

**Center for Medicaid and CHIP Services**

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**July 21, 2016**

**MEDICAID DRUG REBATE PROGRAM NOTICE**

**Release No. 177**

## **For State Technical Contacts**

The following release details specific Medicaid drug rebate program data related issues that are important to states and manufacturers. The release delays the requirements for states to comply with “date of service” rebate reporting for Medicaid Managed Care (MCO) prescription claims until July 1, 2017, and indicates that states could be eligible for enhanced Federal match when updating their state systems. The release also reminds states of their responsibilities to report accurate drug utilization data to CMS as well as make adjustments/corrections to previously reported drug utilization data in a timely way.

### **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), 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 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.

States that need to make changes to drug rebate Medicaid Management Information subsystems should also complete an Advance Planning Document (APD) and submit it to the CMS regional office to determine whether such changes are eligible for enhanced Federal match.

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

### **Non-compliant State Drug Utilization Data Reporting to CMS**

In accordance with section 1927(b)(2)(A) of the Social Security Act, 42 CFR §447.511(b) and Centers for Medicare & Medicaid Services' (CMS) guidance, current quarterly state drug utilization data submissions, as well as adjustments/corrections to previously reported drug utilization data, are due to CMS within 60 days of the end of each rebate period (i.e., calendar quarter) for both fee-for-service (FFS) and, when applicable, managed care organization (MCO) drug utilization data. However, it has come to our attention that some states are not reporting timely and accurate state drug utilization data to CMS. In part, CMS believes this is because states do not have adequate procedures in place to review the data for accuracy. Further, some states are not including adjustments/corrections in prior period data promptly in such reports. This results in a lack of reporting compliance on the state's part, causing disputes and the need to expend additional resources for all parties that use state drug utilization data.

State responsibility for accurate reporting means that states must take reasonable steps, prior to reporting drug utilization data, to review that data for errors. CMS has learned that some of the inaccurate drug utilization data reporting results from having inappropriate or non-existent systems edits (e.g., not applying conversion factors, edits for whole numbers, etc.) in place to ensure that the outliers (e.g., notably over- or under-stated utilization) in state drug utilization data are found prior to transmission to both CMS and the labelers. These outliers often result in significant overstatements and understatement of rebates, which effectively makes the data non-compliant and can cause rebate disputes that require resources to be expended by labelers, states, and CMS. When states find inaccuracies in prior period data, corrected/updated data should be included in the next regular utilization report. Therefore, CMS strongly urge states to consider implementing system edits that will prevent such data outliers from being included in quarterly rebate invoices to labelers and drug utilization data submissions to CMS.

In addition to Medicaid drug rebate invoicing, state drug utilization data are also used to calculate the Medicaid portion of the Internal Revenue Service's (IRS) Branded Prescription Drug (BPD) fee; therefore, any unedited/inaccurate drug utilization data reported to CMS can cause significant disparities in labeler BPD fees, thereby skewing the amount the labeler owes. For example, over- and under-reporting of units results in inaccurate BPD fee assessments, which, in turn, causes BPD disputes. Such BPD disputes ultimately prove to be a resource

drain for the IRS, CMS, labelers, and states, as all parties have to work to resolve the data disparities from which the disputes originate. States that have questions on state utilization reporting should consult the “Medicaid Drug Rebate Data Guide for States”, Section 8: State Utilization Data Reporting to CMS. If further assistance is required, inquiries should be submitted to [MDRUtilization@cms.hhs.gov](mailto:MDRUtilization@cms.hhs.gov).

To address this issue of non-compliant state drug utilization data reporting from the labeler perspective, we have also issued corresponding Manufacturer Release No. 100. This Release encourages labelers to monitor and compare the state drug utilization data reported by states in the Drug Data Reporting for Medicaid (DDR) system to the drug utilization data that are received on the quarterly state rebate invoices to ensure that states are timely and accurate in reporting initial and updated drug utilization data. CMS also asks that labelers work with states to correct any identified discrepancies. Should a state not respond timely to such communications from labelers, we have asked labelers to notify CMS so that we can follow-up with the respective state(s) accordingly.

If you have any questions regarding this information, or regarding the submission of utilization data, please contact [MDRUtilization@cms.hhs.gov](mailto:MDRUtilization@cms.hhs.gov).

Sincerely,

/s/

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