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Advancing Health in America

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August 26, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1803-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically

Re: Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies; 89 Fed. Reg. 55,312 (July 3, 2024).

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including approximately 1,000 hospital-based home health (HH) agencies, and our clinician partners — more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the calendar year (CY) 2025 HH prospective payment system (PPS) proposed rule.

The AHA is very concerned about ongoing access challenges for beneficiaries needing HH care, and the potential for CMS' proposed updates to lead to further disruption. HH agencies are vital to Medicare beneficiaries' recoveries, and they partner with acute care and other hospitals to ensure patients can receive the right care in the most appropriate setting. Hospitals rely on HH agencies for safe and timely discharge of patients and to avoid extended hospital stays. We already see the strain on HH operations — and other post-acute care providers — due to financial challenges, creating ripple effects throughout the continuum of care, including for acute and post-acute hospitals. Despite this, CMS proposes inadequate HH agency payment rate updates and further erroneous behavioral adjustments. **We urge the agency to reconsider these proposals and take steps to ensure HH agencies receive**

payment updates that match their financial reality and enable them to continue to provide high-quality care to Medicare beneficiaries.

In addition, the AHA is concerned about the proposed changes for long-term care facility Medicare conditions of participation (CoPs) requiring ongoing respiratory virus data reporting. We do not believe CoPs are the appropriate lever to impose data reporting requirements, and the proposals are poorly defined.

We provide additional detail on these issues, as well as other proposals in the rule, below.

HH AGENCY PAYMENT UPDATES

HH agencies currently face serious operational and financial challenges, limiting their ability to care for all patients needing their services. CMS market basket updates combined with behavioral adjustments contribute to these difficulties. **The AHA, therefore, urges CMS to reevaluate its market basket methodologies and withdraw its proposed behavioral adjustments to ensure access for Medicare beneficiaries in need of HH services.**

Role of HH in the Continuum of Care

HH agencies are a central part of the Medicare continuum, particularly for hospitalized patients: approximately one in five hospitalized Medicare beneficiaries are discharged to HH.[1] HH agencies allow for a quicker return home for patients who no longer need hospitalization but will be homebound with continuing health and rehabilitation needs. These services alleviate pressure on hospitals, other post-acute sites of care and caregivers, who would otherwise be responsible for these patients. HH agencies also can prevent rehospitalization by safely providing needed interventions at home thus avoiding potential complications and accidents.

There is ample evidence regarding how HH agencies contribute to the safety of hospitalized patients, reduce costs and prevent deaths. Indeed, a CareJourney analysis of Medicare claims indicates that of patients who were referred to HH agencies, those who failed to receive the care had a notably higher risk of readmission than those who did receive the care (see Figure 1).[2]

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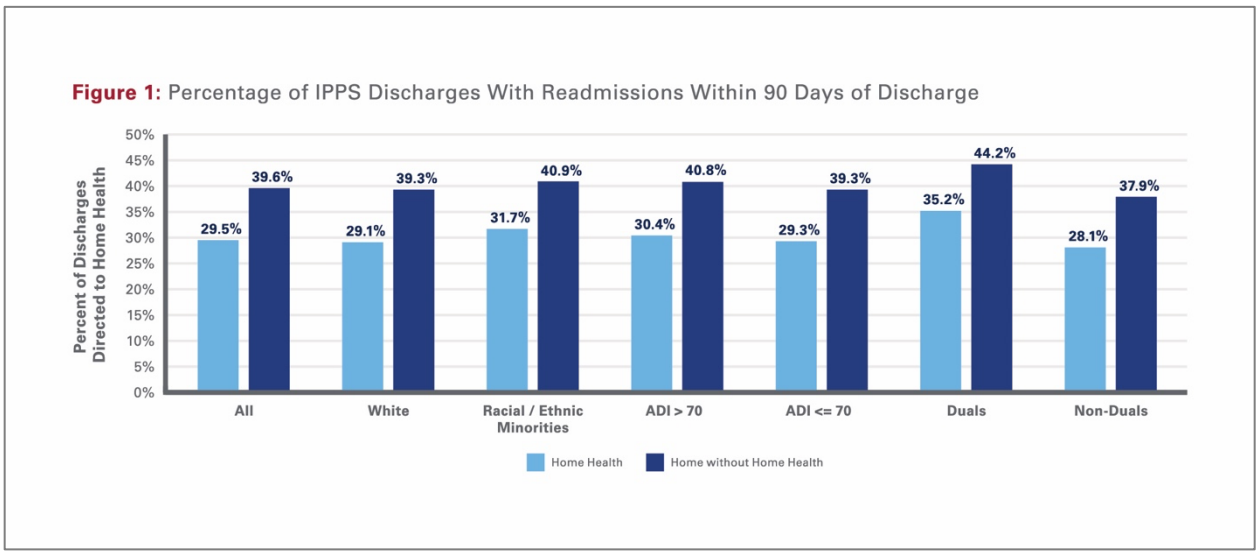
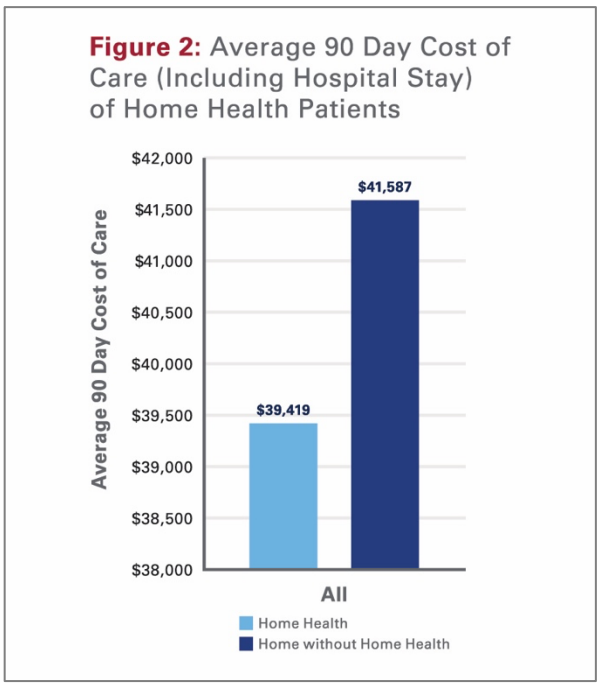
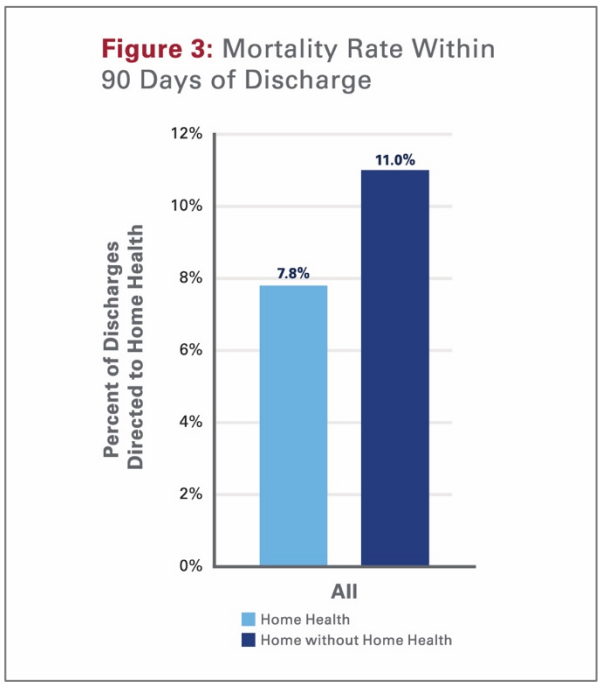
[1] MedPAC; July 2024 Data Book; Section 8, Pg. 107 (https://www.medpac.gov/wp-content/uploads/2024/07/July2024_MedPAC_DataBook_Sec8_SEC.pdf).
[2] CareJourney is a nationally recognized health care analytics platform.



Source: *CareJourney analysis of Medicare fee-for-service claims data, 2023 inpatient claim files filtered for inpatient PPS claims. Discharge data based on Q1-Q3 2023 data.*
ADI: *The University of Wisconsin Neighborhood Atlas Area Deprivation Index (ADI) allows for the rankings of neighborhoods by socioeconomic disadvantage in a region of interest (https://www.neighborhoodatlas.medicine.wisc.edu/)*

Further, even including the cost to Medicare for payments under the HH PPS, patients referred for and who received HH care have considerably lower costs than those discharged home without HH care. The timeliness of receiving such care is crucial to these outcomes. The average 90-day cost of care for beneficiaries who were referred and received HH care within seven days after discharge was 5.5% lower than those who were referred but did not receive HH care (see Figure 2). Finally, beneficiaries who were referred and received HH care within seven days of discharge had a 40% lower mortality rate than those who were referred but did not receive HH care (see Figure 3).





***Source**: CareJourney analysis of Medicare fee-for-service claims data, 2023 inpatient claim files filtered for inpatient PPS claims. Discharge data based on Q1-Q3 2023 data.*

As demonstrated above, HH agencies are crucial to the ongoing recovery of hospitalized beneficiaries. Indeed, as our member hospitals strive to ensure the best patient outcomes, they rely on HH care as an essential partner. Without the availability of these providers, they would be forced to keep patients in the hospital longer than would otherwise be necessary or discharge them to sub-optimal locations.

HH Providers Continue to Face Financial and Operational Challenges

Unfortunately, like many providers, HH agencies have faced ongoing financial and operational difficulties in recent years. Employee and labor costs continue to strain providers. A recent report from the AHA finds that hospital employee compensation has grown by 45% since 2014.[3] This contrasts with total inflation, which only grew by 28.7% in that time according to the Consumer Price Index for All Urban Consumers (CPI-U). While these figures represent hospital costs, HH agencies share much of the same labor pool, including nurses, nurse assistants, therapists, technicians, and other clinical and non-clinical staff. A severe workforce shortage, which the Department of Health and Human Services (HHS) says will persist well into the future, has driven, in large part, this labor-related inflation, and consulting firm McKinsey & Company has found that

[3] American Hospital Association; *America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities*; April 2024 (https://www.aha.org/system/files/media/file/2024/05/Americas-Hospitals-and-Health-Systems-Continue-to-Face-Escalating-Operational-Costs-and-Economic-Pressures.pdf).

resignations per month among health care workers grew 50% from 2020 through 2023.[4,5]

Drug and supply costs also have pressured provider operations due to disruptions in the supply chain and other factors. In fact, HHS found that prices for nearly 2,000 drugs increased an average of 15.2% from 2017 through 2023, notably faster than the rate of general inflation.[6] Further, the American Society of Health System Pharmacists has found that numerous drug shortages are having a critically negative impact on hospital operations.[7] While these figures, again, pertain to hospitals, HH agencies must procure many of the same drugs as hospitals and depend on a wide range of other medical supplies and equipment.

These escalating costs for essential clinicians, personnel, drugs, supplies and other items have strained the entire health care continuum. In all, consulting and data analytics firm Kaufman Hall found that overall expenses have risen 18% for hospitals compared to 2021, a figure that is consistent with concerns shared by our HH agency members.[8] **Unfortunately, these substantial cost increases have come while market basket updates in the HH PPS have fallen well short of actual inflation.**

Market Basket Updates Have Failed to Keep Up with Inflation

During this period of significant cost growth, Medicare payment updates for HH agencies have shown a consistent pattern of failing to both forecast inflation correctly and eventually capture this cost growth. In fact, despite the high rates of medical inflation, HH agency payments have not even kept up with general inflation. **CMS should therefore closely evaluate its current forecasting and market basket practices for further refinement.**

Specifically, since 2021, CMS' market basket forecast contractor, IHS Global Inc. (IGI), forecasted growth for the HH market basket has shown a consistent trend of under-forecasting actual market basket growth. As demonstrated below, there have been four consecutive years of missed forecasts to HH agencies' detriment, beginning in FY 2021. **Based on the market basket adjustments alone, this has resulted in underpayments to HH agencies of more than four percentage points. Combined with the productivity adjustments, this rises to more than five percentage points.**

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[4] ASPE Office of Health Policy, *Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce*, HP-2022-13 at 1 (May 3, 2022).
[5] McKinsey & Company. (Sept. 2023). How Health Systems and Educators Can Work to Close the Talent Gap. https://www.mckinsey.com/industries/healthcare/our-insights/how-health-systems-and-educators-can-work-to-close-the-talent-gap
[6] ASPE. (Oct. 2023). Changes in the List Prices of Prescription Drugs, 2017-2023. https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs
[7] https://news.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf
[8] https://www.kaufmanhall.com/sites/default/files/2024-05/KH-NHFR_2024-04.pdf

While AHA is cognizant of the fact that forecasts will always be imperfect, in the past, they have been more balanced. With four straight years of under-forecasts, the AHA is concerned that there is a more systemic issue with IGI's forecasting.

Table 1: HH Market Basket Updates, FYs 2021-2024

Year	FY 2021	FY 2022	FY 2023	FY 2024	Total
Market Basket Update in Final Rule	2.3%	3.1%	4.1%	3.3%	12.8%
Actual/Updated Market Basket Forecast	3.0%	5.7%	4.8%	3.5%	17.0%
Difference in Net Market Basket Update and Actual Increase	**-0.7%**	**-2.6%**	**-0.7%**	**-0.2%**	**-4.2%**

These missed forecasts have a significant and permanent impact on providers. At current levels, a cumulative underpayment of 4.2 percentage points totals approximately $700 million in underpayments annually. Further, as CMS knows, future updates are based on current payment levels. Therefore, absent action from CMS, these under-forecasts are permanently established in the standard payment rate for HH agencies and will continue to compound. They also influence other payments, including the growing Medicare Advantage patient population, and commercial insurer payment rates.

In addition to inaccurate forecasts, the underlying market basket itself may have shortcomings that fail to properly capture growth**.** As explained above, there has been very large growth in providers' costs in the last several years. This has even exceeded general inflation which totaled 16.8% from 2021 to 2023 according to the CPI-U.[9] However, even the actual market basket growth (not forecasts) totaled only 12.8% during this time. **It is confounding to AHA how providers with labor-intensive services could have a change in the market basket that is significantly below general inflation. Consequently, AHA urges CMS to evaluate and refine its approach to market basket forecasts and the underlying construction of the market basket. Doing so would ensure continued access to HH for Medicare beneficiaries.**

Behavioral Adjustments Exacerbate Financial Difficulties and Threaten Access to Care

[9] https://www.bls.gov/regions/mid-atlantic/data/consumerpriceindexannualandsemiannual_table.htm

Like previous years, CMS is proposing to impose additional permanent reductions to the base payment rate for HH agencies due to the Patient-Driven Groupings Model (PDGM). Specifically, CMS proposed applying an additional 4.1% permanent reduction to the HH base payment rate to account for overpayments from 2020 to 2023. This is in addition to the nearly 10% reductions already applied and those it intends to apply in future years. **These reductions, combined with the current inflationary environment and lagging market basket updates, threaten to disrupt access to HH care and bring further consequences to the entire continuum of care. As such, the AHA strongly urges CMS to withdraw its proposed adjustments.**

To begin, the AHA reiterates its staunch opposition to CMS' approach to applying PDGM budget neutrality adjustments. As we have previously shared the AHA's detailed objections in prior years' comment letters, we will not repeat them in full in this letter. However, among other disagreements, we continue to believe the adjustments are based on a flawed methodology that does not accurately account for shifts in care delivery and utilization under the new payment system and does not accurately compare hypothetical payments under the old payment system to those under PDGM. The result is that CMS overestimates the difference in overall spending between the old and new payment systems, leading to much higher than appropriate budget neutrality adjustments. **We continue to urge CMS to reverse course and instead appropriately calculate these adjustments as described in our past letters.**

Beyond the flawed methodology, the impact of these behavioral adjustments, combined with the previously discussed inflation and market basket shortcomings, is eroding beneficiary access to HH agency care. For example, while CMS has cited Medicare Payment Advisory Commission (MedPAC) findings that HH agencies maintain high margins, those same analyses have found extremely negative margins for hospital-based HH agencies. Indeed, MedPAC most recently found that hospital-based HH agencies had a fee-for-service Medicare margin of *negative 17%*.[10] Further highlighting the eroding access to care, and as CMS noted in the proposed rule, HH periods of care and unique beneficiaries have been declining since 2020.[11] In addition, the percentage of patients referred to HH agencies and were discharged home that began HH care within seven days of discharge has decreased from 62.6% in 2022 to 61.8% in 2023, leaving more than a third of patients with no post-acute care. Further, only half of the beneficiaries referred to HH begin care within the critical three days following discharge.[12]

CMS' cuts have not only disrupted HH agencies and their patients but also acute-care

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[10] MedPAC; March 2024 Report to Congress. Chapter 7: Home health care services, pg. 219 (https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch7_MedPAC_Report_To_Congress_SEC.pdf).
[11] *Proposed Rule* at 55,319.
[12] CareJourney analysis of Medicare fee-for-Service claims data, 2023 inpatient claim files filtered for IPPS claims. Discharge data based on Q1-Q3 2023 data.

hospitals. As HH agencies lose capacity, acute-care hospitals proportionately lose their ability to discharge patients to HH care. This, in turn, forces them to board patients ready for discharge, driving up costs and minimizing capacity to admit new patients. Indeed, AHA members report increasing difficulty finding HH placement for their patients. For example, an analysis from WellSky found that the average length of stay in the hospital for patients discharged to HH increased from 5.4 days in 2019 to 6.2 days in 2022.[13] In addition, Trinity Health at Home, a large national system that tracks its referrals to HH found that in the first six months of 2019, 7% of their referrals were non-admissions due to "Unable to Staff." However, during that same six-month period in 2024, non-admissions due to "Unable to Staff" had tripled to 22% of their referrals.

HOME HEALTH QUALITY REPORTING PROGRAM

Proposed Adoption of Four New Standardized Patient Assessment Data Elements

Beginning with the CY 2027 HH Quality Reporting Program (QRP), CMS proposes to require HH agencies to report four new standardized patient assessment data elements (SPADEs) under the social determinants of health (SDOH) domain. In its proposal, CMS states that the new SPADEs address HRSN not already captured by the existing SDOH elements including food security, living situations and utility difficulties. The AHA shares CMS' goal of advancing health equity and recognizes the value that screening for HRSNs can play in identifying barriers to achieving the best outcomes for all patients. However, we are concerned that the proposed new SPADEs are not well-aligned with similar HRSN reporting requirements across the care continuum. We also believe the proposed SPADEs need further testing and refinement to ensure they work as intended in the SNF setting.

In its proposal, CMS states that it believes these new requirements would "further standardized the screening of SDOH across quality programs," citing the recently adopted quality measures in the Inpatient and Inpatient Psychiatric QRPs that assess whether facilities have screened patients for housing instability, food insecurity, utility difficulties, transportation needs and interpersonal safety. Indeed, CMS states that it believes "using common standards and definitions for new items is important to promote interoperable exchange of longitudinal information between HH agencies and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process." The agency recently finalized the adoption of these SPADEs in the skilled nursing facility, long-term care hospital and inpatient rehabilitation facility programs; thus, we anticipate that CMS will finalize this proposal as well. However, we would like to reiterate some of our thoughts on the elements raised in comments on the FY 2025 proposed rules as they were not addressed in those final rules.

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[13] WellSky Market Insights, July 2024.

While the proposed SPADEs address some of the same HRSNs addressed by the screening quality measures (but not all, like interpersonal safety), the proposed requirements are hardly standardized with those in the Inpatient and Inpatient Psychiatric Facility QRPs. The proposed SPADEs are adapted from the Accountable Health Communities (AHC) HRSN Screening Tool developed for the AHC model; CMS is dictating precisely when and how HH agencies are to assess patients for these HRSNs (that is, asking questions with specific wording during the initial admission assessment). However, inpatient acute care hospitals and psychiatric facilities may use any "standardized HRSN screening" and are only asked to document that a patient was screened, not when or how. In other words, these proposals are unlikely to produce the interoperable data CMS apparently believes they will.

Further, the AHA raises some concerns with the elements themselves. In implementing the AHC HRSN screening tool in the AHC model, CMS directs users to follow particular protocols to determine a patient's eligibility for completing the tool, select domains for use in their communities, and score patient responses to determine the next steps. In this proposed rule, CMS merely picks a few questions from the tool and plants them in the OASIS without much guidance. The AHA is concerned that it will be challenging to glean accurate responses to the AHC items from the HH patient population in particular, considering that HH patients and residents are generally more ill than the average Medicare beneficiary for which the screening tool was developed. For example, the food security questions ask patients to rate the frequency of food shortages using a three-point scale, whereas other questions on the OASIS, such as the resident mood (PHQ-9 tool), behavioral symptoms and daily preferences items, use a four-point scale to determine frequency. These discrepancies may make it difficult for staff to administer the SPADEs, and, given the inconsistency with the scales used in other OASIS items, it may lead to confusion for staff and patients alike. In addition, there is no skip logic included for these questions as there are for other OASIS items. For example, it is unlikely that a patient receiving HH services in their home would respond that they do not have a stable place to live; a referring practitioner would consider that when deciding whether HH services are the appropriate next step for the patient.

Overall, the AHA questions the utility of including these items in the OASIS. While we agree that HH agencies — and other health care providers and facilities — should consider their patients' and residents' HRSN in their care, CMS' evaluation of the use of the AHC HRSN screening tool in the model showed that it "did not appear to increase beneficiaries' connection to community services or HRSN resolution." At a minimum, we believe the proposed new SPADEs need further testing and clearer implementation guidance before CMS adopts them for the HH QRP.

Lastly, we request that CMS articulate its vision of how HRSN information collected in the SPADEs will be used in its quality and payment programs. While CMS appears to be focused for now on HRSN screening, there is evidence that CMS is considering even farther-reaching approaches to holding HH agencies and other health care providers accountable for addressing HRSNs. For example, CMS is also considering measures

that assess connections to community providers and the resolution of HRSNs following care. We believe those measures would inappropriately hold HH agencies and other health care providers solely accountable for social drivers of health that require resources and engagement across an entire community to address. We are concerned that CMS may implement such measures in the HH QRP in the future, using its SPADE collection process as the mechanism to collect measure data. Holding HH agencies solely accountable for community-based outcomes is far outside of the scope of these facilities.

Long-term Care Data Reporting Proposed Requirements. CMS proposes to continue and expand some of the reporting requirements regarding respiratory viruses that were finalized in November 2021 but are set to expire for LTC facilities at the end of 2024. Specifically, CMS would revise the Medicare Conditions of Participation (CoPs) around infection prevention and control for LTC facilities to require weekly reporting of specific information related to COVID-19 as well as influenza and RSV to the National Healthcare Safety Network (NHSN) beginning Jan. 1, 2025. CMS is also interested in the utility of additional reporting on limited demographic data and seeks feedback on whether data collection regarding race, ethnicity and socioeconomic status should be explicitly included as part of these proposed requirements for ongoing reporting. Finally, CMS proposes that during a declared national, state or local public health emergency (PHE) for respiratory infectious disease (or if the Secretary determines a significant threat for one exists), LTC facilities may be required to report additional and/or modified data elements at a higher frequency without additional notice and comment rulemaking.

The AHA's members understand the potential value of selected data on acute respiratory illnesses to inform public health efforts. However, as the AHA noted in 2020 and again in 2022 and earlier this year in response to a similar proposal for hospitals, the use of CoPs to compel hospitals and LTC facilities to share data with the federal government is both needlessly heavy-handed and inconsistent with the intent of CoPs. Furthermore, we are troubled by the potentially unlimited scope of data reporting that CMS could require of LTC facilities during PHEs and ill-defined events the Secretary deems "significantly likely" to become a PHE. Rather than jeopardizing LTC facilities' Medicare participation status through CoPs, **the AHA urges CMS, HHS and the Centers for Disease Control and Prevention (CDC) to invest in the infrastructure needed to make the voluntary sharing of important data on infectious diseases less burdensome and more meaningful**. This investment should go hand-in-hand with a collaborative effort involving multiple stakeholders to chart a sustainable path forward.

This proposed permanent CoP appears part of a troubling trend of CMS using CoPs to achieve policy goals that do not always have a direct and clear link to health and safety standards in health care facilities. The AHA fully understands the potential value of LTC facility data on acute respiratory illnesses to inform broader public health preparedness efforts, but we do not believe that CoPs are either the appropriate or optimal way to achieve this goal.

The AHA also is concerned by how little of the proposed policy would be subject to the notice and comment rulemaking process. This raises questions about how LTC facilities could ensure ongoing compliance and CMS' authority to implement the CoP. Based on the information provided in the proposed rule, the Secretary would grant him or herself the authority to change significant aspects of the rule, like the frequency and format of mandated reporting, seemingly on a whim. For example, while the proposed rule preamble suggests that LTCs would be expected to report the data weekly, the proposed regulatory text at 42 CFR 483.80(g)(1)(i) simply reads that LTCs must report the data "in a standardized format and frequency specified by the Secretary." Furthermore, the Secretary would seemingly grant the authority to expand the set of respiratory illnesses that LTCs would be required to report. To wit, the proposed regulatory text at 42 CFR 483(g)(1)(B) would require LTCs to report "resident vaccination status for a limited set of respiratory illnesses, *including by not limited to the following."* (emphasis added). The proposed rule fails to articulate specific legal authority or other justification that would support making these types of changes outside of the rulemaking process. The proposed policy is inconsistent with the approach CMS uses in its quality measurement programs in which CMS regularly updates reporting requirements — including specific measures, reporting mechanisms and timeframes — through notice and comment rulemaking, and appropriate updates to regulatory text in the Code of Federal Regulations. The quality reporting programs also specifically articulate definitions of substantive versus non-substantive changes to quality measures and articulate both what changes are subject to notice and comment rulemaking, and which ones it would address using sub-regulatory processes such as website updates, listserv announcements and so forth.

Although the Secretary had the flexibility to adjust the frequency and format of the COVID-19 PHE data reporting required under the CoP in section 483.80(g), that flexibility was due to multiple emergency declarations made by the Secretary and the President. With the termination of those emergency declarations and the end of the COVID-19 PHE, we are very concerned that leaving the "form, manner and timing" up to sub-regulatory processes may be inconsistent with the Administrative Procedures Act and other statutes governing agency actions. Presumably, CMS intends to issue interpretive guidance to inform the implementation and enforcement of the regulation. Yet, interpretive guidance is not a substitute for clear, specific requirements in regulatory text. Interpretive guidance is intended to advise the public and providers of the meaning of the regulation. By omitting critical details of the implementation of the proposed CoP, we are concerned that CMS would be implementing the CoP in a manner inconsistent with the APA's intent to ensure that regulated entities have adequate and predictable notice of their responsibilities.

In the short term, we recommend that CMS and CDC instead adopt a voluntary reporting process to accept acute respiratory illness data from LTC facilities. The agencies could retain the NHSN platform for data reporting while adopting the streamlined reporting fields the agency has proposed. This approach would minimize

disruptions to LTC facility processes while also taking away the specter of losing the ability to participate in Medicare if they were to miss a week of reporting.

As noted above, the AHA does not support CMS' proposed CoPs. However, if the agency is intent on implementing a CoP, we offer several recommended changes. First, we urge CMS to allow LTC facilities to report a snapshot of data once per week rather than cumulative totals. Indeed, under the sunsetting CoP, CMS and CDC reduced the reporting frequency to once per week in a well-intentioned effort to reduce the burden for facilities. However, the agency still expected facilities to report relevant data fields from each day of the week. As a result, facilities found that the reduction in the reporting frequency did not reduce their administrative burden as much as hoped. As we understand it, CMS' intent with the proposed CoP is to get periodic insights into acute respiratory illnesses in the community by using LTC facility data as a proxy or indicator. We believe this can be achieved by asking LTC facilities to report data from a single day of the week, which CMS and CDC could then track over time to discern trends.

The AHA appreciates CMS taking steps to streamline the data elements it would require LTC facilities to report. Yet, the proposed rule lacks enough specificity in some places to understand exactly what data the facilities would be expected to report. If CMS adopts the CoP, we urge the agency to provide more detailed information in the final rule. For example, when CMS indicates it wants to collect "limited patient demographic data," we assume that reporting would look like the process used under the expired CoP in which LTC facilities reported patient counts by several broad categories of age (e.g., 18-19, 20-29, 30-39, etc.).

Lastly, we oppose CMS' proposal to allow ramped-up reporting requirements and frequency during events "significantly likely" to become a PHE. The AHA is not aware of any legal standard for a "significantly likely" PHE nor is there any statutory or other authority allows the Secretary to change mandatory reporting requirements based on a "significantly likely" PHE. The AHA is concerned that this language would become a vehicle to introduce new reporting requirements — or ramp up reporting frequency — on an arbitrary basis that is not subject to notice and comment rulemaking. Indeed, it is troubling that CMS seeks comments on what constitutes "substantially likely" rather than proposing concrete criteria in the rule itself. Furthermore, as described above, PHE has a specific meaning in statute and regulation, and the declaration of a PHE conveys significant flexibilities and powers intended to expedite the regulatory process. We would be deeply troubled by the precedent of CMS or any other federal agency using such a vague categorization to circumvent the notice and comment rulemaking process. We urge CMS not to finalize this proposal.

Collection of Race, Ethnicity and Social Driver of Health Data. As noted above, CMS also is interested in whether it should mandate the reporting of data "on additional demographic factors including socioeconomic or disability status that may be associated with disparities in outcome." The agency indicates that it "may decide to finalize a policy

of collecting demographic information on race/ethnicity and/or additional factors" based on public comment.

We appreciate that CMS chose not to adopt more detailed demographic data reporting requirements for the acute respiratory illness reporting requirements for hospitals and CAHs finalized in the FY 2025 inpatient PPS final rule. We believe the agency should follow suit for LTCs. The AHA's members share CMS' goal of advancing health equity. At the same time, as CMS itself acknowledges, federal standards for the collection of race and ethnicity data are undergoing a significant overhaul. On March 28, the Office of Management and Budget (OMB) issued an updated Statistical Policy Directive 15 (SPD-15) that governs how federal agencies collect and use race and ethnicity data in their programs, the first update since 1997. OMB made several groundbreaking changes to the guidance such as consolidating race/ethnicity into a single question, adding a new category for Middle Eastern and North African individuals to identify themselves, and establishing new minimum and detailed categories for each race/ethnicity field. Federal agencies have been given until October 2025 to develop their plans to comply with these new standards and until March 2029 to come into full compliance.

We would anticipate that like other agencies, CMS is undertaking a thoughtful and thorough process to review and standardize its approaches to collecting race and ethnicity data across all of its programs to bring them into compliance with the new guidelines. We are concerned that adopting race and ethnicity data collection as part of this CoP too soon would rush what should be a measured and careful process. We also would be concerned with CMS adopting a set of requirements that could then rapidly change as the rest of the agency's plan comes into place. To be clear, the reporting of these data would constitute a significant change to LTC facility workflows and would add considerable administrative effort. If CMS were to pursue such reporting, its approach to doing so would need to be stable.

As a practical matter, we also believe there are numerous and complex issues that CMS would need to sort through for the reporting of race, ethnicity or other patient self-reported data demographic or social driver of health data. For example, some individuals prefer not to report their race or ethnicity to health care facilities. Some patients also may not wish to share information about their sexual orientation, gender identity or living situation. CMS does not articulate in the proposed rule an approach for honoring the choices of patients who may choose not to share these data while also not penalizing LTC facilities for not reporting "complete" data.

Furthermore, it is not clear what level of data CMS is seeking. For example, is the agency seeking aggregate data on the race/ethnicity of patients with confirmed infections? If it is aggregate-level data, CMS would need to consider how to protect patient confidentiality in LTC facilities where there may be small numbers of a particular race or ethnicity. If CMS is considering the reporting of patient-level data, such reporting would introduce even more questions about how to protect and deidentify patient data

and whether the CDC's reporting systems have the capacity to securely accept such data.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Jonathan Gold, AHA's senior associate director for policy, at (202) 626-2368 or jgold@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development