



**Center for Medicaid and CHIP Services**

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**July 21, 2016**

**MEDICAID DRUG REBATE PROGRAM NOTICE**

**Release No. 100**

**For**

**Participating Drug Manufacturers**

The following release details specific Medicaid drug rebate program data related issues that are important to states and manufacturers. The release: 1) delays until July 1, 2017 the requirements for states to comply with “date of service” rebate reporting for Medicaid Managed Care (MCO) prescription claims; 2) encourages labelers to proactively monitor state-reported drug utilization data for both timeliness and accuracy in order to ensure that the drug utilization data reported to CMS matches the drug utilization data reported on state rebate invoices; and 3) reminds labelers to not report a “best price” that is greater than AMP.

**Reporting Managed Care Drug Utilization for Rebate Purposes**

As you are aware, the Centers for Medicare & Medicaid Services (CMS) published CMS-2345-FC, Covered Outpatient Drugs Final Rule with Comment Period on February 1, 2016, with an effective date of April 1, 2016. This final rule addressed key areas of Medicaid drug reimbursement and detailed changes made to the Medicaid Drug Rebate (MDR) program by the Affordable Care Act. CMS also published CMS-2390-F, Medicaid Managed Care Final Rule on May 6, 2016, with an effective date of July 1, 2017. This rule also included key state contract requirements regarding covered outpatient drug coverage provided by Medicaid managed care entities.

As part of the Covered Outpatient Drug Final Rule, CMS codified changes made by section 2501(c)(2) of the Affordable Care Act. That section amended section 1927(b)(1)(A) of the Social Security Act (the Act) to specify that Medicaid rebate agreements require that the manufacturer provide a rebate for covered outpatient drugs of the manufacturer “including such drugs dispensed to individuals enrolled with a Medicaid managed care organization (MCO) if the organization is responsible for coverage of such drugs[.]” While section 1927(b)(1)(A) of the Act previously referred only to rebates for covered outpatient drugs for which payment was made directly under the state plan, the amended statutory language also requires the manufacturer to provide a rebate for drugs dispensed to Medicaid enrollees of a Medicaid MCO, if the MCO is responsible for coverage of the drug. However, there is no statutory requirement that the MCO make a payment for the drug before rebate responsibility accrues.

In the preambles of both the Medicaid covered outpatient drug and managed care final rules, CMS responded to public comments asking which date states should use when invoicing manufacturers for rebates on drugs dispensed to managed care enrollees: (1) the date of service or (2) the date the claim was paid. In response to those comments, CMS indicated in both rules that states (and their managed care plans) should report utilization data based upon the quarter in which the drug was dispensed (that is, the date of service), as opposed to the quarter in which the managed care plan paid the claim (see 81 FR 5274-5275 and 81 FR 27545-27546). CMS explained that the use of the service date is consistent with the statutory provisions of section 1927(b)(1)(A) of the Act, which explicitly provides for a rebate for drugs covered for a Medicaid enrollee by a Medicaid managed care entity. The use of the service date ensures that states timely collect rebates on all prescription drugs dispensed to Medicaid patients enrolled in MCOs consistent with the statute, even those for which an actual payment may not have been made.

Despite the guidance that was provided in the final rules, CMS has continued to receive questions from states about why the date of payment cannot be used when invoicing for rebates associated with managed care claims the way it has historically been used for fee-for-service (FFS) claims. Further, states have suggested that it would be simpler and more efficient to use the same date for FFS rebate invoicing, regardless of whether the invoiced units reflect MCO or FFS utilization. However, these suggestions fail to account for the statutory distinction between FFS and MCO claims with respect to when a claim becomes rebate-eligible under the MDR Program. Covered outpatient drugs for Medicaid FFS beneficiaries are not rebate-eligible until the state makes a payment for the drug. Until that payment is made, a rebate is not due; therefore, states must submit a rebate invoice for a FFS drug based on date of payment for FFS claims. In contrast, covered outpatient drugs for Medicaid managed care enrollees are rebate-eligible when dispensed to a Medicaid enrollee, regardless of when or whether the MCO pays for the drug. Managed care claims may have zero reimbursement at the time that a drug is dispensed; in those instances, there is no “paid date” that can be reported to tie that claim to a rebate period; rather, the only date available for such claims is the date of service.

This policy was previously communicated by CMS in Manufacturer Release #84 (see <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Program-Releases.html>), which provides that rebates are paid on drugs that are dispensed to Medicaid managed care enrollees.

Consistent with that guidance, CMS also provided in the August 2015 iteration of the State Data Guide, a reference to paid date vs. dispense date (which is posted to the drug data reporting (DDR) system for use by state technical contacts). The invoice/utilization data definition section of the guide says for “Period Covered:”

***Period Covered:*** *The calendar quarter and year in which the 11-digit NDC was paid for by the state (for FFS units), or the calendar quarter and year in which the 11-digit NDC was dispensed (for MCO units). Numeric, 5-digit field, QYYYY*

*Valid values for Q:*

*1 = January 1 – March 31*

*2 = April 1 – June 30*

*3 = July 1 – September 30*

*4 = October 1 – December 31*

CMS understands that there may be operational issues involved in bringing managed care reporting into compliance with the specification that reporting must be based on the dispense date, particularly given the annual cycle of managed care contracting. Therefore, CMS will not require that states comply with this date of service reporting requirement until July 1, 2017, which is the effective date of CMS-2390-F. States should make sure they address potential over or under payment of rebates when making this transition.

If you have further questions regarding this policy, please contact [RxDrugPolicy@cms.hhs.gov](mailto:RxDrugPolicy@cms.hhs.gov).

### **Labeler Monitoring of State Drug Utilization Data Reported to CMS**

Section 1927(b)(2)(A) of the Social Security Act (the Act), 42 CFR §447.511(b), and CMS guidance require that states transmit both current quarterly state drug utilization data submissions, as well as adjustments/corrections to previously reported drug utilization data, to CMS within 60 days of the end of each rebate period. This is the same time frame in which states are required to send current quarter rebate invoices and prior quarter adjustments to labelers; therefore, the initial and updated state drug utilization data included on quarterly state rebate invoices should always match the drug utilization data that the states subsequently report to CMS.

It is the state's responsibility to submit timely and accurate utilization data and states are expected to take reasonable steps to verify the accuracy of the data prior to reporting it. When errors are detected in prior periods, states should promptly correct and update drug utilization data in the next reporting submission. To clarify this responsibility, we have issued State Release No. 177 to provide guidance that states should take reasonable steps to verify the accuracy of utilization data prior to reporting such data, and should include correction/updates in drug utilization data in the first reporting submission after discovery of the need for corrections/updates. Further, we are also encouraging labelers to proactively monitor state-reported drug utilization data in the Drug Data Reporting for Medicaid (DDR) system for both timeliness and accuracy in order to ensure that the drug utilization data reported to CMS matches the drug utilization data reported on state rebate invoices. (Note: the Medicaid state drug utilization data reported to CMS and posted in DDR do not reflect state-only and/or State Pharmacy Assistance Program units; therefore, please do not consider these types of units when performing your review).

Should your review identify drug utilization data discrepancies between DDR and a state rebate invoice, we ask that you please reach out to the respective state and work collaboratively with them regarding any necessary corrections. If you do not receive a timely response, please contact [MDRUtilization@cms.hhs.gov](mailto:MDRUtilization@cms.hhs.gov), and we will follow-up with the respective state directly.

### **Best Price Should Not Be Greater Than AMP**

In accordance with section 1927 (b)(3)(A) of the Social Security Act (the Act), labelers are required to report a quarterly Best Price for all innovator drugs. Best Price is calculated based on the definition in section 1927 of the Act and the rebate agreement, and represents the lowest price available from the labeler during the rebate period to any entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the drug's Average Manufacturer Price (AMP) is computed. As a result, the reported Best Price is generally lower than AMP; however, we continue to see labelers reporting Best Price greater than AMP. To date, CMS has not been made aware of any

situation in which a drug's "best price" is greater than the same drug's AMP. Therefore, a labeler should verify the accuracy of its "best price" when it finds that the drug's "best price" is greater than AMP. Otherwise, the labeler will receive an error message when entering the higher "best price" amount in DDR.

If you have any questions, please contact us at [MDROperations@cms.hhs.gov](mailto:MDROperations@cms.hhs.gov).

Sincerely,

/s/

Michael Nardone  
Director  
Disabled and Elderly Health Programs Group