

September 15, 2025

The Honorable Mehmet Oz, MD
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-1834-P
P.O. Box 8010

RE: [Docket No. CMS 1834-P] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency

Dear Administrator Oz,

Baltimore, MD 21244-8013

The American Pharmacists Association (APhA) is pleased to submit comments on the "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency," Proposed Rule.

APhA is the only organization advancing the entire pharmacy profession. It represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including—but not limited to—community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

CY 2026 Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy (FR 33631)

CMS states that "to comply with statutory budget neutrality requirements, the decreased payments made to 340B hospitals for drugs in CY 2018 through September 27, 2022[,] were budget neutralized by corresponding increased payments to all hospitals for non-drug items and services starting in CY 2018 through CY 2022." CMS goes on to provide that "[w]hen these

<sup>1</sup> Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and

past payments were subsequently increased through the one-time lump sum payments in 2024, the same budget neutrality requirements correspondingly required us to decrease the non-drug item and services payments made from CY 2018 through CY 2022."<sup>2</sup> Rather than adjusting for the entire offset amount in one year, CMS is proposing to implement the offset over several years "[t]o reduce the burden on providers of immediately offsetting the estimated \$7.8 billion of increased non-drug item and services payments made from CY 2018 through CY 2022."<sup>3</sup> CMS finds this approach more "appropriate because it would balance the need to address the past payments for non-drug items and services to ensure budget neutrality while also ensuring that the offset was not immediately overly financially burdensome on impacted entities."<sup>4</sup>

CMS previously "finalized changes to the calculation of the OPPS conversion factor applicable to non-drug items and services beginning in CY 2026" in the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022. At that time, CMS "codified a 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services in the regulations by adding new paragraph (b)(1)(iv)(B)(12) to §419.32," which was estimated to pay back the \$7.8 billion in CY 2041.

Within the proposed rule, CMS notes that "[w]hile [they] continue to believe that a reduction to the OPPS conversion factor is the best way to effectuate budget neutrality, [they] are reconsidering whether the timing we selected – a 0.5-percentage point annual reduction for approximately 16 years—best achieves the overarching goal of the Final Remedy rule [Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022], which is to restore hospitals to as close to the financial position they would have been in had the 340B Payment Policy never been implemented as is reasonably feasible." 7 CMS reasons that "the further away from CY 2018 through CY 2022 the adjustments extend, the less likely that relative hospital utilization of non-drug items and services will correlate to the relative hospital utilization of non-drug items and services from 2018 through 2022."8 CMS also notes that "it is possible that at least some hospitals that benefited from the increased payments from CY 2018 through CY 2022 will leave the market before 2041, increasing the risk that the remaining hospitals might ultimately account for a larger share of the payment reductions than they would have if the annual reduction to the OPPS conversion factor concluded sooner."9 As such, CMS is "propos[ing] to revise the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(12) used to determine the payment amounts for non-drug items and

Hospital Price Transparency, 90 Fed. Reg. 33476, 33633 (July 17, 2025). Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-1125">https://www.federalregister.gov/d/2025-13360/p-1125</a>.

<sup>&</sup>lt;sup>2</sup> *Id*.

<sup>&</sup>lt;sup>3</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-1126">https://www.federalregister.gov/d/2025-13360/p-1126</a>.

<sup>&</sup>lt;sup>4</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13360/p-1127.

<sup>&</sup>lt;sup>5</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13360/p-1128.

<sup>6</sup> *Id*.

<sup>&</sup>lt;sup>7</sup> *Id.* at 33634. Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-1132">https://www.federalregister.gov/d/2025-13360/p-1132</a>.

<sup>&</sup>lt;sup>8</sup> *Id*.

<sup>&</sup>lt;sup>9</sup> *Id*.

services from 0.5 percent to 2 percent," which "would take approximately 6 years to reach the total offset of \$7.8 billion." 10

APhA has heard from its health system pharmacists and members that this change will cause significant financial strain on many hospitals, especially from concerns that this change will disproportionately affect small rural hospitals, which are already struggling to keep their doors open for medically underserved communities. As such, APhA requests that CMS reconsider shortening the recoupment period or consider a gradual approach to increasing the annual percent reduction in the OPPS conversion factor. While APhA understands CMS's rationale for recovering the \$7.8 billion sooner, CMS should propose a solution that does not force more hospitals to close, which would mainly be attributed to lower Medicare reimbursements.

## Notice of Intent to Conduct a Medicare OPPS Drugs Acquisition Cost Survey (FR 33653)

The proposed rule states that "section 1833(t)(14)(A)(iii) requires the Secretary to set payment rates for specified covered outpatient drugs (SCODs) beginning in 2006 at the amount the Secretary determines to be the average acquisition cost for the drug for that year, at least when certain hospital acquisition cost survey data is available." To help the Secretary determine payment rates, "section 1833(t)(14)(D)(ii) requires the Secretary periodically to conduct surveys of hospital acquisition costs for each SCOD." The proposed rule also notes that President Trump issued Executive Order (E.O.) 14273, "Lowering Drug Prices by Once Again Putting Americans First" on April 18, 2025, which "directs the Secretary of HHS to publish in the Federal Register a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments." Thus, CMS is "intend[ing] to survey hospitals paid under the OPPS for their drug acquisition costs, including for SCODs, and drugs and biologicals CMS historically treats as SCODs" in early 2026.

CMS "will survey hospitals only about drugs that are separately paid under the OPPS and will ask hospitals to report the total acquisition cost, net of all rebates and discounts, of each drug by National Drug Code (NDC) purchased during the 1-year timeframe of July 1, 2024, through June 30, 2025." <sup>15</sup> CMS is also "asking hospitals to incorporate all rebates and discounts in their acquisition cost for each NDC, including discounts directly applicable to an individual NDC, but also those discounts that are not necessarily linked to a single NDC, but could be a discount linked to a certain invoice, or discounts linked to purchases made over a certain time period, such as prompt pay discounts, wholesaler discounts, or other discounts." <sup>16</sup> CMS does note that

<sup>&</sup>lt;sup>10</sup> *Id.* at 33634-33635. Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-1133">https://www.federalregister.gov/d/2025-13360/p-1133</a>.

<sup>&</sup>lt;sup>11</sup> *Id.* at 33653. Available at: https://www.federalregister.gov/d/2025-13360/p-1257.

<sup>&</sup>lt;sup>12</sup> *Id*.

<sup>&</sup>lt;sup>13</sup> *Id.* at 33481. Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-1259">https://www.federalregister.gov/d/2025-13360/p-1259</a>.

<sup>&</sup>lt;sup>14</sup> *Id.* at 33832. Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-2416">https://www.federalregister.gov/d/2025-13360/p-2416</a>.

<sup>&</sup>lt;sup>15</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-2416">https://www.federalregister.gov/d/2025-13360/p-2416</a>.

<sup>&</sup>lt;sup>16</sup> *Id*.

"discounts may depend on whether an eligible patient receives the drug," citing those acquired as part of the 340B program as an example. Accordingly, CMS is "asking for hospitals to separately list their acquisition costs for drug NDCs acquired through the 340B program and those drug NDCs acquired outside of the 340B program in order to ensure that all of the discounts are accurately captured and represent the hospital's acquisition costs." 17

APhA members have expressed concern regarding CMS's intent to conduct this survey. More specifically, members have expressed concerns about the impact that the survey results could have on reimbursement, the administrative burden of completing the survey, and the subsequent use of the data submitted. Manufacturers and wholesalers are likely better sources for disclosure of 340B discounts.

Regarding the impact the survey results could have on reimbursement, APhA members are concerned that CMS could use this data to lower reimbursement rates to the point of acquisition costs. The closer the reimbursement rates are to acquisition costs, the less the reimbursement price is reflective of the overhead and other costs associated with operating a hospital pharmacy. APhA urges CMS to ensure that reimbursements to hospitals for these drugs reflect the value that hospitals and patients receive from having a pharmacist ensure that the medication is an appropriate therapy for them, including all additional costs and services to hospital pharmacists and their pharmacies, particularly for specialty medications. APhA notes that over \$528 billion is wasted and 275,000 lives are lost each year in the United States due to non-optimized medication use. Comparing this to the U.S. expenditure on prescription medications, \$340 billion, for every \$1.00 spent on drug therapy, we spend an additional \$1.55 to address the problems associated with non-optimized drug therapy. Accordingly, APhA encourages CMS to focus on address a primary concern of wasted funding by addressing the large disparity in non-optimized medication use to reduce Medicare costs.

Additionally, APhA members also expressed concern regarding the administrative burden of completing this survey. CMS "estimate[s] the total time for each hospital to respond to this survey to be 73.5 hours, which includes time required to review instructions, gather data (including potentially from hospital wholesalers), perform basic addition calculations, and enter data." <sup>20</sup> Of those 73.5 hours, 1 hour is credited to a pharmacist's time in helping complete the survey, and 71 hours are credited to pharmacy technicians. CMS uses this data to find that the

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<sup>&</sup>lt;sup>17</sup> Id. at 33832-33833. Available at: https://www.federalregister.gov/d/2025-13360/p-2416.

<sup>&</sup>lt;sup>18</sup> Jonathan H. Watanabe, et al., *Cost of Prescription Drug-Related Morbidity and Mortality*, 52 Annals of Pharmacology 829 (2018). Available at: <a href="https://pubmed.ncbi.nlm.nih.gov/29577766/">https://pubmed.ncbi.nlm.nih.gov/29577766/</a>.

<sup>&</sup>lt;sup>19</sup> Prescription Drug Spending in the U.S. Health Care System, American Academy of Actuaries (Mar. 2018). Available at: <a href="https://actuary.org/prescription-drug-spending-in-the-u-s-health-care-system/#:%7E:text=Health%20care%20spending%20in%20the,was%20spent%20on%20prescription%20dr.">https://actuary.org/prescription-drug-spending-in-the-u-s-health-care-system/#:%7E:text=Health%20care%20spending%20in%20the,was%20spent%20on%20prescription%20dr.</a>

<sup>&</sup>lt;sup>20</sup> Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency, 90 Fed. Reg. 33476, 33833 (July 17, 2025). Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-2419">https://www.federalregister.gov/d/2025-13360/p-2419</a>.

total estimated annual cost per response will be \$4,053.40.<sup>21</sup> APhA members, especially those in small rural hospitals, have expressed that the time commitment involved in completing this survey will create a burden on the routine of their pharmacy technicians and pharmacists, taking them away from providing direct patient care services without appropriate reimbursement for this time, which amounts to an unfunded mandate. Many of these hospitals are already facing both staffing shortages and financial constraints, and this survey would require a pharmacy technician to take almost two full weeks of work time to complete.<sup>22</sup> Additionally, this may increase as CMS has not finalized the survey. As such, APhA asks CMS to first finalize its survey and publicly disclose the results, and consider the impact on hospital pharmacies when finalizing this survey to minimize the administrative burden it will place on pharmacists, pharmacy technicians, and hospitals.

Thank you for the opportunity to provide feedback on the proposed rule and for considering our comments. If you have any questions or would like to meet with APhA or health system and hospital pharmacists to discuss our comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at <a href="mailto:cwhetzel@aphanet.org">cwhetzel@aphanet.org</a>.

Sincerely,

Michael Baxter

Vice President, Government Affairs

Michael Baxter

<sup>&</sup>lt;sup>21</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13360/p-2425.">https://www.federalregister.gov/d/2025-13360/p-2425.</a>

<sup>&</sup>lt;sup>22</sup> *Id.* (noting that the proposed rule estimates that the survey will take 71 hours for pharmacy technicians to complete).