

Sent To Manufacturer Technical Contacts 09/13/2012

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 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>.

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 may periodically monitor Medicaid.gov (see URL cited above) to review the data submitted by states and ensure that state utilization data reported to CMS each quarter are accurate as compared to the state rebate invoices received by manufacturers (Note: the Medicaid state utilization data reported to CMS and posted on Medicaid.gov 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 2011. If there are differences between quarterly rebate invoices and the state-reported utilization data on the CMS website for the same quarter in 2011, we request that a manufacturer contact the appropriate state's Technical Contact (copying CMS at MDROperations@cms.hhs.gov) regarding the difference. A list of states 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; however, Medicaid.gov is only updated once per quarter with utilization data changes. Therefore, please keep the following schedule of utilization data updates in mind when monitoring Medicaid.gov for updates:

Schedule of Utilization Data Updates to Web (available on URL cited in first paragraph):
The State Drug Utilization Data are updated each quarter and posted to the website during the following months:

1st Quarter (plus 5 preceding years of data):	August
2nd Quarter (plus 5 preceding years of data):	November
3rd Quarter (plus 5 preceding years of data):	February
4th Quarter (plus 5 preceding years of data):	May

State drug utilization data older than the current quarter plus five previous years of data is updated annually and posted to the website during the month of February.

Because the utilization data on Medicaid.gov are updated on a quarterly basis, a state may have reported updated utilization information to CMS, but the adjusted/corrected data may not yet be reflected on Medicaid.gov. Therefore, if a state has agreed to a utilization correction or adjustment, please allow one quarterly web update to pass before checking the website for the updated data or following up with the state. This should allow ample time for the state to report any necessary utilization data adjustments to CMS and for the correction to subsequently appear on Medicaid.gov.

In addition to such utilization adjustments, states are also required to update utilization based on agreed-upon 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 the next scheduled utilization data posting on Medicaid.gov, 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 Manufacturer's 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 they 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.

Sincerely,

CMS MDR Operations