Kansas Hospital ASSOCIATION

October 5, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
PO Box 8013
Baltimore, MD 21244-1850

RE: CMS-1736-P: Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule, Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned 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-1736-P, the proposed rule to update the hospital Outpatient Prospective Payment System (OPPS) for fiscal year (FY) 2021. Our comments are listed below.

Proposal to Eliminate the Inpatient Only (IPO) List

KHA strongly opposes CMS's proposal to eliminate the IPO list, which designates those procedures that are not payable under the OPPS, over a three-year period. The IPO list was created by CMS to identify services that are required to be furnished in an inpatient setting to ensure that Medicare beneficiaries were afforded the proper care due to the invasive nature of the procedure, the need for a lengthened post-operative stay, and other key clinical considerations.

The proposed elimination of the IPO list along with the continued operation of the 2-Midnight Rule would inappropriately result in level of care determinations based largely on the patient's expected length of stay and would increase the paperwork and administrative burdens for physicians and hospitals in supporting the appropriate site of service. The IPO list ensures that procedures designated as inpatient only can be provided on an inpatient basis regardless of the expected length of stay.

The elimination of the IPO list also risks adverse impacts for Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, because the proposed rule fails to address the financial harm

to these beneficiaries for the associated increased burden in cost of coverage disputes. Without the IPO list, it is likely that Medicare beneficiaries with Part C coverage will experience increased denials of inpatient coverage for invasive procedures that require intensive postoperative monitoring and care. There has been an increased trend among MA plans of denying coverage and authorizations for inpatient surgical admissions ordered by physicians and reclassifying them as outpatient surgical admissions. Elimination of the IPO list risks fueling this trend, jeopardizing the health of Medicare beneficiaries and saddling hospitals with the additional administrative burden of appealing denials and reclassifications for procedures that are not appropriately provided in the outpatient setting.

KHA encourages CMS to retain the IPO list as well as CMS's current process for removing procedures based on clinical criteria. The current five criteria established by CMS to evaluate procedures for potential removal address the following: 1) the extent to which outpatient departments are equipped to provide the procedure to the Medicare population; 2) whether the simplest procedure described by the code may be furnished in most outpatient departments; 3) whether the procedure is related to codes that have already been removed from the IPO list; 4) whether the procedure is furnished in numerous hospitals on an outpatient basis, and; 5) whether the procedure can be appropriately and safely furnished in an ambulatory surgery center. By annually applying these clinical and patient safety-oriented criteria on a case-by-case basis, CMS can ensure that the IPS list only covers those procedures that continue to be inappropriate for the Medicare population in the outpatient setting.

Proposed Prior Authorization Process

In the calendar year (CY) 2020 OPPS/ASC final rule, CMS initiated a prior authorization process for five categories of services, citing unnecessary increases in the volume of these covered outpatient department services. The Agency claimed that these categories of services (blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation) were often cosmetic and prior authorization would help to ensure the services would be billed only when medically necessary. The 2020 prior authorization program was finalized and implemented for dates of service beginning on or after July 1, 2020.

For CY 2021, CMS proposes to require prior authorization for two new service categories: cervical fusion with disc removal and implanted spinal neurostimulators. CMS determined again, that based on their analysis, there was a higher than expected volume of increase in these service categories. CMS further indicates the Agency reviewed clinical and industry-related literature and found no medical indication that would justify the increase in volumes, concluding that the increases are due to financial motives. Under the prior authorization process, hospitals would request provisional affirmation of coverage before the service is furnished to the beneficiary and before the claim is submitted for processing. A service for which provisional affirmation was received may still be denied, based on technical requirements or information not available at the time that affirmation was provided.

Cervical fusion and implanted spinal neurostimulators are procedures that are often provided to patients with chronic intractable pain. CMS's prior authorization policy appears to be in direct contradiction with the spirit of the SUPPORT Act in that it diminishes incentives to provide non-opioid treatment alternatives. Furthermore, the recent emphasis on providing non-opioid treatment alternatives may explain some of the increased volume in these services. **KHA strongly advises CMS reconsider its proposal given the direct payment impact to provider as well as the health and welfare of patients that would result from delays in receiving needed medical services.**

340B Drug Payment Policy

In the 2021 OPPS rule, CMS proposes to pay certain 340B hospitals for drugs purchased through the 340B program at Average Sales Price (ASP) minus 34.7%, plus an add-on of 6% of the product's ASP, for a net payment rate of ASP minus 28.7%. CMS estimates that this payment proposal would result in payment reductions totaling $427 million in CY 2021 for separately-payable OPPS drugs. The $427 million would be on top of the approximately $1.6 billion in payment cuts from the current policy of paying ASP minus 22.5%.

KHA adamantly opposes the proposed rule's deepening of cuts in payments for 340B drugs. These cuts decimate the intent of the 340B program and only exacerbate the strain placed on hospitals serving vulnerable communities. These cuts also conflict with Congress' clear intent and defer to the government's inaccurate interpretation of the law. For more than 25 years, the 340B program has helped hospitals stretch scarce federal resources to reach more patients and provide more comprehensive services to vulnerable communities. This proposal will result in the continued loss of resources for 340B hospitals at the worst possible time.

Changes in the Level of Supervision of Outpatient Therapeutic Services

In the CY 2020 OPPS final rule, CMS changed the minimum required level of supervision from direct supervision to general supervision for most hospital outpatient therapeutic services provided by hospitals and CAHs. KHA strongly supported this change, as we repeatedly pushed CMS for a solution to this critical issue for rural hospitals since it was put forth in the 2010 OPPS final rule. This change, however, did not apply to some groups of services, such as non-surgical extended duration therapeutic services (NSEDTS) and pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation.

In March of 2020, CMS issued an interim final rule (IFC) with comment period that gives Medicare providers needed flexibilities to respond effectively to the COVID-19 pandemic. In the IFC, CMS adopted a policy to reduce, during the public health emergency (PHE), the level of supervision for NSEDTS to general supervision during the entire service, including the initiation portion of the service, for which CMS had previously required direct supervision. The Agency also specified that for the duration of the PHE, the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation service includes virtual presence of the physician through audio/video real-time communications technology when the use of such technology is indicated to reduce exposure risks for the beneficiary or health provider.

CMS proposes that these policies which were adopted on an interim final basis for the duration of the PHE, should be finalized for CY 2021 and beyond. **KHA strongly encourages CMS to move forward with these proposals.**

Hospital Star Ratings

CMS proposes to implement significant changes to the overall hospital star ratings methodology starting in CY 2021, and to codify a number of existing procedures and policies in regulations. Most significantly, CMS would reorganize the star rating measure groups and simplify the calculation of measure group scores by taking a simple average, thereby eliminating the use of latent variable modeling (LVM). CMS also proposes to calculate hospitals' readmission measure group scores by placing them into one of five peer groups based on their proportion of dual-eligible patients, an approach similar to that of the Hospital Readmissions Reduction

Program (HRRP). Lastly, before determining the final overall star rating, CMS would place each hospital into one of three peer groups based on the number of measure groups it reports. Given the substantial problems with CMS's current approach to hospital star ratings, KHA is encouraged that the Agency is considering significant methodology changes. While these changes have the potential to result in more equitable and transparent star ratings, CMS should continue to analyze the proposed changes in depth to ensure the methodology reflects the proper performance measure.

Thank you for the opportunity to comment on the proposed rule. If you have any questions, please contact Tish Hollingsworth at thollingsworth@kha-net.org or 785-276-3132.

Sincerely,

Chad Austin
President & CEO