



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



TO: Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Suzanne Murrin
Deputy Inspector General
for Evaluation and Inspections

Ann Maxwell

SUBJECT: *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter of 2020, OEI-03-21-00070*

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 fourth quarter of 2020. 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 shall substitute the payment amount with 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 shall 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 shall not be implemented if the substituted amount would exceed the ASP-based payment amount for the quarter in which the price substitution would take effect. Nor shall price substitutions be implemented for drugs that the Food and Drug Administration (FDA) identifies as being in short supply.

In the fourth quarter of 2020, OIG found that five drug codes met CMS's price substitution criteria by exceeding the 5-percent threshold for two consecutive quarters or three of the previous four quarters, based on complete AMP data. OIG found three additional drug codes that, based on complete AMP data, exceeded the 5-percent threshold. However, at the time of

our analysis, FDA identified these drug codes as being in short supply. Another eight drug codes had ASPs that exceeded the AMPs by at least 5 percent in the fourth quarter of 2020, based on complete AMP data, but these drug codes did not meet other CMS price-substitution criteria.

We will provide you with the results of our pricing comparison for the fourth quarter of 2020, as well as the results for the three previous quarters. This information will be transmitted via our secure file transfer system.