September 11, 2017

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
P.O. Box 8013
Baltimore, MD 21244–1850

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

ASHP is pleased to submit comments to the Center for Medicare & Medicaid Services (CMS) regarding the proposed changes to the hospital outpatient prospective payment system (OPPS) for calendar year 2018 (the "OPPS rule"). ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 44,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP's comments on the OPPS rule center on two proposals — the cuts to reimbursement for drugs acquired under the 340B Drug Pricing Program and the requirement that a modifier be attached for all separately payable drugs acquired outside of the federal 340B program. ASHP supports the 340B drug-discount program. Many of our members practice in 340B-participating hospitals and health systems and have seen firsthand how the federal 340B program allows providers to stretch scarce resources.

The federal 340B program is essential to many hospitals' ability to provide care to uninsured and underinsured patients. The discounts received through the program not only enable patient access to free or low-cost medications, but they also help offset the total cost of uncompensated care, which may include critical services such as chemotherapy and HIV treatments. Hospitals serving the poor shoulder more of the financial burden of caring for patients who are uninsured or underinsured.[1] Unlike other settings, where insurance coverage or ability to pay may be a requirement for service, covered entities within the federal 340B program are often the sole option for poor or uninsured patients to receive care. Absent discounts on 340B-purchased drugs, many covered entities may struggle to keep their doors open, as they would be unable to absorb the cost of providing uncompensated care to the most vulnerable patients.

CMS justifies its proposals as a means to "allow seniors to share in the discounted drug prices hospitals are already getting under Medicare."[2] However, if adopted, CMS's proposed changes would curtail patient access to services, increase costs, reduce hospitals' flexibility to allocate their resources, and increase regulatory burden. The original intent of the program was to enable covered entities that serve the poor to obtain discounted

[1] For example, by law, disproportionate share hospitals (DSH) must serve a disproportionate percentage of low-income patients compared to non-DSH designated hospitals. *See* 42 U.S.C. § 256b(a)(4)(L)(ii).
[2] *See* CMS Press Releases, "HHS Secretary Price Statement on Lower Drug Costs for Seniors" https://www.hhs.gov/about/news/2017/08/02/hhs-secretary-price-statement-lower-drug-costs-seniors.html

medications that would offset the uncompensated care for this population.[3] Thus, we urge CMS to withdraw this proposal and work with hospitals and other stakeholders to implement policies to address drug costs without counterproductive effects on patient care and access. In fact, CMS's own Advisory Panel on Hospital Outpatient Payment recently recommended that the agency drop this cut in reimbursement for drugs purchased through the federal 340B program. In explaining its recommendation, the Advisory Panel cited concerns regarding the negative impacts of the proposed change on covered entities.[4] ASHP shares these concerns and cautions the agency that adopting such a sweeping policy change without a full understanding of the impact puts our nation's most vulnerable patients at risk.

A. Beneficiaries Do Not Benefit from the Proposed Reimbursement Cut.

ASHP strongly opposes setting reimbursement for 340B-purchased drugs at ASP minus 22.5%. As proposed, this change is a reimbursement cut framed as a solution to high drug costs[5]. The federal 340B program is designed to allow providers flexibility to allocate resources where they are needed — largely to support programs that benefit patients but are not reimbursed by federal or private payers.

In practice, cutting reimbursement for 340B-purchased drugs does not equate to either lower costs or better care for patients. CMS argues that there is an "inextricable link" between the Medicare payment rate and the beneficiary cost-sharing amount.[6] However, this statement ignores the fact that many hospitals actually pass federal 340B program discounts to patients in the form of free or reduced-cost medications. If this change takes effect, hospitals may have to rethink the scope of those programs, which could result in higher drug costs for certain beneficiaries. Additionally, the federal 340B program provides hospitals funding to offer other benefits to patients, including charity care and expanded clinical services. Without the federal 340B program, hospitals may not have the revenue to sustain these programs and may be forced to either increase fees for these services or cut them completely. By attempting to make changes around the margins rather than addressing high drug costs directly, the proposed rule merely reduces funding for safety-net hospitals without guaranteeing either lower beneficiary costs or better care.

As CMS is aware, "the statutory intent of the 340B program is to maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive."[7] While we acknowledge that CMS intends to use the funds recouped from the reimbursement cut to bolster rural hospitals, we respectfully suggest that hospitals are best served by retaining control over their own funds. If federal 340B program funds revert to CMS, hospitals lose agility in responding to patient needs. Stripping hospitals of the flexibility to allocate resources effectively not only runs counter to the statutory intent of the federal 340B program, but will also harm beneficiaries in the long run.

ASHP is also concerned that the proposed reimbursement cut could lead to an exodus of providers from the

---

[3] Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b.
[4] Virgil Dickson, *Influential Advisory Panel Asks CMS to Reject $1.65 Billion in Cuts to 340B*, MODERN HEALTHCARE, available at http://news.aha.org/article/170821-cms-advisory-panel-dont-finalize-proposed-340b-cut-for-2018 (Aug. 21, 2017).
[5] *See* CMS Press Releases, "HHS Secretary Price Statement on Lower Drug Costs for Seniors" https://www.hhs.gov/about/news/2017/08/02/hhs-secretary-price-statement-lower-drug-costs-seniors.html (Citing the OPPS proposal as an additional means of lowering drug costs by "allowing [ing] seniors to share in the discounted drug prices hospitals are already getting under Medicare").
[6] CMS, *Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 33558 (July 20, 2017) at 33633.
[7] Id. at 33632.

program, potentially exacerbating the access challenges many patients have in rural and underserved areas. Many of our members have indicated that the policy, if finalized, could force some hospitals out of the program. Over time, this could lead to significant reductions in the number of participating hospitals and the scope of the federal 340B program more generally.

Further, Congress did not explicitly grant CMS statutory authority over the federal 340B program — day-to-day operation of the program resides with the Health Resources and Services Administration (HRSA).[8] While we recognize that CMS retains control over Medicare payment policy, we question whether the proposed reimbursement is an attempt to circumvent HRSA to effect federal 340B program changes without statutory authority. If CMS has concerns regarding the size and scope of the federal 340B program, we strongly encourage the agency to work directly with Congress and HRSA to address these issues. Many participants of the federal 340B program would welcome the opportunity to work with HRSA to further improve and strengthen the program.

B. Faulty Assumptions Regarding the Federal 340B Program Underlie the Reimbursement Cut.

ASHP questions CMS's assumption that increased drug prices or Medicare spending are tied to the growth of the federal 340B program. The growth in the federal 340B program can definitively be attributed to at least one factor — Congress. In 2010, Congress both expanded the list of entities eligible for the federal 340B program and introduced healthcare models that shifted patients away from high-cost inpatient care to lower-cost outpatient care.[9] Based on these shifts, the increases in Medicare Part B drug costs and the growth of the federal 340B program were entirely predictable.

However, in its analysis, CMS appears to ignore these underlying policy factors to assume that the federal 340B program caused the increase in Medicare Part B spending. CMS's incorrect assumption of causation is based in part on a GAO study that did not adequately control for differences in patient populations between 340B-participating hospitals and non-340B-participating hospitals, relying instead on comparison criteria such as "hospital size, teaching status, ownership type (public, nonprofit, or for profit), location (urban or rural), DSH adjustment percentage (high or low), and provision of charity care and uncompensated care (high or low)."[10] Furthermore, despite CMS's assertions that the federal 340B program is driving hospital profits, CMS lacks basic information about the actual costs for 340B-participating hospitals, noting that the "lack of information in the claims data has limited researchers' and our ability to precisely analyze cost of 340B and non-340B-acquired drugs with Medicare claims data."[11] CMS should refrain from making changes to vital safety-net programs until it has reviewed accurate, comprehensive data. Again, this is consistent with the concerns expressed by the CMS Advisory Panel.

---

[8] *See* 42 U.S.C. § 256b; See also H.R. Rept. No. 102-384 (Part 2), at 12 (1992) (Conf. Rept.).

[9] *See* Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, §§ 2501, 2902, 3402, 7101- 03, 124 Stat. 119, 309, 333, 488, 821-28 (2010).

[10] Government Accountability Office, "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals GAO-15-442" (June 2015), *available at* https://www.gao.gov/assets/680/670676.pdf. The GAO Report fails to take into account the significant costs associated with treating poorer, sicker patients. *See, e.g.,* Al Dobson, Kennan Murray, and Joan DaVanzo, *Financial Challenges Faced by 340B Disproportionate Share Hospitals In Treating Low-Income Patients* (Aug. 4, 2017), available at http://www.340bhealth.org/files/Financial_Challenges_Final_Report_08.04.17.pdf.

[11] CMS, *Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 33558 (July 20, 2017) at 33633.

C. The Proposed Modifier Increases the Regulatory Burden on Hospitals.

ASHP supports efforts to increase data transparency, but we are concerned that the proposed modifier for all non-340B-purchased drugs is duplicative and burdensome. At a time when the U.S. Department of Health & Human Services (HHS) has highlighted the reduction of regulatory requirements as a key goal, the proposed modifier significantly adds to a hospital's regulatory burden, regardless of whether the hospital actually participates in the federal 340B program. Based on feedback from our members, the process to implement the modifier would be, at best, extremely time-consuming and, at worst, nearly impossible in some systems. Additionally, our understanding is that some hospitals already attach a federal 340B program modifier to claims to comply with state Medicaid requirements. Given the proposed rule's acknowledged lack of detail regarding the modifier, it is difficult to provide CMS with substantive comments. ASHP respectfully requests that CMS refrain from finalizing any implementation of the modifier until stakeholders are given the opportunity to comment on a more comprehensive proposal.

ASHP appreciates this opportunity to offer our input on the OPPS rule. As noted above, ASHP shares CMS's commitment to reducing drug prices, and we are very willing to work with the agency to help identify and implement meaningful solutions. If you have any questions or wish to discuss our comments further, please contact me via email at jschulte@ashp.org or by phone at (301)-664-8806.

Sincerely,

Jillanne Schulte Wall, J.D.
Director, Federal Regulatory Affairs