DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and CHIP Services

September 12, 2014

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 91**

For

Participating Drug Manufacturers

TIMELY REPORTING OF AVERAGE MANUFACTURER PRICE (AMP) AND BEST PRICE (BP) PRICING DATA

In accordance with section 1927(b)(3)(A) of the Social Security Act (the Act) and the terms of the National Drug Rebate Agreement, manufacturers are required to report pricing information to the Centers for Medicare & Medicaid Services (CMS) on a timely basis. As stated in Manufacturer Release No. 76, issued on December 15, 2006, manufacturers are responsible for reporting monthly pricing data in the Drug Data Reporting for Medicaid (DDR) system no later than 30 days after the last day of each month, and quarterly data no later than 30 days after the last day of each quarter. Each quarter, there are manufacturers that fail to report quarterly pricing data to CMS in a timely manner and there are manufacturers that do not report any data to CMS.

Manufacturers' reported quarterly AMP and BP data are essential in the calculation of the unit rebate amount (URA) under the Medicaid Drug Rebate (MDR) program. When manufacturers submit data to DDR that do not comply with DDR's formatting and/or reporting requirements, DDR generates edit reports which manufacturers may use to ensure their data are reported timely. However, when a manufacturer does not submit data on a timely basis, it is the responsibility of the manufacturer to compute the URA for each of its national drug codes (NDCs) and send rebate payments to the states, consistent with the requirements of section 1927(b) of the Act.

Similarly, the timely reporting of monthly AMP data is critical in the calculation of the Federal upper limit (FUL). In accordance with sections 1927(e)(4) and 1927(e)(5) of the Act, using the most recently reported monthly AMP data for multiple source drugs available for purchase by retail community pharmacies on a nationwide basis, the Secretary is required to calculate a FUL for each multiple source drug for which the Food and Drug Administration (FDA) has rated three or more products therapeutically and pharmaceutically equivalent (A-rated). The FUL is a

calculation based on the weighted average of monthly AMPs of A-rated innovator (I) and non-innovator (N) multiple source drugs that are available for purchase by retail community pharmacies on a nationwide basis. Therefore, in order to accurately calculate the FUL, CMS first establishes FUL groups for therapeutically and pharmaceutically equivalent drugs that are available for purchase by retail community pharmacies on a nationwide basis, and then calculates a FUL based on the monthly reported AMP and AMP units for each drug in the FUL group. When a manufacturer submits an AMP unit greater than zero to CMS for a multiple source drug sold or marketed during a reporting period, we consider that the drug is eligible to be reviewed to calculate a FUL. When manufacturers fail to report their monthly AMP data in a timely manner CMS is prevented from calculating FULs for all of the A-rated drugs which are in the same FUL groups. In accordance with sections 1927(e)(4) and 1927(e)(5) of the Act, it is essential that CMS calculates a FUL for all multiple source drugs for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent and that this pricing benchmark be available to state Medicaid programs.

A manufacturer is required to report monthly and quarterly AMP data for all drugs reported to the MDR program. We are aware that there may be a monthly or quarterly period where the AMP calculation may result in a negative or zero value. In accordance with Manufacturer release No. 80 dated January 5, 2010, when this occurs, manufacturers should report the most recent prior month's or quarter's positive AMP value. As discussed in Manufacturer release No. 86, manufacturers are also required to report a monthly AMP unit value for each one of its covered outpatient drugs. In the case where a manufacturer has no monthly AMP-eligible sales for a covered outpatient drug for that monthly reporting period, then the manufacturer would accurately report zero (and not a prior month's value) for the AMP unit value.

We remind you that it is imperative for manufacturers to report both their monthly and quarterly pricing data to CMS in a timely manner. CMS will refer manufacturers that fail to report the information required under section 1927(b)(3)(A) of the Act within the timeframes established by the statute to the Office of Inspector General, and, in accordance with section 1927(b)(3)(C)(i) of the Act, those manufacturers may be subject to civil monetary penalties.

Any questions regarding Medicaid drug provisions can be submitted through the drug policy resource mailbox at RxDrugPolicy@cms.hhs.gov.

CORRECTLY REPORTING A DRUG CATEGORY

In Manufacturer Release No. 82 issued by CMS on November 1, 2010, we discussed the importance of accurately reporting drug categories. We continue to ask that manufacturers review the drug categories they report to CMS to ensure their drugs are correctly categorized, as it affects not only the rebate liability for the manufacturers but also the reimbursement calculated under the Federal upper limit (FUL) program for multiple source drugs.

Section 1927(e)(4) of the Social Security Act (the Act) requires CMS to calculate a FUL for each multiple source drug for which the Food and Drug Administration (FDA) has rated three or more products therapeutically and pharmaceutically equivalent and that CMS only use such drugs in

the calculation of the FUL. In accordance with section 1927(e)(4), CMS will not use single source (S) drugs in the calculation of the FUL. In general, covered outpatient drugs that are approved under a new drug application (NDA) should be reported to CMS as either "S" or "I" drugs, while drugs approved under an abbreviated new drug application (ANDA) should be reported to CMS as "N" drugs. Manufacturers may need to update their drug category from "S" to "I" in the Drug Data Reporting for Medicaid (DDR) system once the FDA approves a therapeutically equivalent drug product to that single source drug under an ANDA.

We encourage manufacturers to check the FDA's Online Label Repository, at http://labels.fda.gov/, to identify the correct drug category for their drug by referring to the application number assigned to the product.

To ensure the accuracy of drug category data submitted to CMS, manufacturers may access the FDA's Orange Book at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm, and search by Application Number to determine whether a drug has been approved under an NDA (marked by an application number that begins with "N") or an ANDA (marked by an application number that begins with "A"), and whether the FDA approval date reported to CMS is the same date as listed in the Orange Book.

To verify if a drug approved under an NDA has a therapeutically equivalent drug available that is sold or marketed in the United States, manufacturers may:

(1) Access Drugs@FDA at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Addlsearch_drug_name

(2) Search by the Application Number. When a therapeutically equivalent drug is available, the link to "Therapeutic Equivalents" is available on the "Drugs Details" page.

Click on the "Therapeutic Equivalents" link to see if there are therapeutically equivalent drugs available. If there is a therapeutically equivalent drug available for a drug approved under an NDA, then the drug approved under the NDA should be generally reported as an "I".
In accordance with section 1927(b)(3)(C)(ii) of the Act, any manufacturer with an agreement under this section that knowingly provides false information may be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Therefore, we encourage manufacturers to carefully review their drug product data submissions, determine if any update is required, and take the necessary steps to make the update.

Please note that updating a drug category from "S" to "I" or vice versa does not require prior CMS approval because, generally, the rebate percentages are the same for "S" and "I" drugs. Therefore, manufacturers may access the DDR system to make these updates where necessary. For all other drug category changes or questions, please e-mail RxDrugPolicy@cms.hhs.gov to request a drug category change.

GUIDANCEREGARDING REBATE OBLIGATIONS FOR TERMINATED MANUFACTURERS AND TERMINATED PRODUCTS

In accordance with section 1927 of the Social Security Act (the Act) and the terms of the National Medicaid Drug Rebate Agreement (Rebate Agreement), drug manufacturers are generally required to pay rebates on covered outpatient drugs that are dispensed to Medicaid recipients. However, recently we have received numerous questions regarding a manufacturer's rebate payment responsibilities when the manufacturer's Rebate Agreement has been terminated with the Medicaid Drug Rebate (MDR) program or when the manufacturer enters a termination date for a drug product via the Drug Data Reporting for Medicaid (DDR) system long after the quarter in which the termination date falls.

Therefore, the following information outlines CMS' guidance regarding manufacturer rebate payment responsibilities related to termination from the MDR program, the termination of individual NDCs under a labeler code, and late termination dates submitted by manufacturers to CMS.

Termination of a Manufacturer from the MDR Program

In accordance with section 1927(b)(4)(B) of the Act, a manufacturer may terminate its Rebate Agreement for any reason, and such termination shall not become effective until the first day of the first calendar quarter beginning 60 days after the labeler gives written notice to CMS. In addition, CMS has the option to terminate a manufacturer's Rebate Agreement for violations of the agreement or other good cause and the termination shall not be effective earlier than 60 days after the termination notice is written to the manufacturer. However, regardless of whether a labeler's termination is initiated by the labeler or by CMS, section 1927(b)(4)(B)(iii) of the Act states that a manufacturer's termination from the MDR program "shall not affect rebates due under the agreement before the effective date of its termination."

Section 1927(b)(1)(A) of the Act provides that a manufacturer shall provide rebates for covered outpatient drugs for which payment was made, under the approved state plan, for the rebate period. The current state invoice, Form CMS R-144, supports this requirement as it also reflects the quarter in which a state paid for a drug (i.e., the "period covered") for fee-for-service utilization. However, we are aware that pharmacies sometimes bill a state weeks or months after the date on which a drug was actually dispensed to Medicaid beneficiaries. Depending upon how much time has elapsed between the drug's dispensed date and the state's payment date, it is possible that a manufacturer's termination from the MDR program may have become effective during that time. Therefore, as long as the drug in question was <u>dispensed</u> prior to the date on which the manufacturer was terminated from the MDR program, per the requirements of section 1927(b)(1)(A), a rebate is still owed on that product regardless of when the state makes payment for the drug.

A manufacturer's price reporting obligations under the MDR program ends as of the manufacturer's termination date quarter; therefore, if a state pays for a drug in a quarter that falls after that termination date, there may not be a quarterly unit rebate amount (URA) available for

purposes of rebate invoicing. Consequently, for situations in which the state is invoicing a terminated manufacturer for units paid for after the manufacturer's termination date from the MDR program, but dispensed prior to that termination date, the state should use the drug's last calculated URA (i.e., the URA from the last quarter in which the manufacturer was still active in the MDR program) for purposes of rebate billing. Manufacturers should then pay rebates in accordance with the last calculated URA.

Please see below for an example of when a terminated manufacturer owes rebates and another example of when a terminated manufacturer is not responsible for paying rebates.

Example 1: A manufacturer is terminated from the rebate program as of July 1, 2013 (i.e., 3Q2013). A Medicaid beneficiary is dispensed one of that manufacturer's covered outpatient drugs on May 20, 2013 (i.e., within 2Q2013). If the state pays for this claim on August 8, 2013, (i.e., within 3Q2013) and includes the units associated with the claim on the 3Q2013 rebate invoice, then, in accordance with the Rebate Agreement, the manufacturer is responsible for paying a rebate on that utilization since the drug was dispensed prior to the manufacturer's termination date from the MDR program.

Example 2: A manufacturer is terminated from the MDR program as of July 1, 2013 (i.e., 3Q2013). A Medicaid beneficiary is dispensed one of that manufacturer's covered outpatient drugs on July 15, 2013, (i.e., within 3Q2013) which is paid for by the state that same day. In this case, the manufacturer is not responsible for paying a rebate on this utilization since the drug was dispensed after the manufacturer's termination date from the MDR program.

Termination of a Product from the MDR Program

When a manufacturer discontinues a drug from its product line or withdraws a drug from the market, the termination date submitted via DDR should equal the last lot expiration date of the drug or, if applicable, the date on which the drug was withdrawn. Previous guidance on terminated drugs (e.g., Labeler Release #48) has instructed manufacturers to continue to submit quarterly pricing (equal to the pricing from the last active quarter) for four quarters beyond the submitted termination date quarter in order to accommodate late pharmacy billing; however, we are aware that pharmacies sometimes bill a state more than a year after the date on which a drug was actually dispensed to Medicaid beneficiaries. In addition, section II(h) of the Rebate Agreement requires that a manufacturer participating in the MDR program continue "to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the manufacturer continues to market that drug."

Depending upon how much time has elapsed between a drug's dispensed date and the state's payment date, it is possible that, during that time, more than four quarters will have passed since the drug's termination date. As long as the drug in question was dispensed prior to the drug's termination date, a rebate is still owed on that drug regardless of when the state paid for the drug. Since a manufacturer's price reporting obligations for the terminated drug end as of the fifth quarter after the drug's termination date, there may not be a quarterly URA available for the

quarter in which the state paid for the drug. Therefore, for situations in which the state is invoicing a manufacturer for units paid for in the fifth quarter following the drug's termination date or beyond, but the units were dispensed prior to that termination date, states should use the drug's last calculated URA (i.e., the URA from the fourth quarter after the drug's termination date quarter) for purposes of rebate billing. Manufacturers should then pay rebates in accordance with the last reported URA.

Please see below for an example of when rebates are owed on a terminated product and another example of when rebates are not owed on a terminated product. Both examples assume that there is only one package size of the product.

Example 1: A product is terminated on November 11, 2013 (i.e., 4Q2013). The terminated product was dispensed to a Medicaid beneficiary on November 10, 2013 (i.e., within 4Q2013). The pharmacy/provider did not submit the claim timely, resulting in the state paying for this claim on May 19, 2014 (i.e., within 2Q2014). The state includes the units associated with the claim on the 2Q2014 rebate invoice; therefore, the manufacturer is responsible for paying a rebate on that utilization since the drug was dispensed prior to the product's termination date.

Example 2: A product is terminated on July 7, 2013 (i.e., 3Q2013). The terminated product was inadvertently dispensed to a Medicaid beneficiary on July 10, 2013, (i.e., within 3Q2013) and was paid for by the state that same day. Since the dispensed date occurred after the product's termination date, the manufacturer is not responsible for paying a rebate on this utilization.

Late Submissions of Product Termination Dates

In accordance with section 1927(b)(3) of the Act, manufacturers are responsible for reporting accurate product and price information. Additionally, in accordance with section 1927(b)(3)(C)(ii) of the Act, "any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law…." To that end, we want to remind manufacturers that the termination date for a product should be reported timely (e.g., when the last lot of a product is shipped) to ensure that a product will not be dispensed or paid for after the termination date and to support timely and appropriate rebate billing.

In addition, we have become aware that some manufacturers are retroactively submitting product termination dates and requesting credits from the states for rebates that were paid prior to the submission of the retroactive termination date. Manufacturers should not request credits in these instances and should not dispute state utilization on the basis that a product is terminated when the product's termination date was entered late (i.e., after the close of the reporting period for the quarter in which the termination date falls). To assist manufacturers and states in identifying instances of late termination dates, DDR contains a "Date Termination Date Reported" field that displays as part of the package size detail on the "Drug Information" screen for each NDC.

If you have questions regarding dispute issues, please email DRP@cms.hhs.gov. If you have general questions about termination date, please email MDROperations@cms.hhs.gov.

REMINDER OF 12 QUARTER RULE WHEN REPORTING REVISIONS TO QUARTERLY PRICING DATA (AMP/BEST PRICE)

42 CFR 447.510(b) requires manufacturers to submit revised AMP, best price, customary prompt pay discounts, and nominal prices to CMS for a period not to exceed 12 quarters (36 months for monthly AMPs) from the quarter in which the data were due. CMS' receipt of a letter from a manufacturer explaining their intent to restate AMP and/or best price for a specified time period does not extend the 12 quarter time limitation for the submission of this data. Manufacturers must still report such revised AMP and/or best price information within the required 12 quarters as required by 42 CFR 447.510(b). Please refer to the Manufacturer Release #80 for complete instructions regarding the recalculation and reporting process. This release can be accessed at the following web link: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Program-Releases.html

NEW EMAIL RESOURCE BOX FOR BRANDED PRESCRIPTION DRUG (BPD) PROGRAM INQUIRIES

Due to the large volume of emails generated by the Internal Revenue Service's (IRS) Branded Prescription Drug (BPD) Program, we have created a new email resource box specifically for handling BPD related inquiries: MedicaidBPD@cms.hhs.gov.

NEW DIRECTOR OF THE DIVISION OF PHARMACY

We are pleased to announce that John Coster is the new director for the Division of Pharmacy starting August 25, 2014. Please find below a short bio about John.

John M. Coster, Ph.D., R.Ph.

Most recently John served as the Senior Director of Government Relations for Safety Net Hospitals for Pharmaceutical Access (SNHPA), which represents the 340B hospitals that participate in the 340B Federal drug discount program. He also served as Senior Vice President of Government Relations for the National Community Pharmacists Association (NCPA) and was Vice President for Policy at the National Association of Chain Drug Stores. He holds adjunct faculty appointments at the University Of Maryland School Of Pharmacy and the George Washington University School of Public Health. John received a BS in Pharmacy from St. Johns University College of Pharmacy in NY and a MPS and PhD in Health Policy from the University of Maryland Graduate School Baltimore. As a Senate staffer in the 1990s, he helped to create the Medicaid drug rebate program and the 340B drug discount program.

/s/

Barbara Edwards
Director
Disabled and Elderly Health Programs Group