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Disabled & Elderly Health Programs Group

September 12, 2014

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 168**

For State Technical Contacts

GUIDANCE REGARDING 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 provide 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 dispensed 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.

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.

If you have any questions, please contact MDROperations@cms.hhs.gov.

/s/

Barbara Edwards
Director
Disabled and Elderly Health Programs Group