DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

November 16, 2026

TO: Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: Ann Maxwell
Deputy Inspector General
for Evaluation and Inspections

Ann Maxwell

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Date: 2026.11.13 15:29:50 -05'00'

SUBJECT: *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Second Quarter of 2026*, OEI-03-27-00010

This memorandum summarizes the results of the Office of Inspector General's (OIG's) comparison of average sales prices (ASPs) and average manufacturer prices (AMPs) for the second quarter of 2026. By law, OIG must notify the Secretary of Health and Human Services if the ASP for a particular drug exceeds the drug's AMP by 5 percent or more. If that threshold is met, the Secretary may disregard the drug's ASP when setting the reimbursement amount and substitute the lesser of either the widely available market price or 103 percent of the AMP.

In April 2013, the Centers for Medicare & Medicaid Services (CMS) began making price substitutions in accordance with the November 2012 final rule specifying the circumstances under which AMP-based price substitutions occur. Pursuant to the rule, CMS substitutes 103 percent of the AMP for the ASP-based reimbursement amount when OIG identifies a drug code that exceeds the 5-percent threshold for two consecutive quarters or three of the previous four quarters. CMS lowers reimbursement amounts only when ASP and AMP comparisons are based on the same set of drug products (i.e., based on complete AMP data). To prevent CMS from inadvertently raising the Medicare reimbursement amount, a price substitution is not implemented if the substituted amount would exceed the ASP-based payment amount for the quarter in which the price substitution would take effect. In addition, price substitutions are not implemented for drugs that the Food and Drug Administration (FDA) identifies as being in short supply.

OIG found that in the second quarter of 2026, 10 drug codes met CMS's price-substitution criteria by exceeding the 5-percent threshold for 2 consecutive quarters or 3 of the previous 4 quarters, on the basis of complete AMP data. OIG found one additional drug code that, on the basis of complete AMP data, exceeded the 5-percent threshold for two consecutive quarters or three of the previous four quarters. However, at the time of our analysis, FDA identified this one drug as being in short supply. Another 10 drug codes had ASPs that exceeded the AMPs by at

least 5 percent in the second quarter of 2026, on the basis of complete AMP data, but these 10 drug codes did not meet other CMS price-substitution criteria.

We will provide you with the results of our pricing comparison for the second quarter of 2026. This information will be transmitted via our secure file transfer system.

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued in 2020 by the Council of the Inspectors General on Integrity and Efficiency.