September 27, 2019

Ms. Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, D.C. 20201

RE: CMS-1717-P, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children’s Hospitals-Within-Hospitals; Proposed Rule (Federal Register, Vol. 84, No. 154, August 9, 2019)

Dear Ms. Verma:

On behalf of our more than 200 member hospitals and nearly 50 health systems, the Illinois Health and Hospital Association (IHA) takes this opportunity to formally comment on the proposed rule establishing new policies and payment rates for hospital outpatient and ambulatory surgical services for calendar year (CY) 2020. IHA commends the Centers for Medicare & Medicaid Services (CMS) for its thorough analysis in the development of this rule; however, IHA has strong concerns with certain provisions.

In summary, IHA urges CMS to consider the following recommendations:

- Do not finalize the price transparency requirements as proposed as they do not improve patients’ understanding of out-of-pocket obligations and exceed CMS’ legal authority;
- Immediately compensate 340B program providers for the payment amounts withheld thus far, and reimburse 340B drugs at average sales price + 6% moving forward;
- Discontinue the phased-in payment decrease for clinic visits to excepted off-campus provider based departments and compensate such providers for last year’s payment decrease;
- Address the wage index disparity without applying budget neutrality;
• Consider separate payments for non-opioid pain management alternative drugs in the hospital outpatient department setting in addition to ambulatory surgical centers;
• Require National Quality Forum endorsement for future additions to the Hospital Outpatient Quality Reporting Program measure list;
• Do not remove total hip arthroplasty from the inpatient-only list, and consider revising the methodology used for removing services from the inpatient-only list;
• Postpone the inclusion of all claims in calculating the cost-to-charge ratio for computed tomography and magnetic resonance imaging cost centers for one additional year;
• Reconsider whether changes to the clinical laboratory fee schedule date of service exception policy are necessary, and provide ample education and support if changes are finalized; and
• Finalize changes to minimum supervision requirements for outpatient therapeutic services from direct to general.

We also provide comments related to the chargemaster and Medicare cost reports. Detailed comments follow.

**Hospital Price Transparency:** IHA is a strong supporter of price transparency that provides meaningful and relevant healthcare price information to patients for healthcare decision making. While we appreciate CMS’ desire to increase price transparency, we believe this proposed rule will create significant confusion for patients instead of allowing them to better understand their out-of-pocket obligations. These out-of-pocket obligations are set by the health plans for covered patients and would be the appropriate entity for CMS to engage on price transparency. Further, we believe CMS is exceeding its legal authority in redefining “charge” to include negotiated rates, and requiring hospitals to post those negotiated rates on a public website. Beyond the legality of this requirement, we believe making negotiated rates public may ultimately lead to higher healthcare costs as hospitals seek to amend their negotiated rates to mirror those of their higher-paid counterparts. We provide more detail on our significant concerns with this portion of the proposed rule in the accompanying comments: CMS-1717-P, Medicare Program: Price Transparency of Hospital Standard Charges.

**340B Price Reduction:** In CY 2018, CMS began paying a reduced rate of average sales price (ASP) minus 22.5% for non-pass-through separately payable drugs and biosimilar biological products purchased under the 340B drug pricing program. For CY 2020, CMS proposes to continue paying for 340B drugs at this reduced rate, despite losing the recent case brought by the American Hospital Association (AHA) against CMS. CMS is appealing this case while requesting comments on potential payback options should it lose upon appeal.

The 340B program was created to help covered entities stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The
program allows providers to be reimbursed by payers at a higher dollar amount than what they paid the manufacturer. Otherwise, there would be no federal resource to stretch.

By reducing 340B Medicare payments to the amount essentially paid by the provider to the manufacturer, CMS is creating a scenario where the provider is just a pass-through. There is no financial gain to the provider, meaning there are no additional resources to support provider operations and ensure greater access to healthcare services among eligible populations.

In Illinois, 107 hospitals participate in the 340B program. By cutting the payments to program-participating providers so drastically, CMS is misplacing the burden of high drug costs, moving it from pharmaceutical companies to the providers that are often the only health resource for these communities. They are also violating the spirit of the 340B program.

IHA advocated strongly against this change, supporting the recent legal case brought against CMS by AHA which CMS lost. Despite losing this case and being ordered to promptly and fully restore funds, CMS has decided to appeal the decision and keep the cuts in place. Thus, IHA continues to advocate against this reduction as this case makes its way through the appeals process.

Additionally, CMS requested comments on how they should repay 340B providers should they lose on appeal and be ordered to repay the money lost over the past two years. IHA stands with AHA in requesting CMS:

- Compensate 340B providers for the amount reduced plus interest;
- Ensure that budget-neutrality not apply to these repayments;
- Moving forward, reimburse drugs under the 340B program at ASP+6%, rather than ASP+3% as proposed in this rule; and
- Forgo patient co-pays as beneficiaries should not be financially burdened by CMS’ overstep.

Instead of reducing payments to 340B providers, many of whom play an invaluable role in the health and welfare of low-income and rural communities, IHA believes the more beneficiary and provider-friendly action is for CMS to continue efforts to halt the unsustainable increases in the cost of drugs.

**Site-Neutral Payment for Outpatient Clinic Visits in Excepted Off-Campus Provider-Based Departments (PBDs):** CMS is completing the two-year phase-in of reduced payments for hospital outpatient clinic visits in excepted off-campus PBDs. The policy lowers reimbursement for clinic visits to the Medicare Physician Fee Schedule payment, or 40% of the OPPS rate. This reimbursement reduction is not budget neutral, and we estimate that it will result in a 42.9% decrease in CY 2020 OPPS reimbursement in Illinois. This amounts to a decrease in $11.8 million across Illinois hospitals in CY 2020, a quarter of which impacts hospitals outside of the Chicago metropolitan area in our more rural and remote areas of the state. PBDs often serve as the
primary source of care in rural communities, and a decrease of this magnitude could have significant implications on beneficiary access to care. Additionally, Section 603 of the Bipartisan Budget Act of 2015 clearly established that payments for excepted and non-excepted facility services should be different, and this policy effectively equalizes payments made to excepted and non-excepted off-campus PBDs. **IHA supports the recent ruling by U.S. District Court Judge Rosemary Collyer** that CMS exceeded their authority in lowering payments for clinic visits in excepted off-campus PBDs. **IHA urges CMS to forgo additional payment cuts and swiftly repay hospitals impacted by last year's initial phase-in of these payment cuts.** Further, **IHA urges CMS to study the impact of site neutral payments on beneficiary access prior to finalizing changes in the future.**

**Wage Index Disparities:** IHA applauds CMS’ attempt to reduce the wage index disparity across U.S. hospitals. However, as we stated in our comments on the fiscal year (FY) 2020 inpatient prospective payment system (IPPS) proposed rule, we do not recommend increasing reimbursement for some hospitals at the expense of others. While we recognize that CMS deviated from the proposed plan to lower the wage index for the top quartile of hospitals, they still utilized a methodology that included a budget neutrality factor. Thus, although the wage index across the state of Illinois went up as a result of CMS efforts to close the wage index disparity, the net impact of this policy is actually negative across our state. **CMS is not bound by statute to apply budget neutrality to wage index modifications such as this,** and we urge CMS to use its existing authority to close the wage index disparity in a non-budget neutral manner.

**Packaging Policy for Non-Opioid Pain Management Treatments:** In CY 2019, CMS unpackaged and paid separately for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ambulatory surgical center (ASC) setting. Upon reviewing claims in preparation for the CY 2020 proposed OPPS rule, CMS did not find sufficient evidence that packaging non-opioid pain management drugs deterred from their use in favor of opioids in the outpatient hospital department setting. **IHA applauds CMS’ decision to pay separately for non-opioid pain management alternative drugs in the ASC setting, but urges CMS to reconsider their decision to continue packaging such drugs in the outpatient hospital setting.** In 2017, there were 2,202 overdose deaths involving opioids in Illinois, the highest rate on record for the state. Even though the opioid prescribing rate in our state has been steadily declining since 2012, the rate of opioid-related overdose deaths continues to rise. **Given the ongoing opioid use disorder crisis in this country, we can see no downside to encouraging the use the non-opioid pain management drugs, when clinically appropriate, in all care settings, and we urge CMS to pay separately for non-opioid pain management drugs functioning as surgical supplies in outpatient hospital departments.**

**Hospital Outpatient Quality Reporting (OQR) Program:** CMS proposed removing measure OP-33: External Beam Radiotherapy (NQF #1822) from the Hospital OQR Program for CY 2022.

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payment determination because the costs associated with the measure outweigh the benefit of its continued use. Additionally, while CMS did not propose the addition of any measures at this time, they did solicit comments on the future adoption of four patient safety measures: (1) ASC-1: Patient Burn; (2) ASC-2: Patient Fall; (3) ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and (4) ASC-4: All-Cause Hospital Transfer/Admission.

IHA supports CMS’ proposal to remove OP-33. We agree that quality measures are an important part of ensuring that all patients receive effective and efficient care, and we applaud CMS’ vigilance in monitoring the current measure set to ensure it continues to fulfill the goals of the Hospital OQR Program.

We encourage CMS to use this same framework when deciding on the addition of new measures. We also strongly advocate that any new measures be endorsed by the National Quality Forum. We agree that monitoring hospital performance on the four patient safety measures proposed by CMS is important, particularly because the first three are related to “never events” and the fourth may give patients general insight on quality and patient satisfaction. However, we are concerned that none of these measures are currently endorsed by the National Quality Forum, even with CMS’s assurances that endorsement removal was not because they failed the endorsement maintenance process. We therefore propose that CMS work with the measure steward to regain endorsement for these measures by the National Quality Forum prior to requiring their inclusion in the Hospital OQR Program.

**Removing Services from the Inpatient-Only List:** CMS proposed removing total hip arthroplasty (THA) (CPT Code 27130) and possibly six additional services from the inpatient-only list (IPO) for CY 2020. Removing services from the IPO list allows providers to perform and bill for services in both hospital inpatient and outpatient settings. While it is true that some patients are at a lower risk for complications and may not need the services of an inpatient hospital setting, IHA has concerns about both removing THA from the IPO list, and the process for removing services from the IPO list in general.

CMS reports that 60% of Medicare fee-for-service (FFS) beneficiaries aged 65 and older have hypertension, and about one-third of Medicare FFS beneficiaries aged 65 and older have two to three chronic conditions. In general, surgical intervention for a patient with one or multiple chronic conditions comes with increased risk, with the probability for post-operative complications increasing. Thus, for the majority of Medicare patients, the inpatient setting may be more appropriate for performing surgical procedures such as THA. Should complications arise, necessary equipment and personnel are on-hand to address the situation. Additionally, if

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there are complications necessitating inpatient hospitalization post-operation, the patient will already be in the hospital, unlike if the THA was performed in an ASC.

Further, CMS uses five criteria in deciding whether it is appropriate to remove a service from the IPO list. However, all five criteria do not need to be met for CMS to remove a service from the list. In the case of THA, only two criteria were met: the simplest procedure described by the code may be performed in most outpatient departments (criterion 2), and the procedure is related to codes that CMS has already removed from the IPO list (criterion 3). We question why CMS does not require all criteria to be met for a service to be removed from the IPO list. In particular, the three criteria that THA did not meet involve the readiness of outpatient departments to perform the service, whether the service is already being performed on an outpatient basis by numerous hospitals, and a determination that ASCs can appropriately and safely perform the service. In the interest of patient safety, and in reference to the points made above about the increased risk of the Medicare beneficiary base, we urge CMS to revisit the process used for removing any service, including THA, from the IPO list. We believe a more appropriate methodology for making this decision would require a service meet all five of these criteria.

Additionally, ASCs are not subject to Stark self-referral rules. While it is true that the anti-kickback statute does govern ASCs, CMS may find that some Medicare beneficiaries receiving future THAs in outpatient settings would have been better served in inpatient settings. Not only does this put the patient’s health at risk, but it could result in unforeseen financial ramifications for the patient. Specifically, there are no comprehensive Ambulatory Payment Classification (APC) codes containing cost in the ASC setting. Thus, not only is the patient responsible for 20% coinsurance on the total cost of the service and any non-covered facility fees, but also any additional coinsurance costs for complication-related expenses that are addressed in the ASC.

Given these reasons, IHA urges CMS to refrain from removing THA from the IPO list. Additionally, IHA suggests that CMS require all five reviewed criteria be met in order to remove a service from the IPO list in the future.

Clinical Laboratory Fee Schedule Date of Service: CMS is considering three potential changes to the laboratory date of service (DOS) exception, including: (1) changing billing requirements around whether a molecular pathology test or advanced diagnostic laboratory test (ADLT) is separable from a hospital service based on whether the test results guide treatment during current or future hospital outpatient encounters; (2) limiting the laboratory DOS exception to ADLTs and not molecular pathology tests; and (3) excluding blood banks and blood centers from the laboratory DOS exception. We are generally concerned that these proposed changes will be confusing to both hospitals and laboratories, and should CMS decide to finalize these

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changes, we ask that they be prepared to provide education and support to these entities. Additional concerns are detailed below.

Regarding the first proposed change, it may be difficult for an ordering physician to determine with certainty whether a lab will guide treatment during future hospital outpatient encounters. Our reservation with this proposed change to the laboratory DOS exception is that it will cause confusion for both the hospital and the laboratory performing the test. Therefore, we ask that CMS either modify this proposed change to be more straightforward, or elect not to finalize this proposed change.

Regarding the second proposed change, we appreciate that CMS continues to study the issue of beneficiary access to medically necessary ADLTs and molecular pathology tests. However, even if accessing molecular pathology tests does not appear to be problematic, we hesitate to support a change that would limit the new laboratory DOS exception to include only ADLTs. As CMS acknowledges, this would be inconsistent with OPPS packaging policy which may cause unnecessary confusion. Additionally, as it is currently uncommon for hospitals to perform these tests themselves, and the “kits” and laboratory equipment necessary for conducting them may be prohibitively expensive for smaller hospitals, we are not convinced that hospitals will become a reliable provider of molecular pathology tests. Therefore, we recommend that CMS refrain from finalizing this proposed change.

Finally, regarding the third proposed change, we agree that in general blood banks and blood centers are performing molecular pathology tests to support the work of hospitals. However, we are concerned that excluding them from the laboratory DOS exception may, again, create unnecessary confusion. We ask CMS to reconsider this proposal, and ensure that these entities are adequately prepared for the process change should they decide to finalize this change.

Cost-to-Charge Ratios (CCR) for Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) Cost Centers: CMS proposed finalizing the decision to use all claims with valid CT and MRI cost center CCRs for CY 2020, including those that use a “square feet” cost allocation method. We understand that CMS has allowed providers six years to transition their CCR cost allocation method away from the “square feet” methodology to a more accurate methodology, which is two years longer than their original proposed transition period. However, as CMS acknowledged, including all claims in this calculation may result in lower cost center CCRs should hospitals continue to use the “square feet” methodology. Additionally, lower cost center CCRs could significantly impact payments made to providers under the physician fee schedule due to the relationship between the technical component payment for many imaging services and the OPPS payment system. In other words, lower payments could impact availability of services rendered by providers both inside and outside of the OPPS system. We understand that CMS still allows the use of “square feet” methodology, but as approximately half of Illinois hospitals are still using the “square feet” methodology and it could have significant negative payment implications, we ask CMS to postpone including all claims in the CCR
calculation for one additional year. We suggest CMS require hospitals that are still using the “square feet” methodology to attest they intend to continue using this methodology moving forward. If postponing one additional year is not possible, we request CMS to phase-in all claims calculations over two years, a time frame consistent with other phased-in cost-cutting policies under the OPPS.

**Level of Supervision Required for Outpatient Therapeutic Services**: CMS proposed changing the minimum required level of supervision for outpatient therapeutic services from direct supervision to general supervision in all hospitals and critical access hospitals (CAHs). IHA applauds CMS and strongly supports the decision to change minimum required supervision levels to general as opposed to direct for outpatient therapeutic services. This change will positively impact access to and utilization of outpatient therapeutic services in our hospitals, particularly our rural hospitals which have expressed difficulty in meeting direct supervision requirements for years.

**Request for Information on Chargemaster and Cost Reporting**: CMS requested comments on the continued value of and costs associated with the chargemaster in setting hospital payment and cost reporting. We offer the following thoughts.

The chargemaster is an integral part of the way hospitals function, and IHA cannot envision an easy transition away from using this data source in the near future. The chargemaster is the most detailed listing of items and services provided by a hospital, and each hospital’s chargemaster is unique. Furthermore, the chargemaster was originally created because Medicare requires documentation that all payers are charged the same price for rendered services. The entire payer industry has been built around the chargemaster, and third-party payers use it as their starting point.

While maintaining the chargemaster is labor intensive, it is integral to how hospitals run their finance departments. Instead of moving away from the chargemaster, IHA suggests CMS simplify some of the related activities, such as the cost reporting process. We recognize that several improvements have been made in the past few years, particularly around worksheet S-10. However, we strongly feel more can be done by CMS to make the process clearer and more efficient.

Ms. Verma, thank you again for the opportunity to comment.

Sincerely,

A.J. Wilhelmi
President & CEO