August 24, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1780-P

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

Re: Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements (Docket Number: CMS-1780-P)

Dear Administrator Brooks-LaSure:

Premier Inc. appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the *"Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements (CMS-1780-P)"* proposed rule which was published in the July 10, 2023 *Federal Register*.

In our detailed comments below, Premier urges CMS to:

- Advance payments that support home health providers given the current financial landscape and not move forward with payment cuts for CY 2024 while continuing to monitor the Patient Driven Groupings Model (PDGM);
- Continue its work, including the current request for information (RFI), to ensure home health aides are consistently paid wages that are equivalent to other care settings and commensurate with the impact they have on patient care;
- Revise the current 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;
- Ensure equitable and uninterrupted access to intravenous immune globulin (IVIG) therapy by implementing permanent coverage and payment of items and services related to the administration of IVIG in a patient's home for a patient with a diagnosed primary immune deficiency disease (PIDD);
- Not adopt or make public the proposed Quality Reporting Program (QRP) measure - COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure; and
- Begin publicly displaying data for the measures: (1) Transfer of Health (TOH) Information to the Provider - Post-Acute Care (PAC) Measure (TOH-Provider); and (2) TOH Information to the Patient - PAC Measure (TOH-Patient) beginning with the CY 2025 HH QRP.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated

data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters, and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM

In the proposed rule, CMS estimates that Medicare payments to Home Health Agencies (HHAs) in Calendar Year (CY) 2024 under the Home Health Prospective Payment System (HH PPS) would decrease in the aggregate by -2.2 percent compared to CY 2023. This decrease reflects the effects of the proposed 2.7 percent increase to the home health payment update percentage, an estimated 0.2 percent increase that reflects the effects of a proposed update to the fixed-dollar loss ratio (FDL) used in determining outlier payments, and an estimated 5.1 percent decrease that reflects the effects of the proposed prospective, permanent behavioral assumption adjustment.

Premier shares the concerns of CMS and many other stakeholders regarding the fiscal instability of HHAs resulting from the combined effects of the COVID-19 public health emergency (PHE) and the new PDGM that was implemented in CY 2020, just weeks before the PHE began. While the PHE officially ended in May 2023, its impact on HHAs' financial stability persists. In addition to PHE disruptions, Premier is also concerned about the negative effects of labor costs and overall inflation on HHAs. Any disruption in payment to home care providers is likely to have unintended consequences on direct patient care as HHAs and other ancillary providers, such as home infusion providers, are impacted by payment reductions.

Premier is concerned that the data CMS uses to predict real inflation and cost of labor does not reflect the current landscape and will result in a fourth consecutive year where the payment update is not reflective of the actual cost increases HHAs are experiencing now and into the future. Premier firmly believes increased labor costs are not transitory. Long before the pandemic, many staff were in short supply and growing closer to retirement age. For example, according to pre-pandemic research published in 2018, healthcare was projected to be short more than one million nurses by 2020 as a result of nurse retirements, an aging U.S. population and a stagnant talent pipeline.[1] Research indicates the need to replace more that 1.1 million nurses in the United States given current shortages and the growing need.[2] As talent shortages become more severe, providers are paying more to attract and retain scarce staff. These wage increases cannot be taken back and have set a new floor. With these concerns regarding labor costs in mind, ***Premier supports the request for information (RFI) in the proposed rule which includes ensuring that home health aides are consistently paid wages that are equivalent to other care settings and commensurate with the impact they have on patient care.***

At the same time, increased costs for supplies, medication, testing, and protective equipment have placed additional strains on finances for home health providers. Inflation is being driven by a number of factors, including

[1] Zhang, Ziaoming, et al., "United States Registered Nurse Workforce Report Card and Shortage Forecast: A Revisit," American Journal of Medical Quality, 2018, Vol. 33(3) 229–236, https://edsource.org/wp-content/uploads/2019/02/Zhang-Daniel-Pforsich-Lin-2017-United-StatesRegistered-Nurse-Workforce-Report-Card-and-Shortage-Forecast_-A-Revisit.pdf

[2] American Nurses Association, "Post-Pandemic Nursing Shortage: What It Means for Aspiring Nurses," https://nursejournal.org/articles/post-pandemic-nursing-shortage/

increased costs of raw materials, lockdowns and labor shortages, port closures and product backlogs, and increased transportation costs, particularly fuel as a result of the ongoing conflict in Ukraine. While inflation affects all industries, the problem is particularly challenging in healthcare. This is because healthcare providers operate on fixed reimbursement, with no ability to shift costs to payers or consumers. For instance, Medicare and Medicaid payments, which make up the majority of most providers' payer mix, are only updated once per year. In the meantime, providers must absorb the added costs out of existing budgets, which are already strained.

The combined effects of the PHE, increased labor costs, and inflation ***lead Premier to urge CMS to advance a final rule that results in home health payment increases, not decreases, for CY 2024***. Premier recognizes that statutory constraints may limit the actions CMS may take and therefore, ***Premier urges CMS to continue to monitor the PDGM and make no negative adjustment for CY 2024.*** As CMS has done in the past with historic disruptions to providers, Premier urges CMS to use its discretion to ensure reimbursement predictability so that HHAs can continue to care for patients.

III. MEDICARE COVERAGE OF HOME INFUSION THERAPY SERVICES

In previous comments on CMS' home infusion rules (CMS-1689-P, RIN 0938-AT29, CMS-1689-FC, RIN 0938-AT29, CMS-1711-P, 0938-AT68, CMS-1730-P, RIN 0938-AT-06, CMS-1474-P, CMS-1766-P), Premier has raised 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 a patient's home. 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). It is concerning that CMS continues to move forward with a home infusion therapy (HIT) policy that runs counter to the government's overall goals of moving high quality patient care to the most clinically appropriate and less expensive care settings.

Premier's concerns are rooted in the belief that inadequate payment creates patient access barriers to HIT services. Strong evidence to reinforce this belief comes from CMS' own data, released in February 2023, showing that the HIT benefit has failed to attract a sufficient number of providers to ensure equitable access to HIT services.[3] In fact, the CMS report finds that only 40 providers billed for HIT services in the first quarter of 2021, despite that there are almost 1,000 home infusion pharmacies, 11,000 home health agencies, and a significant number of other providers that have the ability to provide these services. Similarly, with the large number of patients who can benefit from HIT, the report showed that fewer than 1,300 patients were billed for HIT services in each quarter that the data was collected. In addition, Premier continues to hear anecdotally from more and more of our members across the continuum about the challenging decisions they must make for their Medicare patients as a result of CMS' implementation of the benefit. Further, no other payors – commercial, Medicare Advantage, the Veterans Administration – require a professional to be physically present in the home to reimburse for a patient's HIT services. Therefore, the Medicare HIT benefit must be revised to ensure patient access and to conform with Congressional intent.

Premier repeats its call for CMS to revise its 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. If CMS feels that it does not have the regulatory authority to make further changes to the benefit in its final rule, Premier urges the agency to work with Congress to advance the *Preserving Patient Access to Home Infusion Act* (H.R. 4104/S. 1976) to ensure beneficiaries have consistent access to key home infusion services.

[3] CMS and Abt Associates. Home Infusion Therapy Monitoring Report. February 2023. https://www.cms.gov/files/document/hit-monitoring-report-feb-2023.pdf

IV. HOME INTRAVENOUS IMMUNE GLOBULIN (IVIG) ITEMS AND SERVICES

CMS is proposing to implement provisions form the Consolidated Appropriations Act (CAA) of 2023 regarding coverage and payment of items and services related to administration of intravenous immune globulin (IVIG) in a patient's home for a patient with a diagnosed primary immune deficiency disease (PIDD). With current coverage under the IVIG demonstration program ending on December 31, 2023, the CAA established permanent coverage and payment of the items and services needed for in-home administration beginning on January 1, 2024. CMS proposes to set the initial payment amount equivalent to the CY 2023 ''Services, Supplies, and Accessories Used in the Home under the Medicare IVIG Demonstration'' payment amount, updated by the proposed CY 2024 home health update percentage of 2.7 percent. ***Premier strongly supports the CMS proposal to ensure patients maintain equitable and uninterrupted access to IVIG therapy in their home.*** CMS should reevaluate the LUPA-based rate calculation to ensure reimbursement is commensurate with the extensive services required to provide equitable access to IVIG treatments in the home, including for those beneficiaries residing in rural areas. We are concerned that the proposed LUPA-based rate calculation for Q2052 may undervalue significant services and resources involved in the provision of home-based IVIG therapy.

V. HOME HEALTH QUALITY REPORTING PROGRAM (HHQRP)

Proposed Adoption and Public Reporting of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure

CMS proposes to adopt the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the CY 2025 HH QRP. The proposed measure is an assessment-based process measure that reports the percent of home health patients that are up to date on their COVID–19 vaccinations per CDC's latest guidance. CMS also proposes the public reporting of the measure beginning with the January 2026 refresh of Care Compare or as soon as technically feasible using data collected for Q2 2024 (April 1, 2024 through June 30, 2024).

Consistent with our prior recommendations regarding the COVID Vaccination measures, ***Premier is generally supportive of aligning with the CDC's definition of "up-to-date," however Premier is concerned this change will impose significant burden on HHAs***. The proposal will require HHAs to track CDC guidance on a quarterly basis and will also require HHAs to change their processes to track whether patients/residents have received multiple doses. If CDC were to update their guidance and require additional boosters, HHAs would then need to validate whether all patients/residents met the new requirements. This will create an added burden for HHAs to adapt to the new recommendations that will take both time and staff resources. If CMS moves forward with the measure as proposed, ***Premier believes it is critical that HHAs are afforded sufficient time for reporting in each instance where the CDC recommendations change.***

Premier also is concerned that the proposed measure for patients/residents may not accurately measure HHA quality, as patient vaccination may be driven by factors that are outside the HHA's control. Lastly, we note the MAP Coordinating Committee reached 90 percent consensus on its recommendation of "do not support with potential for mitigation" when evaluating this proposed measure. For these reasons, ***Premier urges CMS to not adopt COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure.***

Public Reporting of the Transfer of Health Information to the Provider—Post-Acute Care Measure and Transfer of Health Information to the Patient—Post-Acute Care Measure

CMS proposes to begin publicly displaying data for the measures: (1) Transfer of Health (TOH) Information to the Provider - Post-Acute Care (PAC) Measure (TOH-Provider); and (2) TOH Information to the Patient - PAC Measure (TOH-Patient) beginning with the CY 2025 HH QRP. These measures are the percentage of patient stays with a discharge assessment indicating that a current reconciled medication list was provided to the subsequent provider and/or to the patient/family/caregiver at discharge or transfer. With these measures, HHAs are incentivized to maintain strong communication between the pharmacy, the HH care team, and patients and their families/caregivers. In prior comments, Premier supported the adoption of these measures because we

believe the transfer of a reconciled medication list is critical to ensuring consistent care when a patient changes settings. ***Premier supports the public reporting of these measures to provide the public with this key piece of information regarding HH quality.***

VI. EXPANDED HOME HEALTH VALUE-BASED PURCHASING (HHVBP) MODEL

CMS proposes changes to the Expanded Home Health Value-Based Purchasing (HHVBP-E) model that would continue the implementation of the model that began with the 2023 performance year. ***Premier commends CMS for advancing the HHVBP-E.*** A critical component to improving quality and reducing healthcare costs for all Americans is to allow providers to develop innovative approaches for delivering care in value-based arrangements. The coronavirus pandemic showcased that a fee-for-service system (FFS) is unable to adjust to meet healthcare demands, with provider viability tied to volume rather than value and severe limitations on the ability to innovate care. According to a Premier survey, leading health systems and providers operating in value-based models had a head start over other providers in adapting care.[4] Moreover, providers in the most advanced value-based arrangements (i.e., global budgets and capitation) were able to avoid financial challenges that many other providers faced.

The nation is now at a critical juncture where we must rapidly scale alternative payment approaches that allow providers to be in the driver's seat of care transformation. Providers with their local roots and direct role in care delivery are best situated to design population health solutions that are targeted to the needs in their communities, including addressing health equity. Moreover, moving from fee-for-service to value shifts the fundamental incentives from reactive, sickness-based care to proactive, wellness-based care. Without this change, the incentive to achieve health equity is significantly undermined.

This shift will require new partnerships between payers and providers that incent providers to be responsible for the quality and cost of care. Premier provides the following recommendations that are central to a vision for accelerating the movement to value:

- **Ensure all providers have equal opportunity to succeed.** CMS must recognize that the market forces in each region will define which types of entities are best suited for various functions such as financial risk management, benefit design and care management. A truly competitive environment is one in which providers can form unique arrangements and partnerships to best serve their populations. CMS must avoid approaches that advantage one provider type or risk-assuming entity over another. Moreover, CMS must unleash potential for providers to truly innovate care by providing flexibilities and incentives that are equivalent to those that plans in Medicare Advantage (MA) receive. Innovating care requires flexibility beyond what is currently allowable in FFS, yet current models have provided minimal flexibility. Providers are well suited to design unique care approaches for their population. When managing total cost of care, the FFS program integrity concerns are mitigated.

- **Provide adequate reimbursement in APMs.** Current approaches in alternative payment models (APMs) create a race to the bottom where providers must achieve year-over-year savings. A new paradigm is needed where benchmarking approaches are sustainable long-term (e.g., designing benchmarks that reduce spending trend rather than year-over-year savings), address unique population challenges (e.g., approaches specific to rural health providers) and incorporate non-medical costs that can address social

[4] Premier Inc. Survey: Clinically Integrated Networks in Alternative Payment Models Expanded Value-Based Care Capabilities to Manage COVID-19 Surge. May 2020. https://www.premierinc.com/newsroom/press-releases/premier-inc-survey-clinically-integrated-networks-in-alternative-payment-models-expanded-value-based-care-capabilities-to-manage-covid-19-surge

determinants of health. Moreover, there must be comparability between MA and risk adjustment in Medicare APMs.

- **Continue incenting providers to adopt risk-based arrangements.** The bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established incentive payments for clinicians who take on increased financial risk through Advanced APMs. These payments have been critical to increasing participation in APMs as they help clinicians to cover the investment costs of moving to new payment models, as well as to stabilize revenues as they move from fee-for-service. CY is currently the last year that clinicians can qualify for these payments. These payments should be extended, and other incentives should be put in place to encourage APM adoption. For example, the ACA and MACRA established programs that precipitated tremendous gains in quality and patient safety by holding providers accountable. As CMS renews focus on quality and patient safety with progress towards more interoperable data, CMS must shift incentives in those programs to encourage APM adoption. Additionally, CMS should consider other FFS incentives such as exempting providers participating in models from new FFS-centric payment cuts and incenting other providers to adopt APMs**.**

- **Encourage payers to offer risk-based arrangements.** Medicare has been a leader in advancing new payment approaches, with some payers following suit. To truly innovate care, CMS must rethink the roles and responsibilities of payers and providers. Payers have critical functions (e.g., claims processing, marketing) but are unable to innovate the care delivery process. CMS must give providers tools to change care delivery through new payment arrangements. The federal government should work with states and the private sector to spread the movement to APMs. For example, HHS could support states in incentivizing state Medicaid managed care programs to enter into more APM arrangements with providers, rather than remaining on a FFS chassis. Moreover, CMMI must scale some models to create direction and permanence for providers and for private insurers to also scale, creating uniformity across the healthcare landscape.

VII. CONCLUSION

In closing, Premier appreciates the opportunity to submit these comments on the *"Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements (CMS-1780-P)"* proposed rule. Premier looks forward to working with CMS and other stakeholders to develop reforms that strengthen our nation's HHAs and care for vulnerable populations.

If you have any questions regarding our comments or need more information, please contact Shara Siegel, Senior Director of Government Affairs, at shara_siegel@premierinc.com or 646-484-0905.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.