AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

June 13, 2017

VIA ELECTRONIC MAIL
regulations.gov

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Re: CMS-1677-P, FY 2018 Hospital Inpatient Prospective Payment System (IPPS) Notice of Proposed Rulemaking

Dear Ms. Verma:

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Fiscal Year (FY) 2018 Hospital Inpatient Prospective Payment System (IPPS) proposed rule. Our organization is the policy voice for five Seventh-day Adventist health systems that include 84 hospitals and more than 300 other health facilities in 17 states and the District of Columbia.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to California. Therefore, we believe that we can provide an objective and sound policy voice in response to CMS' IPPS proposed rule. Below please find AHPA's comments and recommendations to CMS' proposed policies. Specifically, we comment on the following 12 issue areas:

- Hospital Uncompensated Care Payments
- National Accrediting Organization Requirements
- Physician-Owned Hospitals
- Adjusting for Social Risk Factors
- Value-Based Purchasing Program
- Hospital-Acquired Condition Reduction Program
- Inpatient Quality Reporting Program
- Hospital Readmission Reduction Program
- Long-Term Care Hospitals 25 Percent Threshold Policy
- Autologous and Allogeneic Transfusion Coding
- Cell Acquisition Reimbursement
- CMS Flexibilities and Efficiencies

Hospital Uncompensated Care Payments

Beginning in FY 2018, CMS proposes that hospitals use Worksheet S-10 data as a tool to calculate charity care payments. Under CMS' proposed methodology, hospitals would use low-income insured patient days as a proxy for uncompensated care for two thirds of the calculation in FY 2018 and one third in 2019, with the remainder based on the Worksheet S-10 data. However, in FY 2020, hospitals would solely use Worksheet S-10 data. For several years, CMS has discussed using Worksheet S-10 to calculate hospital uncompensated care payments. However, due to concerns raised regarding the accuracy and consistency of the data, this policy was deferred.

AHPA supports the utilization of Worksheet S-10 to calculate charity care but only if the form is improved. We continue to have concerns regarding the clarity of the instructions and the consistency of the data collection. We have found that the instructions on the worksheet are unclear in certain places and lack specificity. For example, CMS should provide clear instructions as to whether providers should report only charity care charges and bad debt expense related to Inpatient and Outpatient services on line 20 and 26 of the form. In the initial instructions, Worksheet S-10 refers to the statutory requirement for hospitals to report costs that are incurred by the hospital for providing Inpatient and Outpatient hospital services. However, the hospital, through instructions for line 20, is directed to report gross charges for charity care for the entire facility. This can be understood to include portions of the facility that are *not* paid under the Inpatient or Outpatient Prospective Payment System (PPS) on the cost report. This concerns us since charity care is limited to cost on line 21 using the hospital Cost to Charge Ratio (CCR) on line one. This can lead to inappropriate reporting of charity care costs because the CCR for the hospital and the subparts are different.

Worksheet S-10, if given clear instructions and reported in a consistent manner, has the potential to gauge an accurate number of uninsured patients. CMS has stated that the S-10 data worksheet would be trimmed to remove inconsistent data points. However, we believe that this alone does not improve the validity or accuracy of the data. In 2015, the American Hospital Association (AHA) stated that nearly 8 percent of hospitals reported charity care charges of zero and slightly more than 1 percent reported bad debt expenses of zero.[1] The high number of hospitals reporting these balances indicates that there is a need to improve the accuracy of the data being reported. Therefore, we encourage CMS to issue FAQs and provide educational resources to ensure that hospital data is consistently reported for use in calculating uncompensated care payments. Furthermore, we recommend for the data reported to be audited by Medicare Administrative Contractors (MAC) in a consistent manner to ensure accuracy.

CMS also proposes to use three years' worth of data to calculate uncompensated care. **We support CMS' proposal and believe that using a three-year period would make the data more predictable.** The validity of using one year as a cost reporting period is not a reliable measure and does not provide a true representation of uncompensated care provided by hospitals. Using three years' worth of cost reporting gives a better perspective since it is looking at a larger period, which will average out the patients to reflect numbers that are more accurate.

[1] American Hospital Association (AHA). (April 2017). Retrieved at: http://www.aha.org/advocacy-issues/letter/2017/170405-cl-medicare-dsh-payments.pdf

National Accrediting Organization Requirements

CMS proposes to require Accrediting Organizations (AOs) to post final accreditation survey reports and acceptable hospital Plans of Corrections (PoCs) on their public-facing website. AOs would be required to post this information within 90 days after such information is made available to hospitals for the most recent three years. This provision would include all triennial, full, follow-up, focused and complaint surveys, whether they are performed onsite or offsite. According to CMS, this would increase health care transparency by allowing individuals to view a provider's or supplier's compliance with Medicare requirements.

While AHPA supports efforts to increase transparency, we believe that the data included in these AO survey reports would not be meaningful to patients. These reports only provide qualitative data and therefore fail to provide an adequate picture of a hospital's compliance with all health and safety requirements. The reports only contain a summary of deficiency findings for a single week of the year and not an overall examination of a hospital's performance throughout the years. For example, a report may state that on the week of May 15th, an exit door in the hospital was found closed, and therefore the hospital violated a safety requirement. Although this may be true, we do not believe this information would be meaningful to patients. Moreover, survey reports tend to be very lengthy and will likely be misinterpreted by the public. We believe that AO survey reports serve as a tool for hospitals to identify safety issues and implement quality improvement strategies. However, we do not think they are an appropriate tool for individuals to determine the overall safety of a facility.

AHPA is also concerned that sharing these survey reports publicly may compromise the privacy of patients. Although patients are not identified by name or number, AO reports provide the specific date, time and location of an incident. This detailed information can make it easy for individuals to identify the patients referenced in the reports. We believe that only hospitals need that level of detail to investigate an issue. If CMS decides to finalize this proposal, we recommend the Agency to omit sharing details about the date, time and location of incidents.

Additionally, **AHPA believes that CMS' proposal represents a legal conflict for accrediting bodies under the *Patient Safety and Quality Improvement Act of 2005* (PSQIA).** The PSQIA provides for the formation of Patient Safety Organizations (PSOs), through which providers can report patient safety data or Patient Safety Work Product (PSWP) to further their patient safety and quality improvement efforts. PSOs assist providers by providing analysis and feedback on the PSWP reported. The PSQIA also gives providers a federally protected environment in which they may report and analyze PSWP without fear of potential liability. Congress believed this protected, non-punitive environment, would result in the increased reporting of data by providers and a more complete understanding of patient safety issues that can ultimately be used by all providers to improve patient safety and quality. To emphasize the special status of PSWP, Congress included a provision for civil monetary penalties for any "impermissible" disclosure of PSWP. However, Congress recognized there may be certain disclosures of PSWP that would be necessary or important. One such example is a "permissible" disclosure of PSWP to a provider's accrediting body. This permissible disclosure to accrediting bodies allows providers to disclose PSWP without waiving their legal privilege and confidentiality under the PSQIA. In providing this exception for a permissible disclosure, Congress recognized the important relationship between providers and accrediting bodies and how they work in tandem to address patient safety and quality issues. Congress did *not* provide such a permissible disclosure exception for CMS. Presumably, if Congress had intended for CMS to receive PSWP, it would have included such an exception within the PSQIA.

We are concerned that if CMS finalizes its proposal, the PSWP that a provider may choose to share with an AO would potentially end up in the final report that is publicly shared. This places accrediting bodies in the untenable position of having to violate the PSQIA by impermissibly reporting privileged and confidential PSWP. Additionally, CMS' proposal would discourage providers to freely provide PSWP to their accrediting bodies for fear that their rights under the PSQIA will be violated. For these reasons, CMS' proposal will not have the positive effect on patient safety it is intended to foster.

AHPA recommends that the Agency work collaboratively with health care providers, AOs and patient advocate groups, to determine the best method to share information on hospital compliance with Medicare requirements. We believe CMS should not finalize this proposal without conducting further research on the issue and exploring different alternatives to meet the needs of Medicare beneficiaries.

Physician-Owned Hospitals

CMS seeks public comments on the appropriate role of Physician-Owned Hospitals (POHs) in the delivery system. The Agency also seeks comments on how the current scope and restrictions on POHs affect health care delivery.

AHPA supports the current restrictions imposed on POHs by Congress. We believe that POHs represent a significant conflict of interest in which physicians may be incentivized to make medical decisions based on a financial interest. Physician self-referrals resulting from these financial relationships have been an issue of concern for many years. This led to the passage of the Stark law in 1989, which aimed to regulate physician self-referrals for Medicare and Medicaid patients. However, the Stark law included exceptions to self-referral limits, including the "Whole Hospital" exception. This allowed physicians to refer patients to hospitals where they had an ownership interest in the *entire* facility rather than just in a subdivision of the hospital.

In 2010, the *Affordable Care Act* (ACA) amended the Whole Hospital exception to impose additional restrictions on POHs. It banned the expansion of existing POHs and the formation of new hospitals. This ban was the result of 15 years of research, studies and Congressional hearings to assess the impact of POHs on the delivery of health care. This included:

- The *Medicare Modernization Act of 2003* (MMA), which required the Medicare Payment Advisory Commission (MedPAC) to investigate POHs. In its report to Congress, MedPAC noted that POHs generally admitted less severe cases, had lower shares of Medicaid patients than community hospitals and concentrated on diagnosis-related groups expected to be more profitable than the average. Medicaid patients represented 13 percent of a community hospital's patients, while only 3 percent of the median POH heart hospital and 2 percent of the median POH orthopedic and surgical hospital. MedPAC also found that the volume of services provided was higher in areas with POHs than in areas without specialty hospitals.[2]

- A 2003 Government Accountability Office (GAO), which found that POHs treated a lower percentage of patients who were severely ill than did general hospitals.[3] The report also noted that POHs tend to locate in areas that lack Certificate of Need (CON) laws, which led to a spike of

[2] Medicare Payment Advisory Commission (MedPAC). (August 2006). Report to the Congress: Medicare Payment Policy, Section 2C: Ambulatory Surgical Centers.

[3] U.S. General Accounting Office. (October 2003). Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance. Retrieved at: http://www.gao.gov/new.items/d04167.pdf

POHs prior to the ACA. From 1990 to 2003, 96 percent of specialty hospitals that opened were in states without CON laws. The purpose of CON laws is to eliminate duplication of health care resources.

- An estimate by the Congressional Budget Office (CBO) in 2007, which projected that a ban on POHs would save Medicare $2.4 billion over a 10-year period. This estimate was supported by several peer-reviewed studies which concluded that Medicare spends more for patients treated in POHs than those treated in community hospitals or Ambulatory Surgical Centers (ASCs).[4]

The tendency of POHs to focus on less sick and more profitable patients has a negative impact on community hospitals, who then must treat a much larger share of these patients. This jeopardizes the ability of community hospitals to continue providing needed services, particularly to vulnerable populations. POHs also jeopardize the ability of hospitals to obtain specialty coverage. For example, if orthopedic doctors can own a hospital and specialize in orthopedics, the trauma center or any hospital in the area may have difficulty obtaining consult coverage for orthopedics.

Proponents of lifting the moratorium on POHs argue that the data that ignited congressional action is outdated and current data no longer supports the earlier findings. However, a recent study conducted by the health care economics firm Dobson DaVanzo demonstrates that the issues that led to the enactment of the moratorium remain. Moreover, we believe that considerations to remove the POH restrictions need to be supported by robust studies and research. Currently, there are few studies supporting the removal of these restrictions. However, as mentioned earlier, there is substantial Congressional research that demonstrates the need to have a moratorium.

The Dobson DaVanzo Analysis

Published in 2016, the Dobson DaVanzo analysis examined select operating and financial characteristics of hospitals in categories defined by hospital ownership. It provided descriptive statistics for physician-owned and non-physician owned hospitals.

The data used by the analysis was drawn from the FY 2014 Medicare Cost Reports, FY 2016 Hospital IPPS Final Rule and Correction Notice Impact Public Use File, and the 2014 CMS 100 percent Standard Analytic File Limited Data Set (LDS) for Inpatient and Outpatient services.

Below is a chart that outlines the differences found between physician-owned and non-physician owned hospitals.

[4] Congressional Budget Office. (August 2017). Retrieved at: https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/hr3162samjohnsonltr_0.pdf

Exhibit 1: Summary Statistics for Physician Owned Hospitals (POH) and All Other Medicare IPPS Hospitals (Non-POH)[2] from the 2014 Medicare Cost Reports, 2014 CMS 100% Standard Analytic File Limited Data Set, and 2016 Hospital IPPS Final Rule ad Correction Notice Public Use File

	POH	Non-POH
Number of Hospitals	68	3,116
Hospital Operating Characteristics		
Medicaid Discharges as a Percent of Total	2.2%	12.4%
Percentage of Hospitals in Hospital Group with Medicare Maximum Readmission Penalty of 3%	10.3%	0.9%
Percentage of Medicare Inpatient Claims with Emergency Department Services	21.1%	72.4%
Percentage of Medicare Inpatient Claims for Patients with Dual Eligibility	12.2%	27.6%
Mean Number of CC/MCCs[3] per Medicare Claim	1.3	2.4
Hospital Financial Characteristics		
Total All-Payer Margin (Average)	21.0%	8.0%
Uncompensated Care Costs as Percent of Total Hospital Expense	1.6%	3.9%

The data in this analysis indicates that POHs continue to have the same operating characteristics that drove Congress to enact the moratorium. These are:

- POHs treat significantly less Medicaid patients than community hospitals.
- Payers margins for POHs are nearly three times higher than those of non-physician owned hospitals.
- POHs provide few emergency services.
- The readmission rates of POHs are nearly ten times higher than the rates of non-physician owned hospitals.

Proponents of lifting the moratorium also argue that POHs introduce needed competition into the health care market and allow for early initiation of treatment. However, even the U.S. Chamber of Commerce, which represents more than three million businesses of all sizes and sectors, disagrees with that argument. In November 2014, the U.S. Chamber wrote a letter to Congressional leadership stating the following:

"Although the Chamber and many lawmakers strongly opposed the ACA generally in 2010, the Chamber and many bipartisan lawmakers have for years supported the protections and safeguards codified in §6001 of the ACA. This provision is working by appropriately limiting the practice of self-referral to physician-owned hospitals, which increases utilization and costs to businesses and taxpayers, as well as distorting health care markets. The Chamber supports the current self-referral law and opposes any effort to unwind or weaken it."[5]

We do not believe it would be prudent to remove current restrictions imposed on POHs. It has been demonstrated that POHs can lead to increased utilization, higher readmission rates and diversion of complex patients and Medicaid beneficiaries to community hospitals. The ACA moratorium on POHs put

[5] U.S. Chamber of Commerce. Letter Regarding Self-Referral to Physician-Owned Hospitals. (November 21, 2014). Retrieved at: https://www.uschamber.com/sites/default/files/141121_self-referral_reid_mcconnell_boehner_pelosi.pdf

an end to the rapid growth of these hospitals and helped create stability in the health care market. Therefore, we believe that these restrictions should be maintained.

Adjusting for Social Risk Factors

CMS seeks comments on whether to account for social risk factors in the Hospital Readmissions Reduction Program (HRRP), the Value-Based Purchasing (VBP) and the Hospital-Acquired Condition Reduction (HAC) programs. The Agency also seeks comments on what social risk factors to include in these pay-for-performance programs and the potential methods to use for risk-adjustment.

AHPA commends the Agency for recognizing that Socioeconomic Status (SES) factors or Socio-Demographic Status (SDS) factors play a major role in health care. Numerous studies have demonstrated that differences in patient characteristics affect health care outcomes and costs. Therefore, these characteristics or social determinants of health should be accounted for when measuring quality and calculating payments. Currently, patient characteristics included in risk-adjustment only involve few demographic and clinical factors (e.g., age, sex, and clinical comorbidities).

We strongly believe that accounting for social risk factors is crucial to the transition from volume to value-based care. It provides an incentive for providers to examine the health of patients beyond the walls of a hospital or health care facility. It also provides CMS with a mechanism to better track the impact of social risk factors on health care outcomes and potentially identify best practices. This will likely help improve patient outcomes for vulnerable populations. Adequate risk-adjustment for social risk factors would also help lessen the practice of "cherry-picking," in which providers reject the sickest and most vulnerable patients out of fear of being penalized for having worst quality scores. This will increase access to care and strengthen the ability of community hospitals to treat at-risk populations.

Social Risk Factors to Consider

As noted in the rule, on December 21, 2016, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) submitted a Report to Congress about a study on the use of social risk factors in value-based models. This report was required by Congress under section 2(d) of the *Improving Medicare Post-Acute Care Transformation* (IMPACT) Act. ASPE's study analyzed the effects of certain social risk factors in Medicare beneficiaries on quality measures and measures of resource use.[6]
The study identified six social risk factors that are likely to negatively affect performance on Medicare quality measures and value-based reimbursement programs. These are:

- Socioeconomic position (e.g. dual eligible status, income and education)
- Race, ethnicity and cultural context
- Gender
- Social relationships (e.g. marital status)
- Residential and community context (e.g., housing, walkability, transportation options, and proximity to services)
- Health literacy

[6] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (December 2016). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Retrieved at: https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf

AHPA supports the inclusion of all these social risk factors in quality measurement. Moreover, we encourage CMS to adjust measures for dual-eligible status, as is currently proposed for the HRRP. As recognized by Congress in the *21st Century Cures Act*, dual-eligible beneficiaries tend to be expensive to cover, accounting for 27 percent of Medicare spending and 40 percent of Medicaid spending. According to the ASPE study, dual-eligible status was the greatest predictor of poor health outcomes in the quality measures studied. Therefore, we believe that CMS should account for dual-eligibility in *all* the value-based models, not just the HRRP.

Methods to Adjust for Social Risk Factors

In the proposed rule, CMS notes that the Agency is concerned that adjusting for social risk factors may mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. AHPA does not share this concern. However, if there is evidence to demonstrate that adjusting for social risk factors can mask health care disparities, we believe that CMS can adopt a risk-adjustment methodology to address this concern. As ASPE recognized in its study, "value-based programs can be leveraged to enhance, rather than threaten, access to high-quality care for beneficiaries with social risk factors."[7] Therefore, CMS should adopt a risk-adjustment methodology that provides incentives for hospitals to improve patient outcomes for disadvantaged populations.

Appropriate risk-adjustment allows the Agency to assess and compare the quality of care delivered by health care providers, so that differences in patient outcomes are attributed to the quality of care provided rather than factors over which providers have no control. **We believe that to accomplish this, CMS should stratify hospitals into peer groups so that hospitals are compared not to all nationwide hospitals as is currently done, but to hospitals with a similar patient mix.** CMS could then compute separate target rates for peer groups of hospitals. This methodology is consistent with CMS' proposal to account for dual-eligibility in the HRRP and with previous analysis conducted by MedPAC.[8] To incentivize improvements in quality, CMS could also tie payment adjustments to improvement or achievement in performance for beneficiaries with social risk factors.

In addition to adjusting payments based on social risk factors, AHPA recommends that the Agency adjust the measures for public reporting. In its 2013 report to Congress, MedPAC recommended to adjust HRRP penalties for SES but keep them unadjusted for public reporting to avoid masking potential disparities in quality of care. **We believe that failure to adjust measures for public reporting will provide an inadequate picture to individuals about the quality of a provider.** Moreover, some publicly reported measures are currently used for CMS' Five-Star quality rating system. The overall rating shows how well each hospital performed, on average, compared to other hospitals in the U.S. The goal of this system is to help patients make an informed decision when selecting a health care provider. If CMS uses the unadjusted measures to calculate a hospital's star rating, providers that treat a larger share of complex patients may be unfairly perceived as low-quality providers, regardless of their performance.

This is an issue that has been recognized by both CMS and MedPAC regarding Medicare Advantage (MA) plans. In response to significant stakeholder concerns regarding the failure to account for SES in MA plans, CMS adopted a new risk-adjustment model for 2017. The new model accounts for low

[7] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (December 2016). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Retrieved at: https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf

[8] Medicare Payment Advisory Commission (MedPAC). Report to Congress 2013.

income, dual eligible and disability status. According to the Agency, "through this interim adjustment, CMS seeks to more accurately capture true plan performance."[9] We believe that if CMS concluded that this change in the risk-adjustment methodology was necessary for MA plan's star ratings, the same should hold true for hospitals.

Data Used to Adjust for Social Risk Factors

Identifying the appropriate data sources to collect information on social risk factors will be crucial to the effective risk-adjustment of quality measures. However, there is not a single data source that contains all the social risk factors recommended earlier in this letter. Moreover, any social risk factor may require a multimodal approach to data collection.[10] CMS may strive to collect information on certain social risk factors by adjusting Medicare enrollment forms. Electronic Health Records (EHRs) could also be used to collect data on factors such as housing that cannot be captured in Medicare enrollment forms as they change over time.

AHPA recommends that CMS explore using existing data sources for the collection of social risk factors. For factors not currently available in any data sources, we recommend that CMS conduct additional research to accurately collect this data. We believe that efforts to collect SES data should not result in increased administrative burden on health care providers. The IMPACT Act requires ASPE to provide a report to Congress by October 2019 on potential SES data sources to determine payment adjustments. We encourage CMS to use the findings of this report along with stakeholder recommendations to determine best methods to collect data on social risk factors.

Hospital Value-Based Purchasing Program

Changes to PSI-90 Measure

CMS proposes to remove the existing PSI-90 composite patient safety measure from the VBP program beginning with FY 2019 payment. CMS also proposes to adopt the modified version of this measure, the Patient Safety and Adverse Event Composite measure for FY 2023. This refined measure was previously adopted as part of the Inpatient Quality Reporting (IQR) Program and the HAC program. The modified PSI-90 measure, which was recently endorsed by the National Quality Forum (NQF), adds three indicators, re-specifies two and removes one indicator.

Indicators Added:

- PSI 09 -Perioperative Hemorrhage or Hematoma Rate
- PSI 10 -Physiologic and Metabolic Derangement Rate
- PSI 11 -Postoperative Respiratory Failure Rate

[9] Centers for Medicare and Medicaid Services (CMS). (April 4, 2016). Strengthening Medicare Advantage and Part D. Retrieved at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-04.html

[10] Zaslavsky, A. M., J. Z. Ayanian, and L. B. Zaborski. (2012). The Validity of Race and Ethnicity in Enrollment Data for Medicare Beneficiaries. Health Services Research 47(3 Pt 2):1300-1321.

Indicators Re-Specified:

- PSI 12 -Perioperative Pulmonary Edema or Deep Vein Thrombosis Rate
- PSI 15 -Accidental Puncture or Laceration Rate

Indicator Removed:

- PSI 07 -Central Venous Catheter-Related Bloodstream Infection Rate

AHPA supports the removal of the PSI-90 measure in FY 2019 and the adoption of the revised measure. We believe that this refined measure is an excellent example of the value of the NQF maintenance re-endorsement process.

Baseline and Performance Period for Acute Myocardial Infarction (AMI) and Heart Failure (HF)

Beginning in FY 2023, CMS proposes to adopt a 36-month performance and baseline period. Per CMS, the baseline period would begin July 1st (10 years prior to the program year) and end June 30th (seven years prior).

AHPA urges the Agency to reconsider this proposal. We believe that using a baseline period that begins 10 years prior to the program year or payment adjustment would fail to provide relevant data to CMS on hospital performance.

Hospital-Acquired Condition Reduction Program

Proposed Outcomes-Focused Patient-Safety Measures for Domain 1

CMS proposes to include outcome-based patient-safety measures for Domain 1 in the HAC program. These measures include: falls with injury, Adverse Drug Events (ADEs), glycemic events and Ventilator Associated Events (VAEs). For FY 2020, the Domain 1 Patient Safety and Adverse Events composite measure would have a data collection period between July 1, 2016 through June 30, 2018. CMS notes that the NQF identified these as gap areas for the HAC program.

AHPA seeks further clarification on the claims-based definition of the patient-safety measures for Domain 1. We recognize that patients who receive mechanical ventilation have a high risk for complications and morbidity rates. While we agree that assessing performance in these topic areas may be valuable, we request clarification on how the outcome-based patient-safety measures would be defined. We also request additional clarification on how hospitals would collect this data.

We recommend that any patient-safety measures under these topics areas be reviewed by the NQF and achieve endorsement status prior to their adoption. Having NQF endorsement ensures that the measures are reliable and valid. It also provides stakeholders with the opportunity to provide input on the measures.

Disability and Medical Complexity Measures in Domain 2

CMS accepts comments on whether it should consider risk-adjusting the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network's (NHSN) measures in Domain 2 to account for disability and medical complexity. CMS does not currently propose any specific changes to the measures but will consider comments as a guide to potential future action.

AHPA supports risk-adjusting for disability and medical complexity in Domain 2. However, we seek clarification on how CMS will collect data for these measures. If hospitals were left to collect this data on their own, without any guidance from CMS, we have concerns that the integrity of the data would be compromised. Moreover, we recommend that CMS work in collaboration with the CDC and the NQF to ensure that any data used to account for these factors is valid and reliable.

Inpatient Quality Reporting Program

HCAHPS Pain Management

CMS proposes to replace three of the current pain management questions in the HCAHPS survey and update the name of the composite measure from "Pain Management" to "Communication About Pain." According to CMS, the purpose of the modifications is to focus on the hospital's communication to the patient about pain. CMS previously received comments from stakeholders that the pain management questions pressured hospitals to prescribe more opioids. In response, CMS removed the pain management dimension from the VBP Program scoring beginning in FY 2018, but retained these questions in the HCAHPS for purposes of the IQR Program. CMS is now proposing to update and refine the existing HCAHPS Survey Questions for FY 2020.

We support CMS' proposal to revise the HCAHPS questions to focus more on communication about pain but recommend that these questions be first endorsed by the NQF. The NQF is responsible for reviewing the validity, reliability and feasibility of measures. Having the NQF endorse the revised questions would allow the measure to be publicly weighed by different stakeholders, including hospitals and patient advocates. If the current questions regarding pain management are found to have potential negative consequences, then those questions should be removed from the IQR program immediately.

Stroke Mortality Rate Measure

Beginning in FY 2023, CMS proposes to refine the 30-day Stroke Mortality Rate measure by integrating the National Institutes of Health's (NIHs) Stroke Scale as an assessment of stroke severity. The refined stroke scale would decrease the number of risk-adjustment variables from 42 to 20, which allows for a more rigorous risk-adjustment. CMS would use claims data occurring between October 1, 2017 and June 30, 2020 for the dry run calculations to be provided during Calendar Year (CY) 2021. In 2016, the NQF reviewed the refined risk-adjustment version and did not endorse it. During the endorsement process, CMS was unable to test the validity of the NIH Stroke Scale data elements using ICD-10-CM codes.

AHPA generally supports integrating NIH's Stroke Scale as an assessment of stroke severity but recommends that CMS resubmit the measure to the NQF for endorsement prior to its

implementation. We believe that the NIH Stroke Scale enhances the risk-adjustment methodology for stroke patients. We also agree that the NIH Stroke Scale may be a strong predictor of mortality as well as short and long-term functional outcomes. **However, CMS should test the ICD-10 CM codes and receive endorsement by the NQF prior to requiring hospitals to adopt the revised measure**. Having the measure endorsed by the NQF ensures that the measures used are as valid and reliable as possible.

Voluntary Hybrid Hospital-Wide Readmissions Measure

CMS proposes the Hybrid Hospital-Wide Readmission Measure with Claims and EHR Data as a new measure for voluntary reporting. The NQF endorsed this measure (NQF #2879), which would consist of 13 clinical data elements drawn from EHRs. Voluntary reporting of data on this measure would occur for discharges from January 1, 2018 through June 30, 2018. Participating hospitals would be required to submit data values for vital signs and six linking variables. The variables would merge with CMS claims data on more than 95 percent of all Medicare Fee-For-Service (FFS) patients who are 65 years and older and who were discharged from the hospital during the voluntary data collection period.

As a measure endorsed by the NQF, we support the Hospital-Wide All-Cause Unplanned Readmission Hybrid Measure. However, we believe that hospitals will need sufficient time to redesign their EHRs, validate their data, and have time to complete the additional testing that may be necessary to ensure that the measure can be implemented feasibly.

AHPA also recommends that CMS release the results of the voluntary collection efforts prior to the measure being made mandatory in FY 2023. This will allow stakeholders to be more informed on how they are being evaluated and allow them to make needed adjustments and improvements. Moreover, having this data will allow outside stakeholders who may not be participating in the Hybrid Hospital-Wide Readmission voluntary reporting program, to have additional education prior to the measure being adopted.

Measure of Quality of Informed Consent Documents for Hospital-Performed Elective Procedures

CMS proposes to measure the Quality of Informed Consent Documents for Hospital-Performed Elective Procedures. This measure would require hospitals to submit a sample of informed consent documents to be scored through a centralized abstraction or have hospitals submit the results to CMS themselves. The Measure Applications Partnership (MAP) work group of the NQF recommended that this measure be revised and resubmitted prior to rulemaking. The work group cautioned CMS about the potential data collection burden associated with this measure and the complexity of existing guidelines, regulations and state laws related to informed consent. The workgroup recommended that the measure demonstrate reliability and validity at the facility level in the hospital setting. The workgroup also recommended that the measure be submitted to NQF for review and endorsement.

AHPA opposes CMS' proposal to adopt this measure. We agree with the MAP's preliminary recommendation to have the measure revised and resubmitted to the NQF for endorsement. We view NQF endorsement as the preeminent standard by which to confirm measures are evidence-based, reliable,

valid, verifiable, feasible to collect and report, responsive to variations in patient characteristics and consistent across types of health care providers.

AHPA agrees that improving the practice of informed consent may complement efforts to encourage high-quality patient-centered decision making. **However, we request more clarity on how CMS would determine the quality of the Elective Procedures Consent form.** For example, what information would need to be contained in the form to meet CMS' quality standard.

Electronic Clinical Quality Measures

Beginning with the CY 2017 reporting period, CMS proposes to require hospitals to report six instead of the eight Electronic Clinical Quality Measures (eCQMs) currently required under the IQR program. For the 2017 reporting period, hospitals would be required to report two self-selected quarters of data instead of the full calendar year. For 2018, the reporting period would be the first three quarters of the calendar year. CMS states that these modified reporting requirements will reduce the administrative burden placed on providers and facilitate the incremental transition to electronic reporting.

AHPA supports the modified reporting requirements and commends CMS for seeking to address previous stakeholder concerns. We also believe that CMS should maintain the requirement to report only six eCQMs beyond the 2018 reporting period. This will allow providers sufficient time to gain further experience reporting eCQMs.

In the rule, CMS also provides 11 new eCQMs that the Agency is considering for future adoption in the IQR program. The measures address the following issues: malnutrition, tobacco use, substance use and safe use of opioids. **We believe that prior to adopting any new eCQMs, CMS should assess how well are hospitals performing in electronic reporting. This will allow CMS to identify and adequately address any reporting issues prior to expanding the number of eCQMs required.** Moreover, we recommend the Agency to submit all new measures through the NQF endorsement process prior to their adoption in the IQR program. This will allow CMS to develop the protocols and testing environments necessary to validate eCQMs.

Hospital Readmission Reduction Program

Payment Adjustment Methodology for FY 2019

Beginning in FY 2019, the *21st Century Cures Act* requires changes to the Hospital Readmission Reduction Program (HRRP) payment adjustment methodology to account for dual-eligible status. Specifically, CMS is directed to assign hospitals to peer groups based on the proportion of Medicare Inpatients who are full-benefit Medicare and Medicaid dual eligible. No new reporting requirements may be imposed to establish the peer groups and the change must be made in a budget neutral fashion.

CMS proposes to stratify hospitals by quintiles or five peer groups based on a hospital's proportion of dual-eligible patients. Using these five peer groups, CMS proposes to calculate the payment adjustment using a peer group-specific threshold in place of the current formula, which compares a hospital's Excess Readmission Ratio (ERR) to a threshold of 1.000. In developing this methodology, CMS seeks comment on four alternative formulas:

- Replace the current standard of 1.000 with the median ERR for the hospital's peer group.

- Use the mean ERR for the hospital's peer group.
- Use a budget neutralizing ERR instead of 1.000. The budget neutralizing ERR would be calculated as the ERR corresponding to the percentile of the peer group distributions that would maintain budget neutrality for each peer group.
- Standardize the ERRs within each peer group. Specifically, the ERRs for hospitals within a peer group would be standardized so that the within-group distribution of standardized ERRs would have the same mean and standard deviation as the original mean and standard deviation for ERRs across all hospitals.

CMS simulated and compared hospital readmission adjustments under these four options using data for the period July 1, 2012 through June 30, 2015 and base Diagnosis Related Groups (DRG) operating payments for claims from the FY 2015 MedPAR file. CMS found that the median peer group ERR would substantially reduce the penalty for safety-net hospitals from 0.64 percent to 0.55 percent as share of total payments. It would also reduce the penalty per discharge from $157 to $135. CMS reports that the use of the median would not disproportionately increase penalties for non-safety net hospitals. Under CMS' analysis, these penalties increased from 0.61 percent to 0.63 percent as share of total payments. CMS notes that the threshold should not be affected by hospitals with unusually strong or weak performance in the peer group, which can occur when the mean is used.

AHPA supports the use of the median ERR to adjust payments within a peer group. We believe that CMS should strive to lower the payment penalties of safety-net hospitals without significantly increasing those of non-safety net hospitals.

Long-Term Care Hospital 25 Percent Threshold Policy

CMS proposes to extend a regulatory moratorium placed by Congress on the 25 percent threshold policy that applies to Long-Term Care Hospitals (LTCH). Under this 25 percent threshold policy, certain LTCHs cannot have more than 25 percent of their discharges come from a single referring hospital. For LTCHs exceeding the 25 percent patient threshold, CMS reimburses the LTCH at the lower payment rate for general acute care hospitals. This policy seeks to limit incentives for acute care hospitals and LTCHs to join and split a single episode of care into separate acute hospital and LTCH stays. CMS proposes to extend the regulatory moratorium placed on this policy from September 2017 until October 2018.

AHPA supports the extension of this regulatory moratorium. We believe that the 25 percent threshold policy conflicts with the current legislative and regulatory environment. For example, the IMPACT Act requires that hospitals assist patients and their representatives to select Post-Acute Care (PAC) providers by sharing data on quality and resource use measures during the discharge planning process. If, based on that data, a greater number of patients choose a LTCH that provides higher quality of care, then the LTCH would be financially penalized for those patient choices if it exceeds the 25 percent threshold. We urge CMS to consider these policy issues when exploring changes to the 25 percent threshold policy. Health care providers should not be placed in a position of telling patients and their families that they must go to a lesser quality facility because the better one already reached its cap.

Additionally, one out of two LTCH patients have been categorized into the new site-neutral group, under the *Bipartisan Budget Act of 2013* (BBA) reforms. The BBA implemented a two-tiered system, under which LTCHs are paid an LTCH-level rate for treating patients with higher severity of illness levels and a lower site-neutral rate for patients with lower medical acuity. Under this site-neutral payment policy, LTCHs face a 73 percent payment reduction. We believe that there is no need to adopt additional payment penalties to LTCHs.

Autologous and Allogeneic Transfusion Coding

CMS proposes that 26 ICD-10 procedures involving Allogeneic Hematopoietic Cell Transplant (HCT) shift in designation from Operating Room (OR) to non-OR procedures. Per CMS, these procedures do not require the resources of an OR and can be performed at the bedside.

AHPA agrees that it is clinically appropriate to perform these procedures at the bedside. However, this shift can result in the inappropriate reassignment of the ICD-10 HCT transfusion codes into 70 different MS-DRGs. We believe that these codes should flow into either MS-DRGs 014, 016 or 017, depending on the type of transplant and associated complications or comorbidities. We ask that CMS reassign the identified ICD-10 transplant transfusion codes back into the appropriate MS-DRGs following standard pre-major diagnostic categories grouping logic.

Cell Acquisition Reimbursement

The current reimbursement rate for MS-DRG 014, Allogeneic HCT, does not cover the cost of providing transplants to patients who have no other treatment option or possibility for a cure. The current base payment rate for MS-DRG 014 is approximately $69,844. Cell acquisition cost varies and is dependent on clinical factors as well cell source. In 2016, adult donor cells from marrow and Peripheral Blood Stem Cells (PBSC) had an average cost of $48,436 while the average cost of cord blood was $65,117. The cost of these necessary services leaves hospitals with very few dollars from the MS-DRG payment left to cover the inpatient stay, which averages 27.45 days. Therefore, it is not sustainable for hospitals to continue performing Medicare Allogeneic HCTs at the current reimbursement rate.

To prevent any patient access issues, we ask that CMS reimburse the cell acquisition costs for HCT in the same way it reimburses solid organ, particularly, kidneys from living donors. Under this proposed payment policy, cell acquisition costs would be reimbursed on a reasonable cost-basis separately from the MS-DRG payment.

CMS Flexibilities and Efficiencies

CMS seeks comments from the public on ideas for improving Medicare that "reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible."

AHPA commends the Agency for allowing the opportunity to provide feedback on ways to improve our health care delivery system and reduce the administrative burden placed on providers. We believe that these are discussions that the Agency could promote on a regular basis through different vehicles such as Open Door forums, annual proposed rules or through the creation of a CMS mailbox designed for that purpose.

Below we share ideas on the following issues:

- Feedback on Hospital Performance
- Two-Midnight Rule
- De Minimus Rotations of Residents to Non-Teaching Hospitals

Feedback on Hospital Performance

Currently, hospitals' payments are adjusted based on their performance in the HRRP, HAC and VBP programs. Prior to this payment adjustment, hospitals have few means to determine how well they are doing under each program. It is not until the penalty hits the hospital, that we can identify issues and implement further quality improvement strategies.

To help improve hospital performance, AHPA encourages the Agency to provide preview reports of hospital performance in CMS' pay-for-performance programs *prior* to the payment adjustment. These reports would provide an overview of a hospital's performance on all program measures. Similar to the Comprehensive Joint Replacement (CJR) model, CMS could provide these performance reports in the second quarter of the year following a given performance year. For example, if the calculation for performance year 2016 begins in March 2017, hospitals would receive performance reports with their results in the second quarter of 2017.

The Two-Midnight Rule

CMS released the two-midnight rule to clarify the definition of Inpatient status. While we appreciate the Agency's efforts, we remain concerned about the impact of the two-midnight rule on providers and patients. It is our view that the policy inappropriately defines Inpatient care based on length of stay rather than the level of care to treat a patient.

It is difficult for physicians to determine whether a patient will need to stay in the hospital for two midnights before having a diagnosis or treatment plan for that patient. By requiring providers to guess the amount of time a patient will stay in the hospital, the two-midnight rule undermines clinical decision-making. It also inadvertently harms Medicare beneficiaries whose Inpatient status may be affected depending on the time they arrive or are discharged from the hospital. Additionally, patients who do not spend two midnights in the hospital are obligated to pay Medicare Part B copayments despite receiving the same intensity of services in the hospital as an Inpatient stay. This situation is not in the best interest of either the patient or the hospital.

AHPA believes that establishing a short-term stay payment methodology that appropriately reimburses hospitals for the intensity of resources provided, will eliminate the need for the two-midnight rule. We recommend CMS to adopt a payment methodology that reimburses unusually short length of stay as a flat percentage of a DRG. The percentage amount could be determined using empirical data demonstrating how costs within a DRG are incurred throughout a hospital stay. When applying the per diem payment, CMS could reimburse the first two days in any discharge at a higher rate than other days within the discharge. This is due to a greater concentration of costs in the first days of a patient's care. A similar policy was recommended by the House Ways and Means Committee in Section 102 of the *Hospital Improvements for Payment Act of 2014* (HIP).[11]

De Minimus Rotations of Residents to Non-Teaching Hospitals

To date, there is no clear guidance on whether prior acceptance of small numbers of resident rotators from other hospitals inadvertently triggers a new teaching hospital's Per-Resident Amount (PRA) and/or cap-building window. AHPA believes that CMS has informally interpreted current regulations such that a

[11] House Ways and Means Committee. (November 19, 2014). Hospital Improvements for Payment Act of 2014. Retrieved at: https://waysandmeans.house.gov/wp-content/uploads/2015/07/HIP_Discussion_Draft-1.pdf

hospital triggers its PRA anytime a single resident rotates to the hospital, no matter how short the rotation is. This restriction is significantly burdensome as it limits a non-teaching hospital's ability to become a teaching hospital in the future.

AHPA recommends that neither a hospital's PRA nor its cap-building window be triggered by the presence of a small number of residents performing brief rotations at a hospital. Many residency programs are based in settings in which the clinical experience available to the residents is limited. To provide a broad clinical experience, residency programs ideally have their residents do rotations at other institutions. Due to CMS' PRA restriction, rural communities can miss out on opportunities for residents to experience practicing in rural settings at a time when these hospitals are in desperate need of trained physicians. Residents are also, essentially, precluded from an educational exposure that may be necessary to ensure a broad clinical experience. Thus, we urge CMS to provide further guidance on whether the presence of a small number of resident rotators triggers the setting of a hospital's PRA for Graduate Medical Education (GME) or Indirect Medical Education (IME) purposes.

AHPA is confident that CMS has the statutory authority to conclude that de minimis rotations do not trigger a cap. In the *Balanced Budget Act of 1997* (BBA), Congress capped for the first time the total number of residency positions that Medicare would support for new programs. However, Congress did not define what constitutes a new residency program or dictate a methodology for determining cap adjustments for new programs. These decisions were left for CMS to address through rulemaking. The BBA states:

> "The Secretary shall, consistent with the principles [in the same subsection governing resident caps], prescribe rules for the application of [resident caps] in the case of medical residency training programs established on or after January 1, 1995."[12]

Throughout the years, CMS has exercised the authority granted by the BBA to interpret the cap rules for new GME programs. For example, in 2012, CMS extended the cap-building period for new programs from three to five years. This change was not the result of legislative action. In extending the cap-building period, CMS stated that the Agency was seeking to address "concerns about teaching hospitals having insufficient time to 'grow' their new residency training programs and to establish an appropriately reflective permanent FTE resident cap."[13]

[12] 42 U.S.C. § 1395ww(h)(4)(H)(i).

[13] 77 Federal Register. 53258, 53416 et seq. (August 31, 2012). Retrieved at: https://www.gpo.gov/fdsys/pkg/FR-2012-08-31/pdf/FR-2012-08-31.pdf

Conclusion

AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact Julie Zaiback, Director of AHPA, at Julie.Zaiback@ahss.org.

Sincerely,

Jeff Bromme
President
Adventist Health Policy Association