Kansas Hospital ASSOCIATION

July 10, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1735-P
PO Box 8013
Baltimore, MD 21244-1850

RE: CMS-1735-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Administrator Verma:

On behalf of our member hospitals, the Kansas Hospital Association (KHA) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding CMS-1735-P, the proposed rule to update the hospital Inpatient Prospective Payment System (IPPS) for fiscal year (FY) 2021. Our comments are listed below.

Proposed Revisions for Reporting of Medicare Bad Debt

In the rule, CMS is proposing to make a number of the changes to be "effective for cost reporting periods beginning before, on, and after the effective date of the rule". **CMS should not attempt to codify what the Agency indicates are "long standing" Medicare bad debts from information in the Provider Reimbursement Manual into the Code of Federal Regulations**. Such retroactive regulatory changes could cause Medicare Administrative Contractors to reopen Medicare Cost Reports that are already finalized as well as subject the hospitals to additional audits. **KHA believes that any changes to Medicare bad debt policy should be made no earlier than in conjunction with the effective date of the rule.**

CMS is proposing to amend §413.89(e)(2) by adding a new paragraph to specify that when the provider receives a partial payment within the minimum 120-day required collection effort period, the provider must continue the collection effort and the day the partial payment received is day one of the new collection period. CMS proposes to make this revision before, on and after the effective date of the rule because the Agency indicates they are proposing to clarify and codify their long-standing policy. **This is not CMS's long-standing policy, and should not be made retroactive.**

CMS is also proposing to amend §413.89 to define an indigent non-dual eligible beneficiary and further adding requirements to include taking into account a beneficiary's total resources including an analysis of assets, liabilities, income, and expenses. Not only could this requirement could be more prescriptive than some hospitals' charity policy, it also adds burden to the hospital in gathering information from a population that has difficulty having that information available. This shift would add extra and unnecessary administrative burdens to an already highly regulated industry and directly conflicts with CMS's Patients Over Paperwork initiative.

In the proposed rule, CMS is proposing to specify that, effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account, but must be charged to an expense account for uncollectible accounts. This proposal is not consistent with Generally Accepted Accounting Principles (GAAP) guidance on bad debt reporting. When Medicaid is a secondary payer to Medicare, Medicaid usually does not pay more than Medicare and forces hospitals to "write off" the balance less the patient responsibility as an explicit price concession, which is why the crossover "bad debt" is written off to a contractual allowance account instead of bad debt expense. **CMS should not finalize any policies that conflict with GAAP guidance on bad debt reporting.**

Before finalizing the proposals in this section, CMS should assemble a group of hospital finance executives to vet the proposals, provide recommendations and ensure that the CMS requirements align with GAAP.

Collection of Negotiated Payment Rate Data

In the FY 2021 proposed rule, CMS proposes to require hospitals to include on the Medicare cost report what the Agency calls "market-based payment rate information." Specifically, hospitals would be required to report the median payer-specific negotiated charge, by MS-DRG, for all of their third-party payers, including Medicare Advantage plans. CMS states that "we believe that because hospitals are already required to publicly report payer-specific negotiated charges, in accordance with the Hospital Price Transparency Final Rule, that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals."

CMS cites no authority to require hospitals to furnish median payer-specific negotiated charge information by MS-DRG. Instead, CMS relies on the Hospital Price Transparency Final Rule, which was promulgated in 2019, and is scheduled to go into effect on January 1, 2021. The Hospital Price Transparency Final Rule has been challenged by the American Hospital Association and others on statutory, procedural and constitutional grounds. Although the district court denied the hospitals' motion, an appeal has been filed. If the Transparency Final Rule is found unlawful, it would appear that the CMS requirement for disclosure of median payer-specific charge information by MS-DRG would be similarly unlawful.

CMS continues to grossly underestimate the time, resources, cost and complications of requiring hospitals to submit negotiated payment data as directed by the Agency under the Hospital Price Transparency Final Rule. Hospitals are struggling to meet the finalized payment disclosure requirements slated to take effect January 1, 2021. CMS previously estimated that the total annual burden for hospitals to review and post their standard charges to be 12 hours per hospital at $1,017.24 per hospital. In the absence of detailed guidance from CMS on the

specifics of compliance, this estimate is implausible. In addition, hospitals have not been able to find vendors capable to assist with the requirements, regardless of the time involved. Furthermore, hospitals have been consumed by the demands of a national and global COVID-19 pandemic, requiring resources to be re-directed from normal business to the pandemic. Placing additional administrative burdens on struggling hospitals during a time of such disruption further strains staffing that are trying to keep up with the clinical and financial impact of COVID-19.

CMS indicates the Agency is considering adopting a change in the methodology for calculating the IPPS MS-DRG relative weights to incorporate market-based rate information beginning in FY 2024. Mare clarity is needed as to how the new proposed rate information will be used in the Medicare MS-DRG payment methodologies. Relative weights are intended to reflect the relative hospital resources used with respect to discharges classified within that group and not the relative price paid. In proposing to use median payer-specific negotiated charges to set MS-DRG relative weights, CMS has not adequately explained why market price rather than costs is a better measure of hospital resources used.

KHA urges CMS to postpone the January 1, 2021 payer specific negotiated charges by MS-DRG proposed in this rule, and instead, organize a steering committee or technical advisory group to provide hospital feedback about possible market-based weighting and to address the real cost of the annual burden to hospitals to review and post charges.

Medicare DSH Payments

CMS also is proposing to continue utilizing a single year of audited cost report data to determine each hospital's share of the uncompensated care payments. For FFY 2021, CMS is proposing to use the FY 2017 data. Using a single year to determine the uncompensated payment rate can create large changes in individual hospital payments. Hospitals have been calling for stability and predictability for some time in order to stabilize remuneration. To reduce annual fluctuation in payments caused by using a single year of S-10 data, KHA encourages CMS to consider utilizing a blend of historical S-10 worksheets. This blending would smooth variation in Medicare DSH payments.

Promoting Interoperability Program

Reporting Period. Particularly in light of the ongoing COVID-19 emergency, KHA appreciates that CMS proposes to continue certain policies that offer stability to the program and reduce burden for eligible hospitals and CAHs. **KHA consistently has advocated for an EHR reporting period of any continuous 90-day period and strongly supports CMS's proposal to continue this policy for CY 2022.**

Query of PDMP Measure. As noted in previous comments, PDMP integration with certified EHRs continues to pose a number of challenges for eligible hospitals and CAHs. **KHA supports CMS's proposal to retain the query of prescription drug monitoring program (PDMP) measure under the electronic prescribing objective as optional worth five bonus points.** We further support mitigating burden on providers by continuing to require only a "yes/no" attestation vs. a numerator/denominator for this measure. This appropriately recognizes that technical capabilities to count PDMP queries vary across EHRs.

Health Information Exchange Objective. CMS proposes to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to better reflect the measure's intent. The new proposed name would be Support Electronic Referral

Loops by Receiving and *Reconciling* Health Information. **KHA supports this change and concurs with CMS that including the concept of "reconciling" vs. "incorporating" health information will reduce confusion among eligible hospitals and CAHs.** In addition, we continue to support CMS's policy that for cases in which an eligible hospital or CAH determines that no update or modification is necessary within the patient record based on the clinical information received, and eligible hospital or CAH may count the reconciliation in the numerator of the measure without completing a redundant or duplicative update.

Future Direction of the Promoting Interoperability Program. The proposed rule solicits feedback on how CMS can support a variety of established HHS goals including reducing administrative burden, supporting alignment with the Quality Payment Program, supporting alignment with the 21st Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. Specific to the 21st Century Cures Act, CMS identifies areas of overlap with the Office of the National Coordinator for Health Information Technology (ONC) final rule on interoperability, information blocking and the ONC health IT certification program.

KHA urges CMS to approach the future direction of the Promoting Interoperability Program and alignment with the 21st Century Cures Act and other programs based on a holistic view of the full range of regulations that require IT development, upgrades, testing and end-user training. As it stands today, there is an inherent conflict between the department's goal of burden reduction and the reality of the health IT regulatory environment. Over the next several months, hospitals and health systems will require upgraded IT infrastructure to comply with, at a minimum:

- Appropriate Use Criteria (AUC);
- New e-prescribing requirements;
- Compliance with information blocking;
- Implementation of admission/discharge/transfer notifications under the Conditions of Participation;
- Deployment of IT tools to facilitate disclosure of negotiated rates;
- Upgrades for the Promoting Interoperability Program; and,
- New eCQM requirements, particularly if proposals to expand the number of quarters of reporting are finalized.

We have significant concerns regarding EHR vendor capacity to deploy, and hospitals' and health systems' capacity to implement, such a high volume of IT system changes on a short timeline, especially in light of the redirection of resources to support technology and data needs specific to the COVID-19 emergency. Once upgrades are deployed, a period of testing is required to identify and resolve problems with the software and provide necessary training to end users. These activities are critical to ensuring patient safety is not compromised.

As we have seen from past experience with the Promoting Interoperability Program (formerly Meaningful Use), under unrealistic timelines, small hospitals in particular often end up last in line for IT upgrades. Additionally, when EHR vendors are forced to work on condensed timelines driven almost solely by regulatory mandates, other critical pieces of the IT infrastructure that support the continuum of care can be left behind.

With these considerations in mind, **KHA urges CMS to take an aggregate view of upcoming IT-related requirements, particularly in light of the ongoing PHE, and provide much**

needed regulatory relief through delayed compliance dates or enforcement discretion. Moving forward, the recently established CMS Office of Burden Reduction and Health Informatics also should prioritize this issue of "stacking" of IT requirements and emphasize staging of compliance dates as it assesses "the impact of new regulations on health care system operations."

Finally, with regards to information blocking specifically, there is confusion on the part of hospitals and health systems regarding the relationship between the information blocking attestations in the Promoting Interoperability Program and the information blocking requirements and definitions set forth in the ONC final rule. This is especially true in the absence of final rulemaking to establish the "appropriate disincentives" health care providers will face if they are determined to have engaged in information blocking by the HHS Office of the Inspector General (OIG). **We urge CMS to clarify any overlap that may exist for the CY2021 EHR reporting period between the Promoting Interoperability Program attestations and the definition of information blocking under the ONC final rule.**

Updates to the IQR Program and Electronic Reporting Under the Program

CMS proposes increasing the number of quarters required for data reporting to two self-selected quarters for CY 2021 reporting period (FY 2023 payment); three self-selected quarters for CY 2022 reporting period (FY 2024 payment); and a full year (four quarters) for CY 2023 reporting (FY 2025 payment). KHA requests a delay of these proposed changes by at least one year due to the pandemic.

Additionally, CMS proposes to begin reporting eCQM measure results publicly in late 2022, starting with data from CY 2021; and changes to the Promoting Interoperability Program's eCQM requirements to align with changes in the IQR. KHA believes that during a pandemic is not the time to begin public reporting of this data and requests that CMS delay this proposal (indefinitely) at this time.

Regarding the IQR measure validation process, CMS proposes combining the validation process for chart-abstracted measures and eCQMs, requiring hospitals to submit records selected for validation using electronic file submissions, and reducing the maximum number of hospitals selected for validation from 800 to 400. eCQM validation at the beginning of this process would be weighted at zero. The concept of aligning validation processes seems reasonable. **However, KHA requests that CMS delay addressing the data validation process by one year due to the pandemic.**

CAR-T Payment Policies for FY 2021 and Beyond

CMS proposes creating a new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) with a proposed relative weight of 37.1412 to better reflect the high cost of the therapy. With the creation of the new MS-DRG, CAR-T cases would no longer group to MS-DRG 016, so CMS is also proposing changing the title for MS-DRG 016 to "Autologous Bone Marrow Transplant with CC/MCC" from "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy". Additionally, CMS proposes discontinuing new technology add-on payments for the two CAR-T products currently available. A large percentage of the cases that would group to the new MS-DRG 018 could be clinical trial cases, in which case CMS would apply an adjustment of 0.15 to the payment amount for clinical trial cases that would both group to MS-DRG 018 and include an ICD-10 diagnosis code of Z00.6 or contain standardized drug charges of less than $373,000. CMS is also proposing to update the adjustment based on more recent data with the final rule.

Below are some additional comments:

Finalize the Creation of MS-DRG 018 for CAR-T Cases: KHA strongly supports CMS' proposal to create a new CAR-T MS-DRG for procedures involving CAR-T therapies. We urge CMS to finalize MS-DRG 018 for FY2021.

Revise Proposed Relative Weight Calculation for MS-DRG 018: KHA recommends that CMS treat revenue code 0891 charges as drug charges for the purpose of rate-setting, and suggests that a methodology to develop the relative weight for MS-DRG 018 also exclude claims with the Z00.6 ICD-10-CM diagnosis code for clinical trials; and claims with standard drug charges less than $373,000 from the rate setting process until changes to the MedPAR data set can be made.

Review MedPAR Data Dictionary Definition for Organ Acquisition Revenue Codes: KHA urges CMS to review the data dictionary and revise how certain revenue codes in the 081x-089x range are handled in rate-setting for future fiscal years.

Update Methodology to Pay Reduced Amount for Clinical Trials in FY 2021: KHA requests CMS to either require Value Code 90 to collect actual acquisition cost data on claims or utilize some other mechanism to avoid over- and under-payment of FDA-approved, commercially available CAR-T products. If the Agency requires the use of Value Code 90, CMS should release instructions through sub-regulatory guidance.

Revise the Severity Level Assignment for Cytokine Release Syndrome (CRS) ICD-10-CM codes: KHA recommends that CMS assign complication and comorbidity (CC) and major complication and comorbidity (MCC) status to the new CRS codes. We recommend that grade 2 CRS be assigned to a CC MS-DRG and grades 3-5 be assigned to an MCC MSDRG.

Additionally, with many more cell and gene therapies in the pipeline, KHA strongly recommends CMS work with subject matter experts such as the American Society for Transplantation and Cellular Therapies to develop guidance on such issues as new cost centers for cell and gene therapies for the hospital cost report, coding guidance, new MS-DRGs, and appropriate reimbursement levels for these critical, life-saving therapies.

Thank you for the opportunity to comment on the proposed rule.

Sincerely,

Tom Bell
President & CEO