

Sent to Manufacturer Technical & Invoice Contacts on 03/03/2016

Dear Manufacturer,

In accordance with Section 1927(b)(2)(A) of the Social Security Act (the Act), States are required to submit drug rebate utilization data to CMS within 60 days of the end of each quarter. CMS stores this utilization data in the Medicaid Drug Rebate (MDR) system and also performs nightly updates of this data in the Drug Data Reporting for Medicaid (DDR) system. Additionally, CMS periodically posts the data on the CMS website at <http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Programs-Data-and-Resources.html>; however, as this data is only updated quarterly, manufacturers should use the data in DDR for the most current utilization data status.

Consistent with the Branded Prescription Drug program in the Affordable Care Act, state utilization data continue to be used as part of the methodology for calculating an annual fee on branded prescription drug manufacturers and importers. In general, the government drug programs specified in section 9008 (e.g., Medicaid, Medicare Part B and Medicare Part D) are required to report drug sales information to the Department of Treasury each year so that the fees can be accurately calculated. As a result, the accuracy of the state utilization data is essential to ensuring that Medicaid's drug sales information is reported correctly to the Department of Treasury.

To that end, manufacturers are encouraged to monitor utilization data in DDR to ensure that state utilization data reported to CMS are accurate as compared to the state rebate invoices received by manufacturers (Note: the Medicaid state utilization data reported to CMS and posted in DDR does not reflect State-only and/or State Pharmacy Assistance Program units; therefore, please do not consider these types of units when performing your review). The next annual fee calculation will use the data submitted by states for all quarters in 2015. If there are differences between quarterly rebate invoices and the state-reported utilization data in DDR for the same quarter in 2015, we request that a manufacturer contact the appropriate state's Technical Contact (copying CMS at MedicaidBPD@cms.hhs.gov) regarding the difference. A list of state Technical Contacts can be found at <http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html>. If a discrepancy is found, states can resubmit utilization data with corrected units to CMS.

In addition to such utilization adjustments, states are also required to update utilization based on agreed-upon rebate dispute resolutions and adjustments. If a manufacturer has reached agreement on an adjustment and/or dispute with a state and that agreement isn't reflected in DDR by the due date of the next quarterly data transmission from the state, the manufacturer may contact the state to confirm that the adjusted data has been reported to CMS.

Since the CMS State Drug Utilization Data File is being used, in part, to determine the branded prescription drug fee, if the data are understated or overstated, then the fee could also be understated or overstated. CMS encourages labelers to contact states, giving priority to significant disparities in utilization to help ensure accuracy in the calculation of the annual fee.

Note: We have sent this information to the Manufacturers' Technical Contacts for the Medicaid Drug Rebate Program (MDRP). If you are not your company's contact for the branded prescription drug fee (BPD) program, please forward to your company's BPD contact, and be aware that he/she may need

your assistance using/interpreting the rebate data being used for the annual sales fee to more effectively evaluate whether disputes are warranted, and how to present the data in such instances.

Thank you for your cooperation with this effort. If you have any questions, please feel free to contact us via this email resource box, MedicaidBPD@cms.hhs.gov.

Sincerely,

CMS Medicaid BPD Team