August 25, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1625-P, Medicare & Medicaid Programs; Calendar Year 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Proposed Rules.

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations – including approximately 1,100 hospital-based home health (HH) agencies – and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) calendar year (CY) 2017 proposed rule for the home health prospective payment system (PPS). This letter addresses our concerns pertaining to CMS’s proposed changes to outlier payments and negative pressure wound therapy (NPWT). In addition, we share our concerns on proposed changes to the HH quality reporting and value-based purchasing programs.

PROPOSED CHANGE TO OUTLIER METHODOLOGY

CMS proposes to change its methodology for determining which HH claims are eligible for a high-cost outlier payment in order to incentivize agencies that treat complex patients to provide longer visits. To achieve this goal, the agency would change the way agencies report the time spent on each HH visit. CMS’s concern is based on its study of the 2015 HH claims, which found that agencies with a greater percentage of outlier payments are providing shorter, but more frequent, skilled nursing visits. The rule also cites a 2010 Mathematica Policy Research report that found that outlier payments are not generally being used to serve the types of severely, permanently disabled beneficiaries that CMS believes should primarily benefit from these payments.

The AHA has concerns about CMS’s proposal to retool the HH outlier policy and we encourage CMS to postpone implementing the proposed changes until these concerns,
which are discussed below, can be addressed. Currently, CMS calculates HH outlier payments based on a cost-per-visit approach. Beginning in CY 2017, the agency proposes that HH agencies would report services in 15-minute units, rather than total cost per visit, to determine which cases qualify for an outlier payment. CMS believes this change will result in more accurate outlier payments that are better aligned with the length of time per visit and, therefore, the cost per episode. However, we are concerned that CMS proposes to give equal weight to each 15-minute increment of care. In doing so, short visits would receive substantially less payment for fixed costs that do not vary based on the length of the visit, such as travel time. In addition, other costs that occur outside of the actual HH visit, would not be captured through the proposed approach. These include time spent on pre-visit planning, chart review, and care coordination; and phone time with the patient, family or related service providers. As such, we encourage CMS to refine the proposed policy to give greater weight to the initial 15-minute units to ensure such fixed costs are accurately reimbursed. We also ask CMS to consider reimbursing partial 15-minute units on a pro-rated basis to increase payment accuracy and avoid a reporting cliff, which may serve as an incentive for agencies to not provide any partial 15-minute units. Finally, we ask CMS to clarify the reporting protocols that would be required of HH agencies reporting services provided by minute, and, to the greatest extent possible, keep the reporting.

In addition, given the current evolution of HH as a result of the broader health system’s transition to alternative payment models, HH agencies are beginning to treat a sicker case-mix of patients. Most specifically, the HH field is treating a growing volume of cases being transitioned from more expensive post-acute care settings. This expanded role for HH fits with the triple aim principles and the goals of the Affordable Care Act (ACA). Given this progression of the HH role, we urge CMS to proceed cautiously to avoid any unintended reduction in access to care for beneficiaries who have a medical need for HH care and clinically require multiple, short visits per day. Our hospital-based HH members report that their outlier cases include patients with multiple co-morbidities that are more complex and at a higher risk of readmissions – these patients would be wrongly penalized under the proposed change and reduced access could result in extra interventions, including readmissions that would otherwise be preventable.

Further, CMS has proposed a daily cap on 15-minute units that may be counted toward an outlier payment. While the agency estimates that the cap would impact a small segment of the HH patient population, we urge CMS to evaluate the medical complexity of the affected claims – which is not discussed in the proposed rule – to avoid any unintended access barriers for patients who clinically warrant extra HH care and resources.

NEGATIVE PRESSURE WOUND THERAPY (NPWT)

CMS proposes to implement the Consolidated Appropriations Act of 2016 mandate to implement a separate payment to a HH agency for an applicable, disposable NPWT device, beginning Jan. 1, 2017. To qualify for this new benefit, the beneficiary must otherwise qualify for HH services; the service would be provided in addition to that provided for conventional NPWT under the durable medical equipment (DME) benefit and coverage of a single-use, pocket-sized system covered by a HH 60-day episode payment.
The AHA supports CMS’s effort to implement this statutory mandate, which would provide another option to providers and beneficiaries who need this therapy. However, we are concerned that the recommended billing approach is overly complicated and will result in provider confusion with regard to aligning the correct element of the service with the correct bill type. Specifically, the proposed rule notes that the device and related professional services would be submitted on a 34x bill in some circumstances; however, in others, the agency would use a 32x bill, but not include time spent furnishing therapy. CMS’s explanation of these requirements, in addition to the related, additional specifications in the rule, is already generating multiple interpretations and concern in the field. We anticipate that if this provision is finalized as proposed, CMS and providers both will be mired in confusion and an unintended rise in administrative burden. To avoid this problem, we encourage CMS to, before proceeding, streamline its guidelines to eliminate avoidable paperwork and confusion, which could have a negative impact on patient access to this important therapy.

In addition, we ask CMS to clarify the types of clinicians eligible to provide “sometimes therapy services,” such as NPWT. The proposed rule specifies that this category of therapy, which also includes therapies such as wound therapy, may be performed either by a physician or a non-physician practitioner. However, the rule only mentions registered nurses, physical therapists and occupational therapists as qualifying non-physician practitioners. Clarification on which other types of providers also could deliver this category of therapy, such as other levels of nurses, would help ensure HH agencies are using the appropriate personnel.

**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 2018 HH QRP, CMS proposes the removal of 28 measures whose performance is “topped out,” or that no longer add value to HH quality improvement efforts. CMS also proposes four new measures for the HH QRP to meet the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The IMPACT Act is intended to foster greater standardization and alignment of measures across CMS’s post-acute care quality reporting programs, including the HH QRP.

**Proposed Measure Removal for CY 2018**

The AHA supports CMS’s proposal to remove 28 of the 81 measures in the HH QRP and applauds CMS for taking steps to streamline the program’s measure set. Hospitals and their HH agency partners continue to believe that quality measurement efforts can align with the field’s move from volume to value. However, the AHA has long been concerned that the rapid growth in measure reporting requirements is limiting the effectiveness of efforts to improve quality and causing confusion for the public. HH agencies and hospitals alike believe many of the measures in CMS’s programs are not related to high priority opportunities to improve care.
for patients. As a result, the measures increase burden of collecting and analyzing data without adding value for care. Thus, we commend CMS’s effort to analyze the measures in the HH QRP, and identify measures that can be removed because they are either “topped out” or no longer add value to quality improvement efforts.

**However, significant work remains to ensure measurement efforts across the health care system are focused on the most important quality issues.** The AHA stands ready to work with the agency to streamline and focus the measures across its quality measurement and pay-for-performance programs for all providers. As a starting point, we believe CMS must ensure that the quality measurement requirements for all providers share a common set of goals and objectives. Indeed, the significant improvement in outcomes and health that patients expect and deserve is best achieved when all parties in the health care system are working toward the same objectives.

For this reason, we continue to urge CMS to use the recommendations of the National Academy of Medicine’s (NAM) 2015 *Vital Signs* report to identify the highest priority measures for development and implementation in the HH QRP and other CMS quality measurement programs. The *Vital Signs* report notes that progress in improving the quality of health care has been stymied by discordant, uncoordinated measurement requirements from CMS and others. To ensure that all parts of the health care system – hospitals, physicians, the federal government, private payers and others – are working in concert to address priority issues, the *Vital Signs* report recommends 15 “Core Measure” areas, with 39 associated priority measures. These areas represent the current best opportunities to drive better health and better health care, based on a comprehensive review of available literature. Each stakeholder would be measured on the areas most relevant to their role in achieving common goals and objectives. While we caution against using the core measure areas to assess providers on aspects of care that may be beyond the scope of their operations, the NAM report provides an important uniting framework that will help make all stakeholders more accountable and engaged in measurement and improvement.

**Claims-Based Measures Proposed for CY 2018**

CMS proposes three new claims-based measures for the CY 2018 HH QRP – Medicare spending per beneficiary, discharge to community and potentially preventable readmissions. **While the AHA appreciates that CMS is proposing these measures to fulfill its statutory requirements under the IMPACT Act, we believe all three need significant improvement prior to their implementation.** We first comment on several issues pertaining to all three measures, then provide measure-specific comments.

**Overarching Measure Issues.**

*Measure Testing.* The AHA strongly urges that all three measures be tested for reliability and validity, and that full information about measure testing be made publicly available prior to implementation. In addition, we urge that the measures undergo field testing with post-acute care providers – such as through a CMS-convened “dry run” – prior to implementation.
The draft measure documents provided on CMS’s website provide a variety of information about the measure cohorts, exclusions and risk adjustment variables that are proposed for the measures. However, the draft specifications provide limited data that would enable the field to evaluate the impact of measure design decisions. For example, there are few descriptive statistics showing the distribution of performance by characteristics like urban/rural status.

**Given that the measures will be publicly reported, it is imperative that they provide an accurate portrayal of provider performance.** For this reason, CMS must ensure that the measures are fully tested, and that the results of that testing are fully transparent so that all stakeholders have an opportunity to suggest meaningful improvements to the measure. Indeed, these data also would be expected to be submitted as part of the National Quality Forum (NQF) endorsement process, and the AHA strongly recommends that all measures in CMS programs receive NQF endorsement prior to implementation.

**In addition, we recommend CMS conduct a “dry run” in which all HH agency providers are given confidential preview reports of their performance prior to publicly reporting the measure.** CMS has used dry runs in the past – including in its post-acute care quality reporting programs – for new measures so that providers can become familiar with the methodology, understand the measure results, know how well they are performing, and have an opportunity to give CMS feedback on potential technical issues with the measures. Given the relative novelty of all three measures in the HH QRP, we believe a dry run would be a crucially important step to enhancing the understanding and credibility of the measures.

**Sociodemographic Adjustment.** The AHA believes HH agency performance on all three measures may be impacted by sociodemographic factors. We strongly urge CMS to assess each measure for the impact of such factors, and incorporate sociodemographic adjustment where necessary. For example, in submitting the proposed measures for NQF endorsement, the agency could take advantage of the NQF’s sociodemographic adjustment “trial period.” As part of the trial period, NQF is asking for measure developers to conduct a conceptual and empirical analysis of the impact of sociodemographic status on measure performance when measures are submitted for NQF review.

The evidence continues to mount that sociodemographic factors beyond providers’ control – such as the availability of primary care, physical therapy, easy access to medications and appropriate food, and other supportive services – influence performance on outcome measures. For example, in January 2016, the NAM released the first in a planned series of reports that identifies “social risk factors” affecting the health outcomes of Medicare beneficiaries and methods to account for these factors in Medicare payment programs. Through a comprehensive review of available literature, the NAM’s expert panel found evidence that a wide variety of social risk factors may influence performance on certain health care outcome measures, such as readmissions, costs and patient experience of care. These community issues are reflected in readily available proxy data on sociodemographic status, such as U.S. Census-derived data on income and education level, and claims-derived data on the proportion of patients dually eligible for Medicare and Medicaid. The agency also recently adopted a proposal to provide an “interim”
adjustment for sociodemographic factors for several measures in the Medicare Advantage Star Rating program. Yet, to date, CMS has resisted calls to incorporate sociodemographic adjustment into the quality measurement programs for HH agencies, hospitals and other providers.

We are concerned that, without sociodemographic adjustment, providers caring for poorer and sicker patients will appear to perform worse on some outcome measures than others treating a different patient population. Indeed, measures that fail to adjust for sociodemographic factors when there is a conceptual and empirical relationship between those factors and the measure outcome lack credibility, unfairly portray the performance of providers caring for more complex and challenging patient populations, and may serve to exacerbate health care disparities.

More Frequent Measure Data. We encourage CMS to consider providing patient-level measure data to HH agencies on a more frequent basis, such as quarterly. For most of the claims-based measures used in CMS’s programs, the agency gives providers performance data on an annual basis. However, to make effective use of the measures to improve performance, HH agencies and other providers need timelier data to understand whether interventions are having an effect. Thus, we encourage the agency to explore the feasibility of more frequent performance reports on all three measures.

Medicare Spending per Beneficiary for HH agencies (MSPB-HH). The AHA agrees that well-designed measures of cost and resource use that assist with assessing the value of care are needed. However, we urge CMS to carefully evaluate the MSPB measure’s clinical risk adjustment approach. In particular, we are concerned that the measures do not adjust for patient functional status. We believe patient functional status is an important determinant of patient outcomes. Given that HH agencies and other post-acute care providers will be required by CMS to collect information on functional status as part of patient assessments, CMS should explore whether it is feasible and not overly burdensome to providers to incorporate information from these assessments into the risk model.

Discharge to Community. The AHA urges CMS to carefully assess the reliability of patient discharge codes used to calculate the discharge to community measure. The measure assesses the percentage of Medicare fee-for-service (FFS) patients discharged from HH agencies to home or home health care (i.e., “community discharges”) with no unplanned re-hospitalizations or deaths within 31 days of discharge. CMS would identify community discharges using patient discharge status codes recorded on Medicare FFS claims. However, as noted by the Medicare Payment Advisory Commission and in other published studies, patient status discharge codes often lack reliability. Given that they are so integral to the calculation of the discharge to community measure, CMS should test the measure to ensure it provides an accurate portrayal of performance.

Furthermore, we are concerned that there already is a measure titled “discharged to community” in the HH QRP that is calculated in a very different way from this newly proposed measure. The AHA recommends that CMS include only one discharge to community measure in the HH QRP, or at a minimum, publicly report the results of only
one of these two measures. In contrast to the proposed claims-based measure, the existing HH QRP discharge to community measure is derived from the CMS-mandated Outcome and Assessment Information Set (OASIS) tool. The OASIS-derived measure calculates the percentage of patients who are discharged to the community with or without formal assistance. The OASIS-derived measure does not look 31 days out from the discharge, and note whether the patient has returned to the hospital or not. Rather, it simply notes where the patient was sent upon discharge from HH services. As a result, the measure results generated from these two measures will differ, likely resulting in confusion from providers and patients alike. For this reason, we suggest that CMS phase out the OASIS-derived discharge to community measure.

Potentially Preventable Readmissions (PPRs). The AHA is concerned by the overlap of the proposed PPR measure with the HH QRP’s existing readmission measures. We believe using multiple different readmission measures – with results that are likely to differ – may make it confusing for HH agencies to track and improve their performance. We urge the agency to implement a single readmission measure in the HH QRP. The proposed measure assesses the risk-adjusted rate of unplanned PPRs to short-stay acute care hospitals and in the 30 days after HH discharge. The measure includes only those patients whose HH stay was preceded by a “prior proximal” acute care hospital stay in the 30 days prior to HH admission. However, the proposed measure differs from the all-cause readmission measures previously added to the HH QRP in that it includes only those readmissions considered to be potentially preventable. Moreover, the proposed measure focuses on the timeframe following discharge from HH services, while the existing HH QRP readmission measures examine performance from 30 and 60 days from the start of HH care.

The AHA has long urged that readmissions measurement focus on those readmissions that are truly preventable. Over time, the PPR measure may prove to be superior to the all-cause readmission measure. Thus, we urge continued evaluation of the measure. In particular, the categories and lists of “potentially preventable readmissions” should be based on careful evaluation by clinical experts and detailed testing. We appreciate that a technical expert panel (TEP) was consulted on the list of categories and codes of readmissions considered “potential preventable.” However, we strongly encourage CMS to undertake additional empirical testing to ensure there is evidence that the codes actually are associated with the identified categories.

Finally, the AHA urges CMS to review the various readmission measures used across its post-acute measurement programs to ensure they create consistent improvement incentives across the system. We note that the QRPs for HH agencies and inpatient rehabilitation facilities (IRFs), as well as the skilled nursing facility (SNF) value-based purchasing (VBP) program, all include finalized or proposed readmission measures. While the basic construction of the measures is similar, there are some important differences. For example, while CMS has proposed post-discharge PPR measures for HH agencies, IRFs and SNFs, the agency uses a readmission measure in the SNF VBP that assesses readmissions in the 30 days following acute care hospital discharge. The agency also has proposed a “within stay” readmission measure for IRFs. Yet to date, there has not been an assessment of whether the differences in measurement across these providers are appropriate and whether they facilitate readmission reduction efforts. Given the value and importance of readmission reduction, we encourage CMS to work with post-acute care
providers, hospitals and other stakeholders to evaluate whether the readmission measurement is being structured in a way that helps, and not hinders, effective collaboration.

**PROPOSED DRUG-REGIMEN REVIEW MEASURE FOR CY 2018**

The AHA urges CMS to provide a more specific definition of “clinically significant issues” in the drug regimen review measure. We are concerned that a lack of this specific definition will make it challenging to collect reliable and accurate measure data. The proposed measure assesses the percentage of HH stays for which all of the following things are true:

- Drug regimen review was conducted at the time of admission;
- *For clinically significant issues identified at admission*, the HH contacted a physician (or physician-designee) by midnight of the next calendar day and completed prescribed/recommended actions in response to the identified issues; and
- *For other issues identified during HH stay*, the facility contacted a physician (or physician-designee) and completed prescribed/recommended actions by midnight of the next calendar day each time potential clinically significant medication issues were identified.

To report the measure, HH agencies would be expected to complete three items on the OASIS data set that reflect the above activities. However, the items themselves provide no specific indication of what issues may be considered clinically significant. Furthermore, the measure specifications provided by CMS also do not concretely define a “clinically significant” drug issue. Without these definitions, there are likely to be variations in measure performance that are not based on differences in care, but rather on differences in data collection. Moreover, we are concerned that HH agencies may fail any future CMS audits or validation of their quality data based on differing interpretations of measure specifications. Thus, we urge CMS to work with the field to provide more specific guidance on how “clinically significant” events would be defined for the purposes of this measure.

**HH VBP PROGRAM**

Invoking 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 the mostly minor changes proposed for the HH VBP that will affect payment adjustments in CY 2018. Specifically, we support CMS’s proposals to:

- Remove four quality measures from the HH VBP, bringing the total number of measures in the program down to 20 measures;
- Adopt an appeals process allowing HH agencies to contest CMS’s calculation of their performance prior to the application of payment adjustments; and
- Benchmark the performance of HH agencies to all other HH agencies in their state, rather than the HH agencies in their size cohort and state.

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, too fast, 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, whose average Medicare margins were negative 22.4 percent in 2014.

Hospital-based HH agencies are integral to their parent organization’s efforts to reduce readmissions, coordinate care, promote efficiency and participate in innovative care delivery models such as accountable care organizations. As highlighted earlier in this letter, the rebasing cuts impinge upon the ability of HH agencies to invest in the infrastructure for improvement that is required to be successful in a VBP model. HH agencies also face additional reductions in CY 2018 under the Medicare Access and CHIP Reauthorization Act of 2015, which will limit the market-basket update in CY 2018 to only 1.0 percent.

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.

Thank you again for the opportunity to comment. If your team has any questions or would like to discuss our comments, please have them contact Rochelle Archuleta, director of policy, at rarchuleta@aha.org, our lead on post-acute care payment issues, or Akin Demehin, director of policy, at ademehin@aha.org, our lead on post-acute care quality.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development