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CMS 1689-P: Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 900 hospital-based home health (HH) agencies, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2019 proposed rule for the HH prospective payment system (PPS). Specifically, this letter addresses the proposed payment reforms for CY 2020, quality reporting changes, requests for information, and the home infusion therapy provisions.

The AHA appreciates the multi-year effort by CMS to develop an alternative to the current HH case-mix system. In addition, we support the move from the current system's over-reliance on setting payments based on therapy volume to a new model that would base payments on a broader clinical profile of the patient. **Overall, we support the proposed reform model, now known as the patient driven groupings model (PDGM), as it is projected to improve payment accuracy for hospital-based HH agencies that treat a disproportionately large population of medically complex cases and, on average, operate with a substantially negative Medicare margin. However, given our concerns with the PDGM, especially the proposed behavioral adjustment, we urge CMS to continue to refine the model,** which would enable compliance with the HH reform

timeline mandated by the Bipartisan Budget Act of 2018 (BiBA), as well as ensure that the final PDGM reflects the best possible approach to improve HH PPS payment accuracy.

THE PDGM REQUIRES ADDITIONAL REFINEMENT

The PDGM approach of basing payment on five case-mix elements is clearly far more complex than the current HH PPS's approach that uses patients' therapy utilization as a key determination of payment. While we understand and support this effort to increase payment accuracy by basing payment on patients' comprehensive clinical profiles, the transition to such a multifaceted model will be monumentally complex. At this time, the provider community is striving to understand how their mix of patients would fare under the new payment structure and struggling to plan for the extensive operational changes that will be needed to adapt to PDGM.

Proposed PDGM Behavioral Adjustments. Under the BiBA legislation, CMS is required to ensure that aggregate PDGM expenditures in CY 2020 would be equal to CY 2020 payments under the current case-mix system. The transition to a 30-day unit of payment also must be accomplished in a budget neutral manner. As such, the rule discusses these proposed behavioral assumptions for CY 2020:

- Clinical Group Coding: Since PDGM payments would, in part, be set by the diagnosis code on the HH claim, CMS assumes that HH agencies would change documentation and coding practices to put the highest paying diagnosis as the principal diagnosis code.
- Comorbidity Coding: Using the diagnoses reported on the HH claim, PDGM's comorbidity adjustment could increase payments by up to 20 percent. CMS assumes that by taking into account the 24 secondary diagnosis codes listed on the claim, instead of the six OASIS diagnosis codes, more 30-day periods of care would receive a comorbidity adjustment than before.
- Low-utilization Payment Adjustment (LUPA) Threshold: CMS notes that, consistent with current practice, about 1/3 of the episodes near the LUPA threshold would provide 1 to 2 extra visits to qualify for a full 30-day payment.

The rule estimates that, collectively, these behavior changes would require a -6.42 percent adjustment to CY 2020 payments to ensure budget neutrality.

Precedents Show History of Inaccurate Prospective Behavioral Adjustments. There are several pertinent, prior behavior adjustment approaches that are instructive to CMS, as it considers stakeholder input on this rule and prepares the final rule. First, the shift of the inpatient PPS to Medicare Severity Diagnosis Related Groups (MS-DRGs) in fiscal year (FY) 2008 demonstrates that the proposed, single-year -6.42 percent behavioral adjustment is misguided and unwarranted due to its prospective nature and its scale. In that instance, CMS initially implemented a -4.2 percent adjustment to be applied over three years (-1.2 percent in FY 2008 and -1.8 percent in both FYs 2009 and 2010) – annual adjustments

that fall far short of the large, one-time adjustment that CMS proposes for the CY 2020 HH PPS. In fact, subsequent to that final rule, to ensure a more fair and evidence-based adjustment, Congress intervened to instead mandate that prospective cuts be phased in over a three year period, but with a lower aggregate amount per year, coupled with a subsequent retrospective cut based on actual claims history.

In addition, to illustrate the limitations of prospective behavioral adjustments, we note that significantly inaccurate adjustments were made when the HH PPS was implemented in 2000. In that case, the Congressional Budget Office (CBO) used behavioral assumptions and other factors to estimate that HH PPS implementation would reduce Medicare spending on HH services by $49.6 billion from 1998 through 2007, but the actual reduction for that period was far greater – $210.4 billion. In other words, the field's behavioral response was underestimated by CBO and the result was the closure of approximately 2,000 HH agencies, which led to 500,000 fewer HH users in 2007 compared to 1997.

Finally, we turn to a recent example that illustrates how the proposed 6.42 percent offset is inconsistent with the approaches used by CMS for similar payment system reforms. Specifically, we note that the FY 2020 skilled nursing facility (SNF) PPS reforms finalized by CMS last month, which represent an equally transformative PPS redesign, are to be implemented with *no* behavioral adjustment. Instead, the agency will consider any behavioral adjustment at a future date based on actual claims data. The proposed restructuring of the HH PPS is similar in complexity to the overhaul of the SNF PPS – both provider groups would shift from a therapy volume-driven payment structure to one that bases payment on a compilation of clinical factors. If anything, the addition of the 30-day episode change renders PDGM implementation even more complicated than the SNF redesign, and therefore even more suitable for waiting until claims are available to provide a basis for an accurate behavioral adjustment.

Given the track record of inaccurate prospective behavioral adjustments and examples demonstrating the excessive scale of the proposed single-year offset, we urge CMS to withdraw its proposed behavior adjustment. Instead, we urge CMS to, in the future, calculate a PDGM behavior adjustment that is based on actual experience under the new model, as demonstrated by claims data. Further, consistent with these precedents, any behavioral offset amount that exceeds 2.0 percentage points should be phased in over multiple years so that no single year's adjustment exceeds 2.0 percent.

Proposed Rule Lacks Key Details. In addition to PDGM's new case-mix approach, providers also must analyze the effect of transitioning from a 60-day to a 30-day episode, the concurrent change also mandated by Congress. Adapting to a new episode length exponentially raises the difficulty of the PDGM transition. In fact, our members report that shifting from a 60-day to a 30-day episode would change how providers manage patient assessments, clinical care decisions, and financial operations. We note these new policies not only limit providers' ability to accurately project their actual PDGM case-mix and payment profile, it also hampers

policymakers attempting to project how PDGM will impact provider behavior. In addition, while we appreciate the detail provided in the rule to explain each of the three elements of this proposed behavioral adjustment, we find the explanation to lack key elements. These include lacking a description of the rationale for these particular offsets, lacking details regarding the data and methodology used to calculate them, and lacking any discussion of other potential behaviors that were examined but not included. As such, we are unable to meaningfully comment on CMS's proposed methodology.

The PDGM Must Fully Account for Medically-complex Cases. While we support the direction of the PDGM reforms, we are concerned that the PDGM is based on regression analyses using data that reflect a payment environment with limited access to care for patients needing complex nursing, non-routine medical supplies, and other services commonly used by higher-acuity HH patients. The access problem for this subgroup has been noted by the Medicare Payment Advisory Commission (PAC) over the years, and underpayment for the high-cost outlier portion of these cases is recognized by CMS. As these types of patients are treated in greater proportion by hospital-based agencies, we are particularly concerned that due to prior access barriers, medically-complex cases are under-represented in the data used to build the PDGM. Yet, this significant data shortcoming and any related mitigation efforts have not been discussed in the rule. **We urge the agency to use the final rule to address how the model accounts for the costs associated with the medically-complex patients and services that are under-represented in existing claims data.**

Ensuring that PDGM Improves Payment Accuracy. We share the concerns raised by other stakeholders' analyses showing that the model may actually reduce Medicare margins for agencies that already have low and negative margins, and we support their call for CMS to share its evidence that the new model will actually increase payment accuracy to these agencies, which include hospital-based providers, and the field as a whole. In particular, we seek a response from CMS to these partners' independent analysis showing that 22 percent of agencies with below-average Medicare margins (defined as less than or equal to 15 percent) would be paid less under PDGM than under the current model. Collectively, these findings question whether the re-distribution of funds under PDGM would actually improve the HH PPS's payment accuracy for either the overall or limited-access patient populations. As another example of these concerns, it appears that the changes in margins under PDGM are highly varied relative to the current distribution, and follow no clear pattern. In contrast, today we can point to high-therapy cases having a positive margin; yet, under PDGM, there is no discernable clinical, acuity, or other pattern distinguishing high-margin cases from low-margin cases. We urge CMS to address these findings in the final rule as well as the steps being taken by the agency to prevent any such detrimental outcomes, as well as related destabilization of the field.

Taken together, these facts cast doubt on the current readiness of PDGM. As such, we urge CMS to continue to refine the model to address these concerns, and, in doing so, to partner with the field to find solutions to ensure accurate HH PPS payments in CY 2020.

CONSIDER TECHNICAL EXPERT PANEL (TEP) RECOMMENDATIONS ON MMTA

As CMS continues to refine the PDGM, we recommend the agency consider using a TEP – similar to when it developed the SNF PPS reform model. In fact, the SNF model was developed using three TEPs. While these TEPs on their own did not provide the full degree of transparency and collaboration sought by the field, they were still a very worthwhile investment by CMS and the field. They allowed CMS and stakeholders to discuss in depth key design elements of the model prior to rulemaking. Further, the input from the field, in response the advance notice of proposed rulemaking on the new SNF model in 2017, led to additional meaningful improvements prior to rulemaking this year. This incorporation of stakeholder input stands in stark contrast to this proposed rule, which proposes a model that only includes marginal adjustments to the initial iteration, which was proposed and then withdrawn during the CY 2018 rulemaking process.

We recognize and appreciate the adoption of the winter 2018 TEP recommendation to amend the comorbidities element of the case-mix system to recognize the greater costs associated with treating patients with multiple comorbidities. In addition, this change resulted in 216 possible case-mix groups for the purposes of adjusting PDGM payments, an expansion from the 144 case-mix groups in the initial iteration of the reform model, which also aligns with a TEP recommendation. However, we note that the TEP issued many further recommendations that were not acted upon by CMS – in fact, the PDGM looks quite similar to its predecessor, which leaves room to improve PDGM. For example, the structure of one of the diagnostic categories in PDGM's clinical grouping element – the medication management, teaching and assessment (MMTA) category –warrants further consideration. Specifically, it appears that this diagnostic category is too large as it accounts for nearly half of 30-day episodes – a seemingly overly concentrated subgroup of HH cases. We encourage reconsideration of the TEP recommended MMTA subgroups to allow for greater payment accuracy. These include: surgical/procedural aftercare; cardiac/circulatory; endocrine; infectious /blood forming diseases/neoplasms; respiratory; and other.

Moving forward, given the complexity of the PDGM and the SNF PPS reform precedent of three TEPs, we encourage CMS to convene additional TEPs to partner with stakeholders to continue to refine the model, which would provide a productive venue to address remaining design and implementation issues, including concerns related to the behavioral adjustment and MMTA subgroups. While we realize that Congress only required one TEP, there is no limit on additional panels, which would benefit CMS as it finalizes the model prior to implementation in CY 2020.

LOW UTILIZATION PAYMENT ADJUSTMENT (LUPA)

Under PDGM, LUPAs would be handled in a new way. Instead of four or fewer visits per episode triggering LUPA per visit payments, the LUPA threshold would fluctuate from two to six visits per payment group. CMS projects that the current rate of LUPA cases would drop from eight to seven percent under PDGM. Given that the field is expecting that agencies will struggle with planning for the LUPA element of the transition to new 30-day episode and case-mix system, combined with the typical underpayment for these cases, we ask CMS to consider maintaining the current single-threshold LUPA policy during the initial stages of PDGM implementation, which would mitigate the volatility anticipated for the rollout of this untested model.

REMOTE PATIENT MONITORING ADMINISTRATIVE COSTS

We support the rule's new definition of remote patient monitoring under the Medicare HH benefit, which would allow related administrative costs to be included on the HH agency cost report. Specifically, CMS proposes to define remote patient monitoring under the Medicare HH benefit as "the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HH agency." CMS states that although the cost of remote patient monitoring is not separately billable under the HH PPS and may not be used as a substitute for in-person HH services, it believes that the expenses of this monitoring, if used to augment HH care planning, should be reported on the cost report as an allowable administrative cost (operating expenses) that are factored into costs per visit.

We agree with the agency's position that for patients with chronic conditions, such as chronic obstructive pulmonary disease and congestive heart failure, the use of this technology results in lower mortality, improved quality of life, and reductions in hospital admissions. In addition, this proposed change is in line with AHA's broader position in favor of the expansion of patient access created by hospitals' efforts to deliver high-quality and innovative telehealth services. Specifically, we support:

- Expansion of Medicare coverage with adequate reimbursement that takes into consideration the nursing and other costs incurred at the site where the patient is located (the originating site). CMS also should include telehealth waivers in all its demonstration programs and adopt a more flexible approach to adding new telehealth services to Medicare.
- Resolution of legal and regulatory challenges that hinder the provision of telehealth services.
- Additional federal research to determine the cost-benefit of telehealth using larger sample sizes, diverse geographies, and a broader range of conditions and services.
- Improved access to broadband technology for rural areas by improving the Federal Communications Commission (FCC) Rural Health Care Program.

PROPOSED CHANGES REGARDING CERTIFYING AND RECERTIFYING PATIENT ELIGIBILITY

We support CMS's proposal to amend the applicable regulations to also allow medical record documentation from the HH agency to be used to support the basis for certification and/or recertification of HH eligibility, if the following requirements are met:

- The documentation from the HH agency can be corroborated by other medical record entries in the certifying physician's and/or the acute/post-acute care facility's medical record for the patient; and
- The certifying physician signs and dates the HH agency documentation demonstrating that the documentation from the HH agency was considered when certifying patient eligibility for Medicare HH services.

This change aligns with the BiBA mandate to allow, in CY 2019, the use of documentation in the HH medical record in addition to that in the certifying physician's (or of the acute or post-acute care facility) medical record.

PROPOSED ELIMINATION OF RECERTIFICATION REQUIREMENTS TO ESTIMATE THE DURATION OF HH SERVICES

We also support the proposed, burden-reducing elimination of the requirement that the certifying physician include an estimate of how much longer skilled services will be required at each HH recertification, as set forth in subregulatory guidance in the Medicare Benefit Policy Manual (Chapter 7, Section 30.5.2). This change would reduce the time spent by physicians for recertification without diminishing existing documentation requirements.

REQUEST FOR INFORMATION ON INTEROPERABILITY

In this proposed rule, CMS asks for input regarding the opportunity to further advance interoperability of health information through the creation of Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs) and conditions for coverage (CfCs) for other providers. **As explained in greater detail below, the AHA strongly opposes creating additional CoPs/CfCs to promote interoperability of health information.**

The AHA strongly supports the creation of an efficient and effective infrastructure for health information exchange. This is central to the efforts of hospitals and health systems and our other members, including HH agencies, to provide high-quality coordinated care, support new models of care, and engage patients in their health. However, we do not believe a new mandate tied to CoPs is the right mechanism to advance health information exchange.

However, the commitment of health care providers is not sufficient by itself to create interoperability. The technical and organizational infrastructure also must be available to allow for efficient exchange. Additionally, all parties must be using compatible technology in consistent ways. All of this must be achieved in a way that simultaneously allows the free flow of information to others who have a legitimate reason to have the information while protecting the information from hackers and others with nefarious intent. **We urge CMS to recognize the impediments to information sharing described below and address them directly. We do not believe that creating a CoP or CfC that would apply to only one set of actors is an appropriate strategy. Further, it is not clear that such requirements would have any greater impact on interoperability than the existing federal requirements to share information, but they could have unfortunate consequences for some hospitals and communities.**

Greater Availability of Health Information Technology (HIT) is Needed in the Post-acute Care Settings to Support Widespread Health Information Exchange. Sharing information across the continuum of care is a clear priority. Post-acute care providers were not included in the Electronic Health Record (EHR) Incentive Program yet have worked diligently to identify and deploy technology to support their care delivery and care coordination goals. However, challenges to attainment of this goal persist as post-acute providers vary in size and resources and have more limited options than acute care providers when choosing an EHR related to their size, locations and technology, and implementation costs. **The AHA recommends that CMS not implement a CoP/CfC to increase interoperability across the continuum of care because post-acute care providers were not provided the resources or incentives to adopt HIT, and creating this requirement would put another unfunded mandate on these organizations. Such a requirement would only be workable if all facilities were afforded the same opportunity to acquire certified EHRs that actually conformed to standards that enable the kind of interoperability CMS envisions.**

The Imposition of CoPs and CfCs has Practical Implications. CMS's CoPs/CfCs are taken seriously by health care providers because failure to comply carries a heavy penalty. Declaring a hospital or other provider to be out of compliance with the CoPs can be extremely disruptive for patients, providers, and communities, as it means that a hospital or other provider could be removed from these programs and would no longer be able to care for Medicare or Medicaid patients. The penalty of not meeting an interoperability CoP is too stringent, especially given that the journey towards interoperability is still underway. Moreover, use of the CoPs/CfCs to promote interoperability are misguided for the following reasons:

1. **CoPs/CfCs are requirements to ensure safe health care delivery, and care can be delivered safely without the interoperability of EHRs.** To the extent EHRs are capable of meaningful information exchange, hospitals and other providers are already using them. That said, it is not clear that a CoP or CfC would increase the feasibility of information sharing by these health care organizations. Since neither the CoPs nor the CfCs apply to government agencies, patients, or others with whom

hospitals and other providers would be trying to exchange information, we believe such requirements would have limited effect in promoting interoperability. **Instead, the AHA urges CMS to focus its attention on resolving problems created by the lack of a fully implemented exchange framework, adoption of common standards and incentives for EHR and other IT vendors to adhere to standards.**

2. **It is premature for CMS to consider imposing COPs/CfCs until the barriers to exchange have been addressed and all of those affected by the requirements can, in fact, achieve compliance.** Compliance is impossible when there is no commonly accepted operational definition of interoperability and no commonly accepted metrics for interoperability. While our latest data from 2016 show that 96 percent of hospital have a certified EHR, the uptake of EHR systems in other parts of health care is less robust because other care providers did not have the same incentives provided under the meaningful use program.

   Other barriers to interoperability include:

   - The information sent is not useful to recipients;
   - The workflow required to enter and send information from their EHR is cumbersome;
   - Identifying the correct patient between systems is difficult because there is no single patient identifier; and
   - Exchanging information across different vendor platforms is difficult.

   Almost half of respondents noted they experience greater challenges exchanging information across different vendor platforms, and more than one-third reported difficulty matching or identifying the correct patient between systems. Some provider organizations, particularly those that are small or that serve a large number of patients with limited insurance coverage, simply do not have the resources to invest in expensive EHR systems. Further, although the Office of the National Coordinator (ONC) was charged with developing standards for collecting information in EHRs so that they could be readily exchanged with other providers, those standards have yet to be consistently implemented. As a result, exchange across settings, such as between two hospitals or a hospital and a post-acute care setting or clinician office, remains very challenging.

3. **Modification of the CoPs/CfCs require clear and unambiguous evidence that compliance could be readily seen by a survey team charged with assessing the facility's compliance.** Health care organizations want to be in compliance with the CoPs/CfCs at all times. They view this as their obligation to the patients they serve. However, as there are no clear, common metrics of interoperability, the consequence of non-compliance – losing the ability to participate in Medicare and Medicaid – is too steep a penalty. We also are concerned about the costs of compliance.

The AHA urges CMS not to move forward with a plan to require interoperability as a CoP/CfC until such time as it is reasonably feasible to efficiently and effectively achieve such communication across the majority of providers delivering health care in a region. Instead, CMS should coordinate with ONC on implementation of the Trusted Exchange Framework and Common Agreement (TEFCA) and other steps needed to create the infrastructure that would support interoperability.

An Information Exchange Framework is Necessary to Assess Interoperability Across Settings. The AHA supports the advancement of and adherence to a framework for interoperability so that the technology and the rules governing the exchange of health information are universally and consistently implemented and the implementation can be clearly demonstrated. We strongly urge CMS and ONC to focus on creating the infrastructure for exchange and continuing to build toward consistent use of standards across vendor platforms. Any framework and common agreement should address, among other things:

- The minimum standards and implementation requirements that must be met to ensure efficient exchange, including standards to secure information;
- The permitted purposes for exchange;
- A clear understanding of the means to identify and authenticate participants of an individual exchange;
- A clear understanding of how the identity of individuals will be matched and managed across networks; and
- Assurance that each network will be transparent in the terms and conditions of exchange, including any technical prerequisites and costs of participating in exchange.

REQUEST FOR INFORMATION ON PRICE TRANSPARENCY

The AHA is committed to improving patients' access to information on the price of their care and, more specifically, on their out-of-pocket cost obligation. In general, advancing price transparency has been challenging for the health care system due to the inherent uncertainty in the course of disease and treatment, as well as the need to share data and information across multiple payers and providers. With respect to the need for enhanced price transparency, HH services are unique in that FFS Medicare does not charge beneficiaries any cost-sharing for this benefit. Therefore, we do not believe additional steps are needed to improve beneficiary access to pricing information for this benefit specifically. However, we recognize that patients receiving HH care may also be accessing related supplies, such as durable medical equipment (DME). In those instances, HH providers already assist their patients in understanding the co-payments associated with these supplies and will continue to do so. For more detailed comments on how to advance health care price transparency more broadly, we point CMS to our previous comments on this issue that we submitted as part of our response to the 2019 inpatient prospective payment system proposed rule.

HH QUALITY REPORTING PROGRAM (QRP)

The Deficit Reduction Act of 2005 required CMS to establish a program under which HH agencies must report data on the quality of care delivered in order to receive the full annual update to the HH PPS payment rate. Since CY 2007, HH agencies failing to report the data have incurred a reduction in their annual payment update factor of 2.0 percentage points. For the CY 2021 HH QRP, CMS proposes to update the measure removal criteria used to consider whether to retain measures in the HH QRP, and proposes to remove seven measures from the program.

The AHA appreciates CMS's commitment to its Meaningful Measures initiative, which can be seen in the thoughtful analysis and removal of seven measures from the HH QRP. We encourage CMS to continue to apply the measure removal criteria to other measures in the HH QRP, including the measure proposed for removal from the HH Value-based Purchasing (VBP) program.

CY 2020-2021 Measurement Proposals

Proposed New Measure Removal Factor for Previously Adopted HH QRP Measures. In previous rulemaking, CMS finalized factors to determine whether a measure should be removed from a QRP on a case-by-case basis. In this proposed rule, CMS proposes to replace the previously finalized criteria with the seven criteria, called "removal factors," which are used in other quality reporting programs. In addition, CMS proposes to add an eighth factor: "the costs associated with a measure outweigh the benefit of its continued use in the program." CMS defines "costs" as those affecting providers and clinicians as well as the costs to the agency associated with program oversight. The agency also reiterates that the measure removal evaluation process would continue to be done on a case-by-case basis, and measures that are considered burdensome or "costly" might be retained in the QRP if the benefit to beneficiaries justifies the reporting burden. **The AHA supports the alignment of measure removal criteria across QRPs, as well as the long overdue addition of the eighth measure removal factor.**

Proposed Removal of the Depression Assessment Conducted Measure. CMS proposes to remove this process measure from the HH QRP as it meets new measure removal Factor 1, "Measure performance among HH agencies is so high and unvarying that meaningful distinction in improvements in performance can no longer be made." The measure reports the percentage of HH episodes in which patients were screened for depression. CMS determined that the mean and median performance scores for this measure in 2017 were not only high (96.8 percent and 99.2 percent, respectively), but also demonstrated significant improvement since the measure's adoption in 2010 (88 percent and 96.6 percent, respectively).

If finalized, HH agencies would no longer be required to submit OASIS Item M1730 at start of care (SOC) and resumption of care (ROC) *for the purposes of this measure* beginning Jan. 1, 2020. In addition, data for the measure would no longer be publicly reported on *HH* Compare after Jan. 2021. However, this item is also used as a risk adjuster for several other OASIS-based outcome measures currently used in the HH QRP; thus, HH agencies would

have to continue to submit M1730 at SOC/ROC regardless. **The AHA supports the removal of topped-out measures from QRPs. However, because behavioral health is a key aspect of patient outcomes, we encourage CMS to consider how else mood may be assessed in the HH setting.** We appreciate that the agency has indicated that it is working to develop behavioral health stabilization measures for the HH QRP, and are eager to assist in this work.

Proposed Removal of the Diabetic Food Care and Patient/Caregiver Education Implemented During All Episodes of Care Measure. CMS proposes to remove this process measure from the HH QRP as it also meets removal Factor 1. The measure reports the percentage of HH episodes in which diabetic foot care and patient/caregiver education were included in the physician-ordered plan of care and implemented. CMS determined that the mean and median performance scores for this measure in 2017 were not only high (97 percent and 99.2 percent, respectively), but also demonstrated significant improvement since the measure's adoption in 2010 (86.2 percent and 91.7 percent, respectively).

If finalized, HH agencies would no longer be required to submit OASIS Item M2401 row a, and may enter an equal sign (=) in that space at the time point of transfer for an inpatient facility (TOC) and Discharge beginning on Jan. 1, 2020. In addition, data for the measure would no longer be publicly reported on *HH Compare* after Jan. 2021. **The AHA supports the removal of topped-out measures from QRPs. Because the removal of this measure would require a change in how the OASIS is completed, we encourage CMS to provide clear updates to providers about how they should complete items until the new version of OASIS-D is released.**

Proposed Removal of the Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate Measure. CMS proposes to remove this process measure from the HH QRP as it also meets removal Factor 1. The measure reports the percentage of HH episodes in which patients had a multifactor fall risk assessment at SOC/ROC. CMS determined that the mean and median performance scores for this measure in 2017 were not only high (99.3 percent 100 percent, respectively), but also demonstrated significant improvement since the measure's adoption in 2010 (94.8 percent and 98.9 percent, respectively).
If finalized, HH agencies would no longer be required to submit OASIS Item M1910, and may enter an equal sign (=) in that space at the time point SOC/ROC beginning on Jan. 1, 2020. In addition, data for the measure would no longer be publicly reported on *HH* Compare after Jan. 2021. **The AHA supports the removal of topped-out measures from the QRPs, and again encourages CMS to provide updates on changes to OASIS reporting. We also encourage CMS to more carefully consider whether to initially adopt measures when performance is already so high;** this measure (and others proposed for removal) had extremely high performance rates even before it was adopted, suggesting that its adoption was unlikely to lead to significant improvement.

Proposed Removal of the Pneumococcal Polysaccharide Vaccine Ever Received Measure. CMS proposes to remove this process measure from the HH QRP as it meets removal Factor 3, "a measure does not align with current clinical guidelines or practice." The

measure reports the percentage of HH episodes during which patients were determined to have ever received the Pneumococcal Polysaccharide vaccine. When the measure was adopted in CY 2010, it was specified based on the guidelines of the Advisory Committee on Immunization Practices (ACIP). The ACIP has since updated its pneumococcal vaccination recommendations, but the specifications for this measure were not updated to reflect these updates. If finalized, HH agencies would no longer be required to submit OASIS Items M1051 and M1056, and may enter an equal sign (=) in those spaces at the time point of TOC and Discharge beginning on Jan. 1, 2020. In addition, data for the measure would no longer be publicly reported on *HH* Compare after Jan. 2021. **The AHA supports the removal of this measure and appreciates that CMS has closely reviewed clinical guidelines in its measure removal consideration process.**

Proposed Removal of the Improvement in the Status of Surgical Wounds Measure. CMS proposes to remove this risk-adjusted outcome measure from the HH QRP as it meets removal Factor 4, "a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available." The measure reports the percentage of HH episodes of care during which the patient demonstrates an improvement in the condition of skin integrity related to surgical wounds. CMS notes that this measure is limited in scope to surgical wounds incurred by surgical patients and excludes episodes of care where the patient did not have any surgical wounds (or only had wounds that were unobservable or fully epithelialized—i.e., wounds that had made significant progress in healing). Thus, HH agencies without patients with these wounds did not report on this measure; in fact, in 2016 only 13 percent of HH patients had a surgical wound and only 36.6 percent of HH agencies were able to report data on the measure. CMS reasons that another skin integrity measure currently used in the HH QRP (Percent of Residents or Patients with Pressure Ulcers that are New or Worsened and the measure that will take the previous measure's place in CY 2020, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury) more broadly assesses the quality of care provided by HH agencies regarding wounds.

If finalized, HHAs would no longer be required to submit OASIS Items M1340 and M1342 at the point of SOC/ROC and Discharge *for the purposes of this measure* beginning Jan. 1, 2020. In addition, data for the measure would no longer be publicly reported on *HH* Compare after Jan. 2021. However, this item is also used as a risk adjuster for several other OASIS-based outcome measures currently used in the HH QRP, as well as for a Potentially Avoidable Events measure used by HH surveyors; thus, HH agencies would have to continue to submit this data at SOC/ROC regardless. **The AHA supports the removal of this measure, but encourages CMS to continue to monitor the OASIS items to ensure that the other skin-integrity measure(s) actually capture the full range of wounds presented by HH patients.**

Proposed Removal of the Emergency Department Use without Hospital Readmission during the First 30 Days of HH Measure. CMS proposes to remove this claims-based outcome measure from the HH QRP as it also meets removal Factor 4. The measure estimates the risk-standardized rate of emergency department (ED) use without acute care hospital admission during the 30 days following the start of the HH stay only for patients with an

acute inpatient hospitalization in the 5 days before the start of their HH episode. CMS found that this measure was only reportable for 62.6 percent of HH agencies in 2017.

HH agencies are also required to report on the ED Use without Hospitalization During the First 60 Days measure for the HH QRP. This measure includes all Medicare fee-for-service patients regardless of whether they had an acute care hospitalization in the 5 days prior to the HH episode. CMS found that this measure was reportable for over 88 percent of HHAs in 2017. Thus, because this measure captures a broader patient population and also covers the 30-day period relevant to the measure proposed for removal, CMS reasons that the agency can continue to measure the topic of ED utilization for HH patients using only the 60-day measure.

If finalized, data for this measure would no longer be reported on *HH Compare* after Jan. 2020. **The AHA supports the removal of this measure and appreciates that CMS has identified measures for removal that overlap with other, more widely applicable measures.**

Proposed Removal of the Rehospitalization during the First 30 Days of HH Measure. CMS proposes to remove this claims-based outcome measure from the HH QRP as it also meets removal Factor 4. The measure estimates the risk-standardized rate of unplanned, all-cause hospital readmissions for patients who had an acute inpatient hospitalization in the 5 days before the start of their HH episode and were admitted to an acute care hospital during the 30 days following the start of the HH episode. Similar to the previous measure, this measure was reportable for less than two-thirds of HH agencies in 2017.

HH agencies are also required to report on the Acute Care Hospitalization During the First 60 Days of HH measure, which reports the percentage of HH episodes in which patients were admitted to an acute care hospital during the 60 days following the start of the stay. Like the ED Use measure, this 60-day measure also captures all patients regardless of whether they had an acute inpatient hospitalization in the 5 days prior to the HH episode, and was reportable for over 88 percent of HHAs in 2017. Thus, because the 60-day measure addresses the same outcomes as the measure proposed for removal but for a greater number of Medicare fee-for-service beneficiaries, CMS reasons that the agency can continue to measure the topic of hospital utilization using only the 60-day measure.

If finalized, data for this measure would no longer be reported on *HH Compare* after Jan. 2020. **The AHA supports the removal of this measure and appreciates that CMS has identified measures for removal that overlap with other, more widely applicable measures.**

Change in Publicly Displayed Measure Rates. CMS proposes to increase the number of years of data used to calculate the publicly displayed rates of one measure on *HH Compare*. Instead of calculating rates based on one year of data, CMS would use two years of data to calculate the publicly displayed measure rate for the Medicare Spending Per Beneficiary (MSPB) measure. Using two years of data, CMS argues, would increase the

number of HH agencies with enough data adequate for public reporting, and also aligns with the public display period of this measures in the other post-acute care QRPs. If finalized, data on this measure would be publicly reported in CY 2019 based on discharges from CY 2016 and CY 2017 (instead of on discharges from CY 2017 only, as originally finalized in the CY 2018 HH PPS final rule). **AHA supports this change and agrees that using two years of data to calculate rates is more likely to capture provider performance.**

HH VBP PROGRAM PROPOSALS

Using its authority under the ACA to test payment models intended to improve quality and/or reduce cost, CMS launched a HH VBP program on Jan. 1, 2016. Participation in the HH VBP program is mandatory for all CMS-certified HH agencies in nine states: Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee and Washington. HH agencies in these states are subject to maximum upward and downward payment adjustments of 3 to 8 percent based on performance on selected measures. The scoring approach recognizes HH agencies for both their level of achievement versus benchmarks, as well as improvement over their own baseline performance. The program will adjust payments to the affected HH agencies in CYs 2018 through 2022.

The AHA continues to support the concept of a HH VBP program. We agree that a mix of public quality reporting and pay-for-performance measures can align the health care delivery system – including HH providers – toward continuous quality improvement, and reward providers for excellence. We also support several of the provisions in this proposed rule.

However, we continue to be concerned by the level of payment at risk under the program. The AHA believes placing up to 8 percent of HH agency payment at risk for performance is too much, especially in light of the significant Medicare payment reductions HH agencies have endured in recent years. The AHA is especially troubled by the potential impact of the large payment adjustments on hospital-based HH agencies. We strongly urge CMS to monitor the performance of HH agencies under the model, and to consult with the HH field about whether the payment risk under the model is affecting access to HH services. To the extent the model is driving adverse effects on HH care access, the agency should consider either lowering the amount of payment at risk or suspending the model altogether.

Proposed Removal of Influenza Immunization Received for Current Flu Season. This measure was adopted for the first performance year of the HH VBP program. Since its adoption, stakeholders and a technical expert panel convened by CMS's contractor have commented that the measure does not exclude HH agency patients who were offered the vaccine but declined it, or patients who were ineligible to receive the vaccine due to contraindications. Without these exclusions, the measure does not accurately reflect HHA performance in administration of the influenza vaccine. **The AHA has opposed the inclusion of this measure since its first adoption, and thus supports CMS's proposal**

to remove it from the HH VBP program. We also recommend that CMS remove this measure from the HH QRP.

Proposed Removal of Pneumococcal Polysaccharide Vaccine Ever Received. This measure was also adopted for the first performance year of the program. When the measure was adopted in CY 2010, it was specified based on the guidelines of the Advisory Committee on Immunization Practices (ACIP). ACIP has since updated its pneumococcal vaccination recommendations, but the specifications for this measure were not updated to reflect these updates. Because the measure no longer reflects current clinical guidelines, CMS proposes to remove it from the HH VBP program as well as the HH QRP. **AHA supports this change.**

Proposed Adoption of Composite Total Change in Activities of Daily Living Measures. In the CY 2018 proposed rule, CMS noted that it is identifying measures for possible inclusion in the VBP program in future rulemaking in response to several stakeholder comments that the measures currently used in the model do not reflect the patient population served. Specifically, these stakeholders voiced concerns that the measures are primarily focused on outcomes and clinical improvement and do not address patients with chronic illness or deteriorating/terminal illness. Thus, in order to highlight the value of stabilization measures in the program, CMS suggested adopting a potential composite measure on Total Change in Activities of Daily Living (ADL)/Instrumental Activities of Daily Living (IADL) Performance by HHA Patients.

In this rule, CMS would replace the OASIS measures: Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion, and replace them with two new composite measures: Total Normalized Composite Change in Self-Care and Total Normalized Composite Change in Mobility. The composite measures would still use the OASIS items required to report on the three measures proposed for replacement, but would also combine them with six additional ADL measures "to create a more comprehensive assessment of HH agency performance across a broader range of patient ADL outcomes." In addition, these measures would report the magnitude of patient change (either improvement or decline) rather than just any change, as the current measures do.

In general, the AHA supports the concept of using outcome measures rather than less meaningful process measures to evaluate quality of care. We appreciate the simplicity of the scoring methodology presented in the proposed rule: the methodology clearly ties related OASIS items together, which will result in measure outcomes that are more relevant for both providers and patients (and their caregivers); the normalization method facilitates logical comparisons of scores across disparate OASIS items.

The risk-adjustment method is similarly straight-forward, and on its face appears to be able to account for differences in severity of illness into account. However, this measure would rely wholly upon several OASIS items; last year, CMS removed over 200 items and added or modified dozens more. Because the OASIS item set has undergone and will continue to experience such significant change, **the AHA encourages CMS to develop a type of risk-**

adjustment method that relies either on items that are expected to be static in the OASIS or is based on other patient-level data not subject to the changing list of OASIS items. Specifically, CMS should consider the factors included in the risk-adjustment methodology and to incorporate recent work done by the Assistant Secretary for Planning and Evaluation and the National Academy of Medicine to appropriately account for social risk factors in this outcome measure.

Proposed Changes to Measure Weights. CMS proposes to change the methodology for calculating the Total Performance Score (TPS) by changing the weights of the measure categories contributing to this score. As finalized in CY 2016 HH PPS final rule, the TPS is comprised of measure scores in four categories:

- OASIS-based measures
- Claims-based measures
- HHCAHPS measures
- New Measures (Measures not currently reported by Medicare-certified HH agencies to CMS, but that may fill gaps not completely covered by existing measures in the home health setting)

The first three categories account for 90 percent of the TPS, and HH agency performance on New Measures accounts for 10 percent of the TPS. Currently, the scoring methodology weights each measure in the first three categories equally. Because there are more OASIS-based measures than any other category of measure, scores on these measures contribute more to the TPS than claims-based measures or HHCAHPS measures.

In this proposal, CMS would still weight each HHCAHPS measure equally (at 6 percent each), and would redistribute weights in the OASIS-based claims so that the proposed composite measures would account for 7.5 percent each and the other OASIS measures would account for 5 percent each. The Claims-based Hospitalizations measure would be weighted much more heavily, at 26.25 percent, and the Outpatient ED Utilization measure would be weighted more heavily as well, at 8.75 percent.

CMS rationale behind this change is that HH agencies have steadily improved their performance in OASIS-based measures, but improvement in claims-based measures has been comparatively flat. Thus, giving more weight to the claims-based measures would, CMS reasons, provide more incentive for providers to concentrate on improving the aspects of care relevant to those measures. **The AHA believes that providers should be evaluated based on the most important aspects of care, not based on whichever category is mathematically more significant to their payouts. While AHA agrees that the measures should not necessarily carry the same weight, this proposed change is arbitrary; instead, CMS should consider other methodologies to determine the appropriate weights for measures based on their importance or predictive value for improved patient outcomes.**

Proposed Reduction of Potential Improvement Points. As finalized in the CY 2016 HH PPS final rule, participating HH agencies can earn up to 10 points based on either how well the HH agency performed in the performance year ("achievement") or how much the HH agency improved on each measure since the baseline period ("improvement"), whichever is higher. In this rule, CMS proposes to reduce the maximum number of improvement points that HH agencies can earn.

CMS reasons that rewarding achievement is more in line with the goals of the HH VBP model than rewarding improvement. Specifically, CMS notes that "[w]e expect that at this point several years into participation in the Model, participating HH agencies have had enough time to make the necessary investments in quality improvement efforts to support a higher level of care." Thus, similar to the rationale used to reweight the contribution of claims-based measures as previously described, CMS would award fewer points for improvement than for achievement, which would incentivize HH agencies to focus on their achievement in the performance year rather than relying solely on their improvement since the baseline.

CMS proposes that beginning with performance year 4 (CY 2019), HH agencies only could achieve a maximum of nine points for improvement, as opposed to 10 as previously finalized. This would apply for all measures except for the proposed new composite measures, for which the maximum number of improvement points would be 13.5; because these two composite measures replace three individual OASIS measures, they each contribute a maximum of 15 points to the TPS (instead of 10 each). Reducing this maximum by 10 percent, as CMS proposes to do for the other measures, would result in a maximum improvement score of 13.5 percent. **The AHA understands the rationale CMS relies upon in proposing this change, and cautiously supports the change as it aligns with other VBP programs currently in use, such as the hospital VBP. However, we also encourage CMS to analyze how this change affects payments as the amount of risk increases over time.** While this change is modest on its face, it could result in significant payment decreases for HH agencies when 8 percent of payments are at risk. Such decreases could drastically affect an agency's ability to provide care.

HOME INFUSION THERAPY SERVICES BENEFIT PROPOSALS

Section 5012 of the 21st Century Cures Act of 2016 (Cures Act) established a new home infusion therapy benefit. The Cures Act defines a "home infusion drug" as a drug or biological administered intravenously or subcutaneously for an administration period of 15 minutes or more, in the patient's home, through a pump that is an item of durable medical equipment (DME). This definition does not include insulin pump systems or any self-administered drug or biological on a self-administered drug exclusion list. Rather, the benefit establishes payment for professional services, including nursing services.

The AHA believes that CMS potentially misrepresents the nature of home infusion therapy. It could be misleading to include proposed provisions for the benefit in the HH PPS proposed rule, and even more so when there is a dedicated section (VI.C.2.f) that outlines

the relationship between HH agencies and home infusion therapy providers. In reality, many home infusion therapy providers are hospital-based and are run independent from the home health department of the organization.

In addition, CMS's interpretation of the Cures Act's coverage of "professional services" commonly associated with home infusion therapy is too narrow and could threaten the sustainability of this benefit. By defining these services around nursing services—that is, by establishing the payment basis as the day home infusion therapy are provided by a nurse in the home—the agency neglects to account for the significant contributions of other professionals, specifically pharmacists. **The AHA recommends that CMS consider amending the definition of professional services to incorporate pharmacy services associated with preparing drugs for home infusion therapy, and accordingly adjust the per diem amount paid under the benefit to adequately cover those services.**

We thank you for the opportunity to comment on this proposed rule. If you have any questions concerning our comments, please feel free to contact me, or have a member of your team contact Rochelle Archuleta, director of policy, at rarchuleta@aha.org regarding the payment provisions, or Caitlin Gillooley, associate director of policy, at cgilooley@aha.org, pertaining to the quality reporting provisions.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy