

September 27, 2019

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-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

Dear Ms. Verma:

On behalf of the Washington State Hospital Association's 103 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. In summary, we have strong concerns about the proposed price transparency provisions, as well as the application of site neutrality to grandfathered hospital clinics. We also comment on potential 340B remedies. Lastly, we strongly support the general supervision change.

Proposed Price Transparency Provisions

We are deeply committed to ensuring patients have the information they need to make informed health care decisions, including timely, accurate estimates of their out-of-pocket costs. The agency's approach would confuse – not help – patients in understanding their potential out-of-pocket cost obligations, would severely disrupt contract negotiations between providers and health plans, and exceeds the Administration's legal authority.

We support efforts to encourage voluntary adoption of cost-estimator tools for patients. We encourage CMS to take steps to facilitate the development and voluntary adoption of patient cost-estimator tools and resources by convening stakeholders to identify best practices, recommending standards for common features of cost-estimator tools, and developing solutions to common technical barriers. We believe this approach will best serve patients by providing information regarding their *own* out-of-pocket costs.

We believe CMS lacks the legal authority to require hospitals to make public their payer-specific negotiated charges. Section 2718(e) of the Public Health Service Act (PHSA) does not provide CMS with authority to establish these requirements. CMS' proposal is contrary to the plain language of the statute, as negotiated charges are not "standard charges." By definition, a "standard charge" is not privately negotiated and does not contemplate different charges for different payers. "Standard

charges” has long been understood to be a technical term that means a hospital’s usual or customary chargemaster charge applied to all patients.

There are numerous technical and contractual issues that have not been addressed in the proposed rule. In addition, we have significant operational concerns with this proposal. We believe CMS’ estimate of 12 hours reflects only a small fraction of the actual time and cost necessary to implement the proposal. We estimate the cost to our member hospitals would be much greater. These resources would be much better used in ways to provide patients information regarding their own out of pocket costs.

Application of Site Neutrality to Grandfathered Hospital Clinics

We strongly urge CMS to rescind its reduction to clinic services provided at grandfather off-campus hospital department sites in the final rule, particularly considering the U.S. District Court’s recent decision that CMS exceeded its authority in applying these cuts. While the court remanded to CMS the issue of remediation of cuts that occurred since January 1, 2019, we believe at a minimum, the final rule should reflect the court decision and address the 30 percent cut implemented for calendar year 2019 and ensure the cuts are not finalized for 2020.

Besides the legal grounds for restoration of payment, we believe the payment is justified 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. 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.

Below are two examples of WSHA members that illustrate these points. Olympic Medical Center in Port Angeles, Washington. Olympic Medical Center (OMC) is the sole provider hospital that provides nearly all the specialty services for Clallam County, a large county which spans the width of the Olympic Peninsula. OMC also provides clinic and other outpatient services in Sequim, a community a 30-minute drive from the hospital with a large Medicare population. The next closest source of specialty services for the region’s residents is several hours away by car and/or ferry. Because of unsustainable payor mix there are no other freestanding or independent clinics in the region. The payer mix is 58 percent Medicare with a combined total of 84 percent Medicare, Medicaid or other government. In addition to

primary care, OMC provides the bulk of the specialty care referred from the local federally qualified health center and tribal centers through its off-campus hospital-based clinic sites.

Another example is Virginia Mason Memorial Hospital (VMM) in Yakima, Washington. VMM is the safety net hospital in that region, and like Olympic Medical Center has a challenging payor mix with a patient population of 70 percent Medicare and Medicaid. Most impacted with these cuts is the North Star Lodge Cancer Center and the Water's Edge Pain Center. Currently, there are no other providers within 35 miles of these facilities that offer similar cancer care and pain management services. At a time when the nation is searching for ways to respond to the opioid epidemic, it makes no sense from a patient or fiscal perspective to adopt policies that will reduce access to these services.

Proposed Changes to Supervision Requirements

We strongly support the proposal to permanently adopt a general supervision standard rather than a direct supervision standard for outpatient hospital services. This will help ensure continuing access to services, particularly in rural areas.

CMS Request for Comment on Potential 340B Remedies

We appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment on potential remedies for the nearly 30 percent reduction in reimbursement for certain 340B hospitals that a district court judge ruled were unlawful. Specifically, the agency seeks potential remedies for the calendar year (CY) 2018 and 2019 payments and for use in CY 2020 payments in the event the agency receives an adverse ruling by the U.S. Court of Appeals.

We believe the remedy should be as follows: Refund payments should be made to each affected 340B hospital and calculated using the JG modifier, which identifies claims for 340B drugs that were reduced under the 2018 and 2019 hospital outpatient prospective payment system (OPPS) rules, and other hospitals not adversely impacted by the reductions should be held harmless. This remedy would not disrupt the Medicare program and is consistent with those for past violations of law. Our detailed comments follow.

The Proper Remedy Is Straightforward and Easily Administered. There is a straightforward remedy that is easy to implement, will not be disruptive, does not require new rulemaking, and is comparable to those the courts and agency have adopted to correct other unlawful Medicare payment reductions. Specifically, the agency can recalculate the payments due to 340B hospitals based on the statutory rate of average sales price (ASP) plus 6 percent provided by the 2017 OPPS rule. Hospitals that have already received partial payment should receive a supplemental payment that equals the difference between the amount they received and the amount they are entitled to, including ASP plus 6 percent plus interest. Claims that have not yet been paid should be paid in the full amount, including ASP plus 6 percent.

While the claims will be for different total amounts, the percentage of the claim that the hospital was underpaid is identical in each case. These calculations should be on a hospital-by-hospital basis. Once the total amount that each hospital was paid is calculated, that amount can be multiplied by a single factor — which will be uniform across hospitals — to determine how much should have been paid and

thus how much the reimbursement was reduced. Each hospital can be compensated according to the amount that its reimbursements were reduced plus interest.

There Is Ample Precedent for Full Retroactive Adjustments that Are Not Budget Neutral.

There is ample authority for the Department of Health and Human Services (HHS) to remedy the underpayments caused by its unlawful rule, including: *Cape Cod Hospital v. Sebelius*, (D.C. Cir. 2011) (HHS corrected errors for the future and past claims for which hospitals had been underpaid), *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar*, (D.D.C. 2018), (HHS may make a retroactive adjustment without applying the budget-neutrality requirement to cancer hospitals that received a statutorily mandated adjustment a year later than the law required), and *Shands Jacksonville Medical Center v. Burwell*, (D.D.C. 2015), (HHS compensated hospitals for three years of across-the-board cuts with a one-time, prospective increase of 0.6 percent).

The remedy need not be budget neutral. The authority the agency cites is not applicable because such expenditures would be required by a court decision in service of fixing a prior unlawful underpayment. Moreover, the agency does not consistently apply budget neutrality to fix its missteps and in other relevant instances. For example, HHS allows for retroactive correction of the wage index without any budget-neutrality adjustment when it made the error and it was not something a hospital could have known or corrected. In addition, budget neutrality does not apply to changes in enrollment or utilization for drugs when the average sales price increases.

There Is No Basis for Paying Hospitals Less than the Statutory ASP Plus 6 Percent. The OPDS mandates HHS reimburse hospitals for covered outpatient drugs at ASP plus 6 percent. This was the methodology used from 2013 to 2017. HHS has now requested comment on adjusting the payment for 2018, 2019 and 2020 from ASP plus 6 percent to ASP plus 3 percent. Although the agency has some authority to deviate from this law, the agency is attempting to use a policy rationale that is inconsistent with the law itself and, therefore, it would be unlawful to reduce ASP to 3 percent.

New Patients Co-Pays Are Not Required. Medicare reimburses hospitals 80 percent for covered outpatient and the remaining 20 percent is collected from the patients or their insurance. Because HHS deviated from the lawful payment rate for 2018 and 2019 with a 30 percent reduction, in theory hospitals could collect from patients or their insurance companies the difference between 20 percent of the lawful payment rate and the 20 percent copay that was actually collected. HHS has requested comment on the “most appropriate treatment of Medicare beneficiary cost-sharing responsibilities.”

Although the agency has raised the specter that a remedy would require patient co-pays to be adjusted retroactively, we do not believe that there is any law that would require hospitals to collect payments altered by the agency’s illegal act. Neither the False Claims nor anti-kickback statutes would apply since patients would not have been induced to seek services. Patients who reasonably believe that they have fully paid for hospital care provided months, or in some cases years ago should not have to make these payments if hospitals are willing to forego them. We urge HHS to state this clearly in the final rule.

Proposed Changes to Children's Hospitals

We support the proposal to allow children's hospitals within other hospitals to expand their number of beds and retain their grandfathered Medicare payment status. We agree that these hospitals should not have to choose between their Medicare payment status and meeting the access needs of their communities.

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

Sincerely,



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