AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

June 24, 2019

VIA ELECTRONIC MAIL
regulations.gov

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS–1716–P, FY 2020 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) 2020 Hospital Inpatient Prospective Payment System (IPPS) proposed rule. Our organization is the policy voice of five Seventh-day Adventist affiliated health systems that include 85 hospitals and more than 300 other health care facilities in 17 states.

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 urban areas of California. With such diverse facilities, populations served and geographical locations, we strive to provide an objective and sound policy voice. Specifically, we offer comment to CMS on the following issue areas within the IPPS proposed rule:

- Policies to Address Wage Index Disparities
- Rural Floor Classifications
- New Technology Add-on Payments (NTAPs)
- Chimeric Antigen Receptor (CAR)-T Therapies
- Pain Management for Cancer Patients
- Peripheral Extracorporeal Oxygenation (ECMO)
- Inpatient Quality Reporting (IQR) Program
- Hospital Readmissions Reduction Program (HRRP)
- Hospital-Acquired Condition (HAC) Reduction Program
- Value-Based Purchasing (VBP) Program
- Promoting Interoperability (PI) Program

Policies to Address Wage Index Disparities

To reduce payment disparities between urban and rural hospitals, CMS proposes to increase the wage index value for certain hospitals with low wage index values and decrease the wage index value for certain hospitals with a high wage index. Hospitals with a wage index value below the 25th percentile would have their values increase by half the difference between the otherwise applicable final wage index value for that hospital and the 25th percentile wage index value across all hospitals. To make the proposal budget neutral, hospitals whose wage index value is above the 75th percentile of all hospitals would have their values decreased. CMS proposes to make the policy effective for at least four years in order to allow employee compensation increases implemented by rural hospitals sufficient time to be reflected in the wage index calculation.

AHPA commends the Agency for seeking to improve payments for rural hospitals and address potential barriers. However, we believe that these changes should *not* be made by lowering hospital payments in states where the cost of living and employment are higher. The wage index was instituted to ensure that Medicare payments fairly reflect the cost differences between different regions of the country. We believe that such policy remains appropriate. Moreover, Section 1886(d)(3)(E) of the Act does *not* require the Department of Health and Human Services (HHS) to adjust for differences in the hospital wage index in a budget neutral manner. **With this is mind, we recommend that CMS apply the proposed wage index increase for rural hospitals in a non-budget neutral manner.** This change would assist rural hospitals without penalizing urban hospitals that provide care in areas where the cost of labor is higher.

We also recommend that CMS seek additional avenues to improve the financial viability of rural hospitals and improve the health of the communities they serve. Workforce development programs, expanded coverage of telehealth services and investments to address social determinants of health are examples of this. CMS could also develop new payments models for rural hospitals and expand loan forgiveness programs to help attract clinicians to rural areas.

Rural Floor Classifications

CMS proposes to remove urban to rural reclassifications from the calculation of the rural floor, such that, beginning in FY 2020, the rural floor would be calculated without including the wage data of hospitals that have reclassified as rural.

AHPA supports this proposal as we believe it would help address inappropriate wage index disparities resulting from the reclassification of urban hospitals to rural.

New Technology Add-on Payments (NTAPs)

Beginning October 1, 2019, CMS proposes to increase the add-on payments for new technologies from 50 to 65 percent. The goal of this policy is to provide a sufficient incentive for hospitals to use new technology.

AHPA supports the increased payment as it will help encourage the use of new technologies that will ultimately improve care for Medicare beneficiaries.

Chimeric Antigen Receptor (CAR)-T Therapies

CMS proposes to increase the NTAP for CAR-T cell therapy from 50 to 65 percent, raising payments from $186,500 to $242,450. CMS seeks comments on other payment alternatives for CAR-T therapy and whether or not to develop a new MS-DRG that would provide separate payment for it.

AHPA applauds the Agency's effort to improve reimbursement for this innovative cancer therapy. Under CAR-T therapy, doctors isolate immune cells from a patient's blood and add an artificial receptor called a "Chimeric Antigen." Once infused into the patient, this receptor enables the cells to produce chemicals that help fight cancer. CAR-T cell therapy is unique because it allows clinicians to genetically reprogram patients' own immune cells to find and attack cancer cells. Multiple studies have demonstrated that this therapy is highly effective in high-risk patients with relapsed or refractory cancers.[1] [2] Given the potential of CAR-T cell therapy to kill cancerous tumors, we support any policies designed to encourage its use.

Pain Management for Cancer Patients

Beginning with the FY 2022 payment period, CMS proposes to remove the three pain management questions from the PPS-Exempt Cancer Hospital Quality Reporting Program. These questions have previously been removed from the Hospital IQR and VBP programs. There is concern that these questions

[1] Rosenberg, S. A. Chemotherapy-Refractory Diffuse Large B-Cell Lymphoma and Indolent B-Cell Malignancies can be Effectively Treated with Autologous T Cells Expressing an Anti-CD19 Chimeric Antigen Receptor. Journal of Clinical Oncology.

[2] Sattva S. Neelapu. Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. The New England Journal of Medicine.

incentivize providers to prescribe more opioids in order to improve their ability to score highly on these measures. Additionally, CMS seeks input on measures or measure concepts for future inclusion that could better assess pain management for cancer patients.

AHPA supports the removal of the three pain management assessment questions. The removal of these questions will make it more consistent with the Hospital IQR and VBP programs**. AHPA also supports the inclusion of a measure to evaluate the pain management of cancer patients that use non-opioid alternative treatments**.

Peripheral Extracorporeal Oxygenation (ECMO)

CMS proposes to reassign payments for Percutaneous (Peripheral) Extracorporeal Oxygenation (ECMO) back to MS-DRG 003. In the final IPPS FY 2019 rule, CMS changed this policy, requiring hospitals to use MS-DRGs 291, 296, 207, 870 or 215, depending on disease state. This change resulted in lower payments for the procedure.

AHPA commends CMS for reversing its policy to address the concerns of health providers. In our experience, the current reimbursement rate for ECMO is not enough to cover the cost of care for patients in need of this treatment. This affects the number of patients that hospitals can place on this life-saving treatment, which replaces the function of the heart and lungs while providers treat the underlying disease or injury. Data from the Extracorporeal Life Support Organization (ELSO), an international non-profit consortium of health care institutions, demonstrates that patients cannulated peripherally are not less critically ill then those cannulated centrally and the resources required to manage them are no less intense. **We therefore recommend that all patients placed on ECMO, regardless of the method of vascular cannulation, be reassigned back to MS-DRG 003.**

Inpatient Quality Reporting (IQR) Program

Safe Use of Opioids—Concurrent Prescribing eCQM

CMS proposes to include the *Safe Use of Opioids—Concurrent Prescribing* Electronic Clinical Quality Measure (eCQM) beginning in the CY 2021 reporting period. CMS believes that this measure could help combat the current opioid epidemic by reducing preventable deaths and the costs of adverse events related to prescription drug use. The numerator is the number of patients that are prescribed two or more opioids

or an opioid and benzodiazepine at discharge. The denominator is the number of patients 18 or older that are prescribed an opioid or benzodiazepine at discharge from a hospital-based encounter during the measurement period.

AHPA supports the inclusion of this measure in the IQR program. We believe that it will help providers to reduce the usage of unnecessary opioid prescriptions. Moreover, we believe that there should be a long-term strategy to use this information for future measure development in the PI program.

Hospital Harm—Opioid-Related Adverse Events eCQM

CMS proposes to adopt the *Hospital Harm—Opioid Related Adverse Events* eCQM beginning in the CY 2021 reporting period. CMS believes that this measure would incentivize hospitals to track and improve the monitoring of patients that receive opioids during hospitalization. Instead of looking at the administration of excessive amounts of opioid medications, this measure would assess the proportion of encounters where naloxone is administered as a proxy. This would not include naloxone in the operating room. The numerator would be the number of patients who received naloxone outside of the operating room either 1) after 24 hours from hospital arrival or 2) during the first 24 hours after hospital arrival with evidence of hospital opioid administration prior to naloxone administration. The denominator is all patients eighteen and older discharged from a patient encounter.

AHPA supports the inclusion of this measure once it has endorsement from the National Quality Forum (NQF). AHPA believes that the measure should not disincentivize the appropriate use of naloxone, however, CMS should wait for NQF endorsement before it is included in the IQR program.

If adopted for FY 2020, we recommend that CMS consider the following recommendations:

1. **Clarify that the measure rate is not expected to be zero.** Rather, an improvement would be indicated by a decrease in the measure score. This way, the measure could become a useful tool for providers to take a more in-depth look at prescribing practices and conduct a risk assessment for patients that are elderly or non-informed about opioid use.

2. **Exclude patients with a diagnosis of cancer or an order for palliative care from the measure.** The pain management needs for this population differ from other patient populations.

3. **Exclude cases in which naloxone is administered to address suspected opioid overdose but the incident is later found not to be related to opioid harm.** Naloxone may be given in a code or unresponsive patient situation when the cause of the event is initially unknown and opioid

overdose is suspected. In some of these situations, naloxone is not effective, indicating that the code is not related to opioid administration and thus not an opioid-related harm. Naloxone is not effective in treating alcohol overdoses or overdoses of benzodiazepines, barbiturates, clonidine, GHB or ketamine.[3] It is also not effective against overdoses of stimulants, such as cocaine and amphetamines.

Hybrid Hospital-Wide Readmissions Measure

CMS proposes to adopt the *Hybrid Hospital-Wide All-Cause Readmission* (Hybrid HWR) measure in place of the *Claims-Based Hospital-Wide All-Cause Unplanned Readmission* (Claims-Based HWR) measure. The Hybrid HWR measure would be voluntary from July 1, 2021 through June 30, 2023 until it replaces the Claims-Based HWR measure and becomes mandatory on July 1, 2023. CMS believes that this measure differs from the Claims-Based HWR measure only in that it uses core clinical data elements from the hospital's Electronic Health Records (EHRs) in addition to the claims data. The numerator is the number of readmissions predicted within 30 days based on the hospital's performance with its observed case mix and service mix. The denominator is the number of readmissions expected based on the nation's performance with each particular hospital's case mix and service mix.

AHPA supports the inclusion of this measure but believes that it should not yet be made mandatory. The results from the initial 2018 voluntary Hybrid HWR reporting period will not be available to hospitals until the summer of 2019. Without these results, hospitals will not be fully informed about the implications of the measure. AHPA recommends that CMS does not make this measure mandatory until hospitals are aware of the impact it will have to patients within the claims-based measure and are better familiarized with the measure.

As advocated in our previous comments related to readmission measures, AHPA believes that CMS should only account for unplanned readmissions that are related to a previous admission or diagnosis. AHPA recommends that hospital readmissions not be accounted for if they are planned due to treatment staging, reoccurring blood transfusions for other treatments or incidents unrelated to the previous admission or diagnosis. For example, a readmission of a passenger in a car crash that was discharged three weeks prior with an acute Myocardial Infarction is currently captured in Medicare's readmission measures even though there is no relationship between the two events. Patients often obtain

[3] The Substance Abuse and Mental Health Services Administration. Opioid Overdose Prevention Toolkit.

their treatment from the same facility in their community for different, unrelated reasons. AHPA recommends that CMS collaborate with stakeholders to identify the best method for determining whether a readmission is related or not to the previous diagnosis. Identifying this relationship would ensure the fair adjustment of hospital payments and better align with Congress' intent, as specified under Section 3025 (q)5 II of the Affordable Care Act, which states that "such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital."[4]

Additional Measures for Future Inclusion

CMS seeks feedback specifically on the unintended consequences of adopting three potential measures in the IQR program for the future. These measures are *Hospital Harm – Severe Hypoglycemia* eCQM, *Hospital Harm – Pressure Injury* eCQM, and *Cesarean Birth (PC-02)* eCQM. All three measures also are under consideration for the PI Program.

1. *Hospital Harm – Severe Hypoglycemia eCQM*

This measure assesses the proportion of patients who experienced a severe hypoglycemic event or a low glucose test result of less than 40mg/dL within 24 hours of the administration of an antihyperglycemic agent. CMS believes that this measure will help hospitals track and improve appropriate dosing practices and the monitoring of patients receiving glycemic control agents.

AdventHealth does *not* support this measure because it provides no clear guidance on the medications to be monitored or the types of glucose tests that would apply. Without such guidance, it would be difficult to implement this measure. We also recommend that CMS clarify from where this measure would be abstracted from the EHR.

[4] Affordable Care Act. Section 3025 (q)5 II, page 292.

2. Hospital Harm—Pressure Injury eCQM

This measure seeks to increase transparency regarding the rate of pressure injuries and promote best practices for treating pressure injuries. The measure includes inpatient admissions for patients initially seen in the emergency department or in observation status. The numerator is the number of admissions where a patient has a newly-developed stage two, three or four pressure injury; a deep-tissue pressure injury or an unstageable pressure injury that was not documented as present in the first 24 hours of hospital arrival. The denominator includes all patients 18 years or older discharged from an inpatient hospital encounter during the measurement period.

AHPA agrees with the NQF's Measure Application Partnership that this measure has the potential to reduce patient harm due to pressure injury. **However, AHPA asks that CMS consider the lack of standardization on who determines staging, which creates challenges in comparing the data for this measure across the country.** According to the National Database of Nursing Quality Indicator (NDNQI)[5] Guidelines for Data Collection and Submission on Pressure Injury Indicators, the staging of a pressure injury is complex and has a wide variation depending on who is making the determination of such stage (the size, depth and extent of the pressure injury). There is also little standardization in the reporting of what is present on admission and the duration of time for the discovery of an injury before it is deemed hospital-acquired.

AHPA would support this measure if there was a standard for who stages a pressure injury and the length of time it takes for an injury to be discovered before it is deemed hospital-acquired. For example, in some facilities, it is a physician or a nurse who determines the stage. In other facilities, an RN who specializes in pressure injuries would perform the staging for the entire hospital. The different practitioners staging the pressure injuries create discrepancies in how the injuries are documented.

3. Cesarean Birth eCQM

This measure assesses the rate of nulliparous women with a normal-term, singleton fetus in the vertex position undergoing a Cesarean-section (C-section). CMS believes that this measure can reduce the number of unnecessary C-sections, which can improve patient safety and reduce health care costs. The

[5] The Online Journal of Issues in Nursing. The National Database of National Quality Indicators.

numerator includes women delivering by planned C-section due to obstetric indications and for other reasons. The denominator includes the number of nulliparous women with a singleton, vertex fetus at greater than or less than 37 weeks of gestation who deliver a liveborn infant. This measure excludes patients with abnormal presentations or single stillbirths during the encounter, or patients with multiple gestations recorded less than or equal to 42 weeks prior to the end of the encounter.

AHPA supports the future inclusion of this measure. We believe it has the ability to accurately track and improve the quality of care provided to first-time mothers who are not giving birth to twins or breech-positioned babies. Additionally, quality data on cesarean births is already being collected by many private payors. Since the data for this measure is already being collected, we do not believe there will be a significant burden to report this measure to CMS. We believe that incorporating this measure into federal programs will help providers decrease the number of preventable C-sections and advance quality.

Hospital Readmissions Reduction Program (HRRP)

Dual-Eligible Definition Modification

Beginning with the FY 2021 program year, CMS proposes to modify the definition of dual-eligible for the HRRP's payment adjustment factors. This modification would account for the number of dual-eligibles that died within the month of discharge. Currently, the State Medicare Modernization Act (MMA) files underreport the number of dual-eligible beneficiaries for the month that a beneficiary dies, leading to inaccurate reporting. CMS believes that excluding this population would not have a significant impact and would be a more accurate way to report data.

AHPA supports this change as we believe that using a one-month lookback period to determine dual-eligible status for beneficiaries who die in the month of discharge will improve the accuracy of the data.

Adoption of the Measure Removal Factors

For FY 2020, CMS proposes to adopt the following measure removal factors in the program:

1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped out" measures).
2. Measure does not align with current clinical guidelines or practice.
3. Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic.

4. Measure performance or improvement does not result in better patient outcomes.
5. Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic.
6. Measure collection or public reporting leads to negative unintended consequences other than patient harm.
7. Measure is not feasible to implement as specified.
8. The costs associated with the measure outweigh the benefit of its continued use in the program.

AHPA commends CMS for continuing to develop tools to streamline program measures and reduce the administrative burden on providers. **AHPA agrees that the eight measure removal factors are appropriate criteria for the evaluation of measure removals.**

Hospital-Acquired Condition (HAC) Reduction Program

New Measure Removal Factor

CMS also proposes to adopt the previously-listed measure removal factors within the HAC program. Measures meeting the criteria listed above will be considered by the Agency for removal.

AHPA supports the adoption of these removal factors by the HAC program as their use will reduce administrative burden and promote efficiency within the program. We agree that measure removal should not be automatic, but rather that the removal factors serve as a guide when evaluating ways to streamline the HAC program.

Validation-Targeting Methodology

CMS proposes to change the language explaining their validation-targeting methodology for National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures from "exactly 200 hospitals" to "up to 200 hospitals."

AHPA supports this change and believes that correcting the language is true to the Administration's intent for validation. Allowing CMS the freedom to select the number of hospitals it deems appropriate for validation prevents over-selection to meet an arbitrary numerical requirement.

Value-Based Purchasing (VBP) Program

Administrative Policies for NHSN-HAI Measure Data

CMS proposes to adopt the same administrative requirements for submitting and correcting HAI data within the VBP program as those used in the HAC Program. The VBP program would rely on the HAC program for data validation.

AHPA supports adopting the HAC processes for validating NHSN-HAI measures within VBP. We believe the HAC program's validation process to be sufficient for insuring data integrity.

Promoting Interoperability (PI) Program

Electronic Prescribing Measure Changes

CMS proposes to remove the *Verify Opioid Treatment Agreement* measure in CY 2020 and make the currently-mandatory *Query of the Prescription Drug Monitoring Program (PDMP)* measure a voluntary, "yes/no" attestation.

AHPA supports the removal of the *Verify Opioid Treatment Agreement* measure. We believe that the measure is vague and duplicative, thus causing unnecessary administrative burden, as the definition of an Opioid Treatment Agreement varies widely between states and providers. As currently defined, the measure offers little clinical value to health care providers. For example, Opioid Treatment Agreements are not required to be created or maintained in a standardized, electronic format. Ascertaining the legitimacy of paper agreements is often difficult. With a majority of states mandating that providers query PDMPs, patient prescription history is already available.

AHPA supports the conversion of the *Query of the PDMP* measure to a voluntary, "yes/no" attestation. We believe that this measure holds value, as it incentivizes providers and hospitals to deploy the PDMP query over the next year. In addition, AHPA urges CMS to work with the Office of the National Coordinator for Health IT (ONC) to develop standards-based interfaces between Certified Electronic Health Record Technologies (CEHRT) and PDMPs. This will help to greatly reduce the administrative burden associated with tracking providers' querying of the PDMP.

EHR Reporting Period

CMS proposes to adopt a reporting period of any continuous 90-days for CY 2021 for new and returning hospitals and Critical Access Hospitals (CAHs).

AHPA supports the adoption of a self-selected 90-day reporting period. We believe that allowing individual hospitals and CAHs to select the 90-day period for reporting increases the stability of the PI program and reduces administrative burden. A reporting period longer than 90 days would likely prove difficult for EHR software vendors, who must refine EHR software each year to remain compliant.

CMS proposes that all numerator actions must occur within the EHR reporting period beginning in CY 2020.

AHPA agrees that the reporting of PI numerators and denominators should be limited to the self-selected reporting period. In previous years, some measures were limited to the reporting period while others were counted across the calendar year, causing confusion.

CMS also proposes to eliminate the October 1, 2019 deadline for hospitals who have not demonstrated meaningful use. The removal of the October deadline would be contingent upon changing the *Query of the PDMP* measure to a "yes/no" attestation."

AHPA supports the elimination of the October 1, 2019 deadline for eligible hospitals that have not demonstrated status as a meaningful EHR user in the prior year. Even with the modification of the *Query of the PDMP* measure, we believe that facilities will have an adequate period of time do their reporting for the FY 2020 payment adjustment year.

Potential Opioid Measures for Future Inclusion

CMS requests comment on PI measures that could be included in the program, specifically any measures that provide opioid-related data, and any modifications that may be necessary to maximize opioid measures' efficacy and accuracy.

AHPA advises CMS to consider adopting either mandatory or voluntary measures within the PI program that capture: 1) Use of an opioid risk tool prior to opioid prescription and 2) Offering of non-opioid alternatives post-surgery.

Other Improvements and Opportunities

The PI program provides CMS with a powerful tool to drive interoperability and increase health IT innovation. **AHPA recommends that CMS include "Admission, Discharge, Transfer" (ADT) event notifications as a high-priority health IT activity.** CMS could work with the ONC to ensure that EHRs have the capability to collect the data elements needed to support ADT notifications and include standardized ADT data classes within the U.S. Core Data for Interoperability standards.

AHPA recommends that the HHS recommendation set forth in December of 2018 urging clinicians to "strongly consider" prescribing or co-prescribing naloxone to patients with elevated risk for opioid overdose be made into a quality or PI measure. These patients include those prescribed opioids who receive relatively high doses (e.g. >50 MME/day), those who take other drugs that may enhance opioid complications (e.g. benzodiazepines) or those with underlying health conditions.

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 me at Carlyle.Walton@AdventistHealthPolicy.org or Julie Zaiback-Aldinger, Director of Public Policy and Community Benefit, at Julie.Zaiback@AdventHealth.com.

Sincerely,

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