

GUIDANCE ON AVERAGE MANUFACTURER PRICE (AMP) AND BEST PRICE (BP) METHODOLOGY RECALCULATIONS

This guidance responds to request we have from manufacturers to modify their methodology for calculating the Average Manufacturer Price (AMP) or best price (BP) under the Medicaid drug rebate program. In many cases these requests have been pending prior to the effective date of regulations that set the 12 quarter time limitation for the submission of this data. We have decided that manufacturers with pending recalculation requests may implement the revised pricing methodology for the specified periods without prior review and approval by the Centers for Medicare & Medicaid Services (CMS). Manufacturers may also proceed with changes to AMP or BP for a period not in excess of 12 quarters pending with us that were received after the 12 quarter limitation took effect.

Additionally, a manufacturer that needs to make future recalculations regarding AMP and/or BP methodology may do so without prior review and approval by CMS. However, we continue to request that manufacturers notify us of the change in the method used to calculate their AMP and/or BP, along with revised AMP and/or BP data to support the change for the drugs affected, the relevant 11-digit NDC numbers, the fiscal magnitude of the change, and a statement as to the reason for the change in methodology. Manufacturers must report to CMS these revisions to AMP and/or BP for a period not to exceed 12 quarters from the quarter in which the data were due.

Recognizing the financial impact that the recovery of these historical incorrect payments may have on some States, we suggest that each manufacturer work with all States to limit the recovery of overpayments so that no State is unduly burdened. Specifically, we suggest that manufacturers limit recoveries from each State to a maximum of 25 percent of the amount otherwise payable in one quarter.

Because of the recalculations at issue, manufacturers should contact MDROperations@cms.hhs.gov to obtain instructions regarding the data resubmission process.

As in the case with all pricing data submitted under the Medicaid drug rebate program, if a subsequent review of a manufacturer's methodology for calculating AMP, BP or other pricing data by CMS, the Office of Inspector General, or another authorized government agency determines or reveals that additional adjustments or revisions are necessary, the manufacturer is responsible for complying with that determination. Additionally, in accordance with Section 1927 and Federal regulations at 42 CFR § 447.510(f), manufacturers must maintain records (written or electronic) for 10 years from the date the manufacturer reports data (or reports revised pricing data) to CMS for that rebate period, including the reported data, and any other materials from which the calculations of AMP and BP are derived, as well as any assumptions made in the calculations. A manufacturer must retain records beyond the 10-year period if they are the subject of an unresolved

audit or government investigation of which the manufacturer is aware relating to pricing data that are used in AMP or BP.

CMS is not expressing an opinion as to whether the revised pricing calculation is consistent with the methodology set forth in the statute and rebate agreement or the requirements of the Medicaid drug rebate program. CMS' receipt of revised pricing data, a recalculation request (or any acknowledgment of such receipt), or this Medicaid drug rebate program release is not, and may not be considered to be, CMS approval of the revised methodology or an advisory opinion under Section 1128D (b) of the Social Security Act. Only the Inspector General of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under that section. Further, CMS' receipt of a recalculation request (or any acknowledgement of such receipt), revised pricing data or this Medicaid drug rebate program release is not a release of any liability.