submitted on the proposed home infusion rule (CMS-1689-P, RIN 0938-AT29) and the final rule (CMS-1689-FC, RIN 0938-AT29), we have serious concerns that CMS adopted a narrow and inappropriate definition of "infusion drug administration calendar day" that only reimburses when a skilled professional is present in the patient's home. It is disconcerting that CMS proposes to advance this definition permanently for Medicare Part B through this proposed rule, even after providers have shared with CMS that they can no longer serve patients, as is, and have shifted patients to alternatives sites of care as a result of the policy. Furthermore, the definition oversteps Congressional intent in passing the services payment structure in section 50401 of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115-123) and section 5012 of the 21st Century Cures Act of 2016 (CURES) (Pub. L. 114-255). Premier hopes that we, along with home infusion stakeholders, can work with CMS to fix the limited definition to one that is

workable for providers and beneficiaries. **As a result, we again urge CMS to revise the existing definition of infusion drug administration calendar day to allow for reimbursement of home infusion professional services each day that an infusion drug physically enters the patient's body, irrespective of whether a skilled professional is in the individual's home.**

The agency's final rule inappropriately undercuts extensive professional services needed for home infusion

In the BBA and Cures, Congress explicitly defined the "items and services" to be covered under the home infusion benefit as:

> (A) **Professional services, including nursing services, furnished in accordance with the plan**,
> (B) **Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)),** remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

Congress understood at the time that Medicare was not separately paying for home infusion professional services and that the new ASP + 6% methodology, mandated by Cures, and the DME benefit would not be sufficient to allow home infusion providers to treat Medicare beneficiaries. It is clear that Congress intended that the professional services reimbursement for home infusion include those services provided remotely by a pharmacist. The benefit was intended to be separate from the durable medical equipment (DME) reimbursement and not solely a nursing benefit. Home infusion requires a range of professional services, starting with pharmacy and care intake, drug delivery and care coordination, and remote and direct patient monitoring. Additionally, these professional services must be performed in compliance with state pharmacy laws and with sterile dose preparation requirements established by the United States Pharmacopeia (standards <797> and in the near future <800> where applicable) and requires maintenance of a rigorously controlled "clean room" environment. Home infusion services, in addition to nursing services, need to be appropriately reimbursed to ensure consistent and appropriate home infusion care for beneficiaries. **CMS should refine the definition of "professional services" to appropriately include services performed by a pharmacist.**

CMS should maintain the five-hour payment proposal

CMS proposes to carry forward the current three temporary transitional payment categories for the home infusion therapy services payment in 2021, but it proposes that the payment equal 5 hours of infusion per day rather than 4 hours. **We support the creation of three permanent payment categories and the 5 hours of payment that CMS proposes but, again, urge CMS to remove the requirement that a skilled professional be in a patient's home for the reimbursement to occur. This is essential for a payment structure that appropriately reimburses home infusion providers for all the services provided to patients receiving infusion care in the home setting**.

CMS should monitor the permanent benefit to ensure no patient harm

The stability of a comprehensive home infusion benefit should be monitored closely by CMS to ensure it is an economically viable option for beneficiaries and providers. We are particularly concerned about the services benefit in the context of the payment reductions that resulted from the change in drug reimbursement from CURES. As stated in our previous comments, it is our understanding that CMS relied upon the belief that the services benefit should not exceed an estimated $60 million in payment per year

because that is the amount of payment that, starting in 2017, CMS believes was reduced from the infusion drug reimbursement payment (when, pursuant to CURES Section 5004, drug reimbursement was moved from 95% of "average wholesale price" to 106% of "average sales price"). However, when Cures was passed in 2016, there was no published average sales price (ASP) for several commonly used infusion therapies, including milrinone lactate. The Congressional Budget Office (CBO) did not use comprehensive data to assess the cost to home infusion suppliers of transitioning from AWP to ASP. Looking to the public data recently made available, the actual reduction to providers for DME-infused drugs associated with the HIT services benefit was -$220M for 2017, not $60 million. This 73 percent rate cut for home infusion suppliers is unsustainable and will result in patient access issues.

We recommend that CMS engage in continuous monitoring of the permanent benefit while continuing to work with stakeholders to ensure that every patient can rely on home infusion services where appropriate. CMS should collect the data necessary to construct an appropriate permanent rate that will reflect the complexity and duration of services necessary to delivery home infusion therapy, will incentivize the delivery of safe, effective and high-quality care, and will inform future policy discussions as new and emerging medications become available.

TRANSFER OF HEALTH INFORMATION

CMS proposes the addition of two new process measures for the Home Health Quality Reporting Program (HH QRP) beginning with fiscal year (FY) 2022 for a new quality domain entitled Transfer of Health Information: 1) Transfer of Health Information to the Provider – Post-Acute Care (PAC) and 2) Transfer of Health Information to the Patient— PAC. CMS notes that both proposed measures support their meaningful measures priority of promoting effective communication and coordination of care, specifically the transfer of health information and interoperability.

Premier supports CMS' proposals to ensure the transfer of health information to other providers and to the patient; however, CMS can help make this process more efficient and accurate by focusing on additional efforts to advance interoperability across the care continuum via electronic data exchange.

The IMPACT Act of 2014 requires the Secretary to 1) implement specified clinical assessment domains using standardized (i.e. uniform) data elements; 2) develop and implement quality measures using standardized assessment data; and 3) develop processes for data reporting. Using standardized quality measures and standardized data will help enable interoperability and access to longitudinal information to facilitate coordinated care, improved outcomes, and overall quality comparisons.

Ensuring interoperability across electronic health records (EHR) systems and settings of care can unlock barriers to data sharing and care coordination between health systems, physician group practices, independent physicians, and PAC settings. CMS' pilot testing of the proposed measures confirms that the most common mode of information transmission to the patient and to the provider was paper based.[1] This long-standing reliance on paper-based transmission of information presents a significant barrier for PAC providers to implement EHR systems. Additional barriers for PAC providers to adopt EHR systems include a lack of financial incentives under the Health Information Technology for Economic and Clinical Health (HITECH) ACT and no mandated EHR adoption requirements. As a result, many SNFs and other PAC providers are not using EHRs or are using EHRs that are not designed for interoperability. [2]

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[1] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-2018-Pilot-Test-Summary-Report_Final.pdf

[2] https://www.newswire.com/news/post-acute-care-the-next-frontier-for-health-systems-under-risk-black-20056199

We urge CMS to enhance its efforts to develop standards and measures for data exchange and sharing across all care settings, including post-acute care. The transfer of information between HHAs and other providers most often occurs via cumbersome and resource-intensive manual processes. CMS needs to consider ways to incentivize HHAs and other PAC providers to more readily adopt health IT in support of wider efforts to standardize patient data, improve care quality, and reduce costs. Standardized data elements and common data reporting processes alone will not achieve interoperability across the care continuum.

Transfer of Health Information to the Provider – Post-Acute Care (PAC)

The proposed process-based measure of Transfer of Health Information to the Provider–Post-Acute Care (PAC) assesses whether a current reconciled medication list is given to the subsequent provider when a patient is discharged or transferred to a subsequent provider setting. The proposed measure would be calculated as the proportion of HH quality episodes with a discharge or transfer assessment indicating that a current reconciled medication list was provided to the admitting provider at the time of discharge or transfer

Premier strongly supports CMS efforts to improve data exchange and interoperability between care settings. We support the measure at discharge because it will improve the exchange of patient specific information about medications between a HHA and other PAC providers. This will help ensure continuity of drug therapy, which is critical for patients during transitions. This measure will contribute to improved health outcomes and help reduce avoidable hospital readmissions.

Transfer of Health Information to the Patient – Post Acute Care (PAC)

The proposed Transfer of Health Information to the Patient–Post-Acute Care measure assesses whether a current reconciled medication list was provided to the patient, family, or caregiver when a patient was discharged from a PAC setting to a private home/apartment, board and care home, assisted living, group home or transitional living.

Premier applauds CMS for proposing that a HHA furnish medication reconciliation information to either the patient, family member, or caregiver when a patient is discharged. We believe that providing medication reconciliation information to the patient, family, or caregiver at discharge from a PAC setting will help improve patient compliance with medication therapy once the patient leaves a HHA. This flexibility is essential because it allows the HHA to determine the most appropriate individual to provide this critical information to during a care transition. For example, HHA residents may have a cognitive impairment, making the family member or caregiver the best option to understand the information and to follow-up as appropriate.

While we support the concept of both proposed Transfer of Health Information measures, Premier cautions about the additional administrative burdens and challenges they will place on HHAs and other PAC providers. As already noted, most PAC providers do not have access to EHRs or health information technology systems that facilitate their ability to electronically share (send and receive) this information. PAC settings, unlike acute and ambulatory care settings, were not included in CMS' meaningful use program and therefore do not have mechanisms in place to incentivize the use of electronic health records. Therefore, many do not currently have the digital tools necessary to allow for the efficient and appropriate transfer of electronic health information. We encourage CMS, as it considers more measures around the transfer of health information, to ensure the standards incorporate the PAC setting. We further urge CMS to work with ONC to ensure that the US Core Data for Interoperability (USCDI) includes data

classes and elements relevant to SNFs and other PAC providers. Furthermore, we urge CMS to work with ONC to:

- Leverage ongoing efforts to adopt data standards and implementation guides for certified EHRs (such as the USCDI); and
- Build on efforts to base measures and calculations (numerators/denominators) on data within certified EHRs.

Additionally, while the dichotomous yes/no approach for medication reconciliation is an important next step, Premier encourages CMS to continue to refine the measures to ensure a quality medication reconciliation is performed. Consideration for future measures could capture quality metrics, such as the accuracy of the medication reconciliation and the extent to which the reconciliation influenced the care when the patient moves to a new setting. As CMS continues to refine these measures, Premier encourages CMS to pursue moving from process-based measures towards outcome-based measures to better understand how the transfer of a medication reconciliation list at discharge impacts patient outcomes.

HH QRP QUALITY MEASURES, MEASURE CONCEPTS, AND STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS UNDER CONSIDERATION FOR FUTURE YEARS: REQUEST FOR INFORMATION

CMS solicits a Request for Information seeking input on the importance, relevance, appropriateness, and applicability of measures, SPADEs and concepts for future years in the HH QRP.

Premier has previously offered comments to CMS about data and interoperability standards and expressed our concerns about the lack of incentives for PAC providers to implement health information technology. We again urge CMS to explore approaches to incentivize the adoption of EHRs across the care continuum and develop future measures and SPADEs that use data that are available within EHRs used by PAC providers.

CMS needs to incentivize PAC, behavioral health (BH), and home and community-based services (HCBS) providers to more readily adopt health IT in support of wider efforts to standardize patient data, improve care quality and reduce costs. To provide these incentives, the Center for Medicare & Medicaid Innovation (CMMI) should develop a pilot program to provide a prospective payment for PAC, BH, and HCBS investment in health IT resources to advance interoperability. CMS has previously structured a similar prospective payment to “improve system linkages” for prescription drug plans (PDPs) in the CMMI Enhanced Medication Therapy Management demonstration model that began in 2017. The demonstration should support investment in health IT, while evaluating outcomes through measurement of interoperability and patient outcomes.

Adoption occurring in non-acute care settings is often supported by partnering health systems that were both eligible for HIT adoption incentives and subject to penalties under the meaningful use – now Promoting Interoperability – program. CMS currently provides Stark Law and Anti-kickback statute waivers to support these efforts for providers’ participation in CMMI programs. These waivers should be further expanded beyond the Medicare Shared Savings Program and CMMI initiatives to permit collaborative investments by health systems and physician groups into interoperable EHR systems in PAC, BH, and HCBS settings.

Measuring interoperability across settings will provide valuable insight into providers’ ability to share information that supports care coordination. CMS should focus on developing cross-continuum standards, rather than extending the collection of standards developed for siloed settings of care to additional providers. The IMPACT Act mandated the establishment of standardized patient assessment data elements across PAC settings. However, this assessment is still effectively siloed since it applies only to PAC.

Extending these data collection requirements to hospitals and physicians represents a workaround to interoperability that does not consider how care is provided across settings.

A holistic approach is needed for data standards whereby standards are developed for use across care settings, though provider types vary in the level of acuity and types of conditions they are clinically appropriate to serve. There are at present a limited number of common data elements across inpatient, outpatient, and PAC care; however, these elements could serve as a starting point for cross-continuum patient assessment. For example, medication reconciliation is currently collected in the inpatient setting and has been included in the IMPACT Act-mandated PAC assessment. Interoperable sharing of medication reconciliation information is particularly relevant to improving care coordination and preventing adverse drug reactions. Developing data standards that consider how medication reconciliation occurs in various settings and what information is shared across settings will enhance interoperability in this area. As the proposed US Core Data for Interoperability (USCDI) and data standards are developed, adopted and implemented, CMS and the Office of the National Coordinator should consider how data will be collected and exchanged across care settings.

Conclusion

In closing, the Premier healthcare alliance appreciates the opportunity to submit comments on CMS–1711-P. Premier looks forward to working with CMS and other stakeholders to develop reforms that meet the agency's goals and are appropriate for beneficiaries and providers.

If you have any questions regarding our comments or need more information, please contact Shara Siegel, Director of Government Affairs at shara_siegel@innovatix.com or 212-901-1264.

Sincerely,

Blair Childs
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Premier Inc.