Washington State Hospital Association

October 5, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1736-P Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Addition of New Categories for Hospital Outpatient Department Prior Authorization Process

Dear Ms. Verma:

On behalf of the Washington State Hospital Association's 105 member hospitals, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for services paid under the Hospital Outpatient Prospective System. In general, we support the comments to the proposed rule made by the American Hospital Association. The focus of our comments are specific provisions of the rule that we believe are of greatest concern and impact to our members.

We have strong concerns regarding the proposed changes to:

- the inpatient-only list and oppose its elimination. The inpatient-only list (IPO) avoids unnecessary administrative burden and provides safety and certainty of coverage for patients.
- the Ambulatory Surgical Center (ASC) Covered Procedures List. Proposed changes to the process and additions to the list fail to provide adequate safeguards for patients for intensive procedures that may require emergency hospital resources; and
- further reductions in payments to hospitals for 340B drugs, and the continued application of site neutrality to grandfathered hospital clinics.

WSHA Opposes Elimination of the Inpatient-Only List

We support the detailed comments of the American Hospital Association and the Federation of American Hospitals regarding the proposal and urge CMS to retain the IPO list. We believe it plays an important role in promoting safety and affordability for patients for extensive procedures.

WSHA strongly urges CMS not to finalize its proposal to eliminate the IPO list over three years. The IPO list was put into place to protect beneficiaries. Many of its services are surgical procedures that are high risk – complicated and invasive procedures with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period, and which require the care and coordinated services provided in the inpatient setting of a hospital. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which could make these procedures even more complicated and risky if furnished in outpatient settings.

Given the depth and breadth of services that are the IPO list, as discussed above, it is premature to adopt a policy to eliminate the IPO list over three years. Instead, CMS should continue with its standard process for removing procedures. It could enhance determinations about individual procedures that could be safely removed from the IPO list by setting general criteria for procedure selection based upon peer-reviewed evidence, patient factors including age, co-morbidities, social support, and other factors relevant to positive patient outcomes.

The IPO list reduces administrative burden and provides financial certainty for patients. It is beneficial for patients and hospitals to have certainty regarding coverage and payment for specific services where there is a high likelihood inpatient resources will be necessary. 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. It would subject patients to uncertainty regarding payment level and potentially subject them to higher cost share under Part B, depriving them of Part A benefits. This would also increase the paperwork and administrative burdens where a patient is admitted for a short stay to undergo a procedure that should only be performed on an inpatient basis.

CMS Lacks Sufficient Data to Assign Procedures on the IPO List to Appropriate Outpatient Ambulatory Payment Classification (APC) Payment Rates. Although the Proposed Rule includes proposed APC assignments for 266 musculoskeletal-related services, it fails to provide any data or rationale for the proposed assignments. In past years, CMS has based APC assignments for procedures removed from the IPO list on the estimated costs derived from available claims data and the 50th percentile IPPS payment for the procedure without major complications or comorbidities to determine the appropriate APC assignment. This proposal is premature because CMS does not have the claims, cost and other data that would be needed to appropriately determine into which ambulatory payment classifications (APCs) the procedures should be incorporated. It also does not have adequate data for creating new APCs to capture IPO list procedures. With over 1,700 IPO services, grouping procedures into APCs and creating new APCs where necessary will be a huge undertaking. Three years is clearly not enough time to do so. We have grave concerns regarding CMS' capacity to quickly provide accurate assignment of APCs and appropriate payment amounts for the number and volume of services that are on the IPO list. Without any explanation of the methodology for proposing APC assignments for these procedures that would be eliminated from the IPO lists, stakeholders cannot meaningfully comment on the proposed assignments, particularly in the short period of time since the proposed rule was released.

Elimination of the IPO List Can Create Adverse Impact for Medicare Part C Beneficiaries. Finally, the elimination of the IPO list risks adverse impacts for Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, due to increased burden and cost of coverage disputes. The IPO list plays an important role in the Part C context, ensuring that MA organizations provide appropriate inpatient coverage for the invasive and risky procedures that warrant inclusion on the list. Without the IPO list, however, it is likely that Medicare beneficiaries that elect Part C coverage will experience increased denials of inpatient coverage for invasive procedures that require intensive postoperative monitoring and care. There has been and continues to be a significant trend among MA organizations of denying

coverage and authorizations for inpatient admissions ordered by physicians and reclassifying them as outpatient observations stays, even in cases where the patient stay crosses two midnights. 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. Some plans adopt the policy that only allowing services on the IPO list to be covered in an inpatient setting and requiring all others to be provided outpatient.

Elimination of the IPO List Would Increase Financial Jeopardy for Hospitals. In addition, we are concerned about the financial and administrative burden of the elimination of the IPO list over such a short period of time while hospitals are grappling with the COVID-19 pandemic**.** That is, when a procedure is taken off the IPO list, it tends to be generally healthier Medicare beneficiaries, with shorter lengths of stay whose care migrates to the hospital outpatient department, leaving the sicker and more complex patients as inpatients. Eliminating the entire IPO list over three years will magnify this impact on hospital costs. Furthermore, in the experience of our members, when CMS removes procedures from the IPO list, commercial payers adopt this policy as well, but Medicare's "option" for the outpatient setting becomes the commercial payer's justification for making it the default location. This results in access issues for patients where the service is not available or cannot be safely provided on an outpatient basis and puts the MA plan policy in charge of the site of care, not the physician. It would be unconscionable to finalize this policy when the financial impact of the COVID-19 PHE has already been devastating for hospitals – and there still remains an uncertain future as to the path of the pandemic.

Proposed Changes to the ASC Covered Procedures List

*WSHA strongly opposes both proposals to modify the agency's process and criteria for adding surgical procedures to the ASC-CPL***.** The current regulatory general inclusion and exclusion criteria serve two critical purposes. First, they are important patient safety guardrails intended to exclude from coverage those procedures that would pose a high-risk of complications that ASCs are not equipped to handle. Second, they allow appropriate surgical procedures to be added to the ASC-CPL. It is not appropriate for CMS to eliminate such meaningful patient safety guardrails. For example, the agency should not eliminate a criterion that prevents a provider that does not have emergency capabilities from conducting surgeries that are emergency or life-threatening in nature. Therefore, WSHA strongly recommends that CMS preserve these five general exclusion criteria. The current standards and exclusion criteria for the ASC-CPL appropriately prioritize patient safety while still allowing the ASC-CPL to evolve with advancements in surgical care, and they should therefore remain in place. Although ASCs can safely perform a growing array of surgical procedures without having the capacity to provide inpatient care in the case of complications and without having satisfied other hospital conditions of participation (or being licensed and accredited as hospitals), ASCs should not be treated as the equivalent of hospital outpatient departments. ASCs are not regulated as hospitals, and since November 29, 2019, ASCs have not been required to have written hospital transfer agreements or hospital physician admitting privileges. ASCs generally lack the emergency equipment and staffing needs in case of a intraoperative or postoperative medical emergency. Thus, procedures that pose significant patient safety risks (*e.g.*, procedures that generally result in extensive blood loss, that

require major or prolonged invasion of body cavities, directly involve major blood vessels, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy) should continue to be excluded from Medicare coverage in ASCs to ensure that Medicare beneficiaries receive these services in a setting that allows for rapid intervention and elevation of the level of care in the case of life-threatening complications.

We urge CMS not to add THA to the ASC-CPL, as it would be clinically inappropriate. Specifically, doing so would pose serious risks and have negative quality of care implications for vulnerable Medicare patients. THA is a complicated, invasive surgical procedure, with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period. While these procedures may be successfully performed in an ASC for some non-Medicare individuals, we do not believe it is appropriate for the Medicare population. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which will make even a simple procedure more complicated.

WSHA Opposes Reductions to Payment for 340B Drugs

We appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment regarding payment for 340B drugs to 340B eligible hospitals. We strongly oppose the proposal to further reduce Medicare payment for 340B drugs from its current level to a new lower level of net level of ASP minus 28.7 percent. We believe the survey methodology used to develop the proposed rates was flawed by unduly limiting the hospitals from which the survey data was drawn to 340B hospitals, rather than all hospitals. We also believe the period for which the data was drawn is too short to be considered valid, particularly as the survey was done during the midst of the COVID emergency, and survey participation and results were of questionable statistical validity. For the reasons outlined above, the WSHA strongly believes that HHS's survey used to develop this new payment approach does not meet the statutory requirements and may not be relied upon in establishing the payment rate.

For more than 25 years, the 340B program has been critical for hospitals to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services. Hospitals rely on these savings to provide important services and resources that they may otherwise be unable to provide, many of which are targeted to low-income and otherwise vulnerable communities. These savings have proved especially important as 340B hospitals are also on the front lines of the COVID-19 PHE. We, therefore, continue to argue, as documented in our court filings, that HHS does not have the legal authority to punitively target 340B hospitals in this manner. On Sept. 14, the AHA, Association of American Medical Colleges, America's Essential Hospitals, and three hospital plaintiffs called on the full U.S. Court of Appeals for the District of Columbia Circuit to reconsider the July 31 non-unanimous decision by a three-judge panel that upheld the authority of HHS to cut 2018 and 2019 Medicare OPPS payments for 340B hospitals by nearly 30% per year. CMS should postpone any additional reductions through rulemaking until after the reconsideration has been completed. WSHA continues its opposition to any payment cuts made to 340B hospitals and asks HHS to immediately reverse this harmful policy and ensure these hospitals can continue to provide vital services for the patients and communities they serve.

Washington State Hospital Association

WSHA Opposes the Continued Application of Site Neutrality to Grandfathered Hospital Clinics

While this topic received little mention in the proposed rule, we strongly urge CMS to rescind its reduction to clinic services provided at grandfather off-campus hospital department sites, particularly considering the ongoing litigation that CMS exceeded its authority in applying these cuts. For CY 2021, CMS would continue to pay for the hospital outpatient clinic visit services in off-campus excepted PBDs at 40% of the OPPS payment amount. WSHA continues to believe that the payment cut for hospital outpatient clinic visits threatens access to care, especially in rural and other vulnerable communities, and that CMS has undermined clear congressional intent and exceeded its legal authority. The AHA is seeking a rehearing by the full U.S. Court of Appeals for the District of Columbia Circuit of the recent decision overturning a lower court's ruling in favor of AHA and hospitals that invalidated HHS's policy finalized in the CY 2019 rule to pay for clinic visit services in excepted PBDs at the "PFS-equivalent" payment rate of 40% of the OPPS payment amount.

In addition to the legal grounds for restoration of payment, we believe the hospital-based payment is justified based on health care policy and access. Clinics operated by hospitals and health systems provide a significant proportion of the primary care and specialty care physician services available to Medicare patients, particularly in rural areas. The cuts threaten hospitals' ability to provide needed services, in some cases where there are few or no freestanding clinic alternatives in the community.

We disagree with CMS' rationale that services provided by hospital clinics are financially "unnecessary" and could be provided in different setting. For several reasons, including unsustainable low reimbursement on Medicare fee schedule payments, payer mix, and increasing regulatory and technology requirements, many private practices have closed or severely limited access for Medicare patients. Specialized services such as cancer care, wound care and other specialized services are clinically and financially unsustainable in a non-hospital context. As a result, many communities, hospital-based clinics are the primary or only source of clinic services for Medicare and Medicaid. In some cases, establishment of off-campus hospital clinics was necessary to preserve services that would otherwise be forced to close, in other cases to meet growing demands for services that had previously been unmet. During the current COVID emergency, hospital clinics have generally remained open to care for patients where many of their freestanding counterparts where not available.

Blaming increases in OPPS expenditures on the "unnecessary" shifting of services from physician offices to PBDs in response to payment differentials ignores the many factors outside of hospitals' control that also result in increases in OPPS volume and expenditures. This includes such things, as changes in patient demographics and clinical needs, technological advances, changing economic incentives from CMS and other payers, the impact of other Medicare policies that are intended to increase the volume of services in PBDs, drug price inflation, or the fact that physicians often refer Medicare beneficiaries to HOPDs for services they do not provide in their offices. Finally, the entire premise of CMS's site-neutral policies is based on the flawed assumption that Medicare PFS payment rates are sustainable rates for physicians. However, the truth is much different. Our members tell us that when they have acquired independent physician practices, it occurs because the physicians have reached a tipping point – their practices are failing due to poor payer mix, increasing Medicare and Medicaid regulatory burden, and declines in Medicare and Medicaid reimbursement. Instead of allowing these physician services to be lost to the community, or in communities where there are already health care deserts, hospitals

purchase the practices in order to ensure continued access to these services. Expansion of the proportion of care provided through hospital-based clinics is a reflection and result of hospitals' efforts to address access issues that are result of an unsustainable physician payment model. Hospital-based clinics are not the cause of these issues.

All of this discussion supports the conclusion that CMS should reverse its unlawful and harmful policy reducing payment for outpatient clinic visits in excepted hospital-based clinics

We thank you for the opportunity to comment on this proposed rule.

Sincerely,

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