AIMEDALLIANCE

September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022–CMS-1793-P

Dear Administrator Brooks-LaSure:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to provide feedback on the Center for Medicare and Medicaid Services (CMS) proposed rule on the remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022–CMS-1793-P.

As stated in our comments below, Aimed Alliance supports CMS's proposal to provide lump-sum payments, including beneficiary cost-sharing, to affected providers for 340B-acquired drugs for the period of CY 2018 through the third quarter of 2022.

I. Background

The Medicaid 340B drug pricing program requires drug manufacturers participating in Medicaid to provide outpatient drugs to participating entities at significantly reduced prices.[1] The federal initiative, established in 1992 as part of the Public Health Service Act (PHSA), was designed to benefit eligible hospitals and facilities, termed "covered entities," by granting them access to drugs at reduced prices, thereby promoting accessible and affordable healthcare.

Covered entities include: Federally Qualified Health Centers (FQHCs), or community-based healthcare providers that offer comprehensive primary care services to underserved areas and populations;[2] Ryan White HIV/AIDS Program Grantees;[3] certain children's hospitals; critical access hospitals;[4] disproportionate share hospitals, which serve a large number of low-income,

[1] 340B Drug Pricing Program, Medicaid.gov, https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/340b-drug-pricing-program/index.html#:~:text=The%20340B%20Program%20requires%20drug,entities%20at%20significantly%20reduced%20prices.

[2] Federally Qualified Health Center, HeathCare.gov, https://www.healthcare.gov/glossary/federally-qualified-health-center-fqhc/.

[3] Organizations that provide medical care and support services to individuals living with HIV/AIDS Ryan White HIV/AIDS Program Grantees, Health Resources & Services Organization, https://www.hrsa.gov/opa/eligibility-and-registration/ryan-white.

[4] These are small rural hospitals that ensure access to essential healthcare services in underserved areas Critical Access Hospitals, Centers for Medicare & Medicaid Services, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.

underinsured, uninsured, and Medicaid patients;[5] freestanding cancer hospitals;[6] rural referral centers;[7] sole community hospitals;[8] and specialized clinics.[9] By enabling these entities to purchase medications at significantly reduced prices, the 340B program is intended to improve their financial capacity to serve underserved communities and enhance access to essential medications for the most vulnerable patients.[10]

In 1997, Congress intervened to manage costs, promote efficiency, and standardize payments for outpatient services.[11] Congress assigned CMS with the responsibility of creating the Outpatient Prospective Payment System (OPPS), through which Medicare would decide how much money a hospital or community mental health center is reimbursed for outpatient care provided to Medicare patients.[12] This initiative mandated that CMS establish reimbursement rates for separately payable drugs, which includes drugs covered by the 340B program.[13]

The statute establishes two options for setting Medicare reimbursement rate: (1) if reliable acquisition cost data for each drug are available, CMS must base rates on those costs, or (2) if such data are unavailable, reimbursement must be based on the Average Sales Price (ASP), a defined quantity under a different statutory provision, plus 6 percent.[14] CMS adopted the default method, ASP plus 6 percent, for all individually payable drugs.[15] This default rate remained unadjusted until January 1, 2018.[16]

Despite the implementation of the OPPS, certain program efficiencies inadvertently opened the door to exploitative practices. Some hospitals capitalized on the advantages of the 340B program, acquiring drugs at reduced costs and then reselling them to privately insured

---

[5] Disproportionate Share Hospitals, Health Resources & Services Organization, https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals.
[6] These are independent, non-profit hospitals that treat patients with cancer. Freestanding Cancer Hospitals, Health Resources & Services Organization, https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/freestanding-cancer-centers.
[7] These are hospitals that specialize in high-volume acute care, managing a substantial caseload of complex medical instances. Rural Referral Centers, Health Resources & Services Organization, https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/rural-referral-centers.
[8] These hospitals are required to meet specific classifications, including private nonprofit hospitals providing care to low-income individuals not eligible for Medicare or Medicaid under government contracts, hospitals owned/operated by state/local governments, or nonprofit corporations granted governmental powers by a state/local government unit. Sole Community Hospitals, Health Resources & Services Organization, https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/sole-community-hospitals.
[9] Specialized clinics include Black Lung clinics, comprehensive Hemophilia diagnostic treatment centers, Title X Family Planning clinics, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics 340B Drug Pricing Program, Health Resources & Services Organization, https://www.hrsa.gov/opa/eligibility-and-registration.
[10] 340B Drug Pricing Program, Health Resources & Services Administration, https://www.hrsa.gov/opa.
[11] Teri Guidi, Medicare's Hospital Outpatient Prospective Payment System: OPPS 101, 6 Journal of Oncology Practice 321-24, (2010).
[12] Teri Guidi, Medicare's Hospital Outpatient Prospective Payment System: OPPS 101, 6 Journal of Oncology Practice 321-24, (2010).
[13] Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System, OEI-03-09-0042, Dep't. of Health & Human Serv., https://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf
[14] 42 U.S.C. § 1395l(t)(14)(A)(iii).
[15] 76 Fed. Reg. 74121, 74204 (2011).
[16] Complaint, 11, *American Hospital Association v. Becerra*, Case 1:18-cv-02084-RC.

patients at elevated prices.[17] This approach enabled these hospitals to achieve financial gains that far surpassed the program's original objectives.[18]

In an attempt to respond to this evolving landscape, the U.S. Department of Health and Human Services (HHS) issued the January 2017 final rule on 340B, implementing a significant reduction in the prescription drug payment rate, to address concerns about the program's increasing costs and potential overuse.[19] HHS intended for the payment cut to align the reimbursement rates more closely with the actual acquisition costs of drugs for participating hospitals.[20] HHS stated this measure would foster proper utilization of the program, ensuring that the intended savings were directed to serve vulnerable patient populations, in line with the program's original purpose.[21]

The decision to implement the reduction prompted legal action by the American Hospital Association (AHA) and other hospital groups, which filed a lawsuit against HHS to stop the cuts.[22] They argued that the 340B regulations in the final rule for CMS's OPPS violated the Social Security Act, and, consequently, should be set aside under the Administrative Procedure Act as unlawful and in excess of the HHS Secretary's statutory authority.[23] Ultimately, in June 2022, the Supreme Court unanimously intervened and rejected the substantial payment cuts to hospitals participating in the 340B drug discount program, deeming the payment cuts unauthorized due to the agency's failure to adhere to the mandated survey of acquisition costs.[24]

In light of the Court's ruling, CMS proposed a rule to address the issue of the 340B-acquired drug payment policy for the years 2018 to 2022.[25] It proposes to disperse lump sum payments to providers affected by this policy. Additionally, the proposed rule outlines measures related to beneficiary copayments and a prospective offset to ensure budget neutrality.

II. Statement of Support to Finalize Rule

---

[17] Rena Conti and Peter Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, 33 HEALTH AFFAIRS 1786-92 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4591849/.

[18] Rena Conti and Peter Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, 33 HEALTH AFFAIRS 1786-92 (2014),

[19] Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 Proposed Rule (CMS 1793-P) (Jul. 7, 2023), https://www.cms.gov/newsroom/fact-sheets/hospital-outpatient-prospective-payment-system-remedy-340b-acquired-drug-payment-policy-calendar.

[20] 82 Fed. Reg. 33,558 (2017).

[21] 82 Fed. Reg. 33,558 (2017).

[22] American Hospital Association, *Hospital Groups File Lawsuit to Stop Significant Payment Cuts for 340B Hospitals*, https://www.aha.org/press-releases/2017-11-13-hospital-groups-file-lawsuit-stop-significant-payment-cuts-340b-hospitals.

[23] American Hospital Association, *Hospital Groups File Lawsuit to Stop Significant Payment Cuts for 340B Hospitals*, https://www.aha.org/press-releases/2017-11-13-hospital-groups-file-lawsuit-stop-significant-payment-cuts-340b-hospitals.

[24] *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022).

[25] Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 Proposed Rule (CMS 1793-P) (Jul. 7, 2023), https://www.cms.gov/newsroom/fact-sheets/hospital-outpatient-prospective-payment-system-remedy-340b-acquired-drug-payment-policy-calendar.

a. Lump Sum Payments for 340B-Acquired Drugs

CMS has proposed to make a one-time $9 billion lump-sum combined payment to certain hospitals and clinics serving large numbers of low-income patients for underpayments for 340B-acquired drugs between CY 2018 and 2022. Approximately 1,600 affected hospitals are anticipated to receive owed funds.

Aimed Alliance supports CMS's decision to provide a lump-sum payment to address the underpayment stemming from the unlawful 340B-acquired drug payment policy, which caused financial shortfalls for affected hospitals serving large numbers of low-income patients over several years. The proposed adoption of a lump-sum payment demonstrates an efficient approach to remedying the situation and reinforces the importance of ensuring that these essential healthcare providers can continue offering crucial services to their communities by reducing unnecessary financial burdens.

b. Beneficiary Copayments

Typically, beneficiaries would pay through coinsurance approximately 20 percent of any 340B drug payments that 340B covered entity hospitals would have received, absent the drug payment policy in place for 2018 to 2022. To maintain fairness in the remedy framework and prevent any impact on beneficiary copayments due to hospitals, CMS intends to reimburse hospitals for what they would have received from beneficiary cost-sharing. Consequently, out of the $9.0 billion payment, $1.8 billion is allocated to compensate for what affected 340B covered entity hospitals would have collected from beneficiaries for these 340B-acquired drugs, had the 340B payment policy not been in effect. As a result, these hospitals will not be allowed to bill beneficiaries for coinsurance on remedy payments.

Aimed Alliance supports CMS's decision to repay both the HHS underpayments and beneficiary cost-sharing components in a one-time lump sum payment. This approach, contrary to reprocessing the claims, protects patients from significant changes in cost sharing for claims they believed had been resolved several years ago. We support CMS's commitment to preventing unexpected changes in cost sharing, particularly for low-income patients.

III. Conclusion

We support CMS's proposed rule to rectify the underpayment stemming from the 340B-acquired drug payment policy and are pleased with the incorporation of cost-sharing considerations into the remedy structure. We appreciate the opportunity to comment on this critical matter and look forward to the positive impact of these efforts on the lives of countless individuals who rely on the 340B program for their healthcare needs.

Sincerely,

Olivia Backhaus
Counsel