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

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 183**

For State Technical Contacts

We want to inform states that the following guidance was issued to manufacturers.

Manufacturer Reporting and Rebate Payment of Inner/Outer NDCs

Manufacturer Reporting and Payment Requirements
In accordance with section 1927(b)(3)(A) of the Social Security Act (the Act), manufacturers that have signed a rebate agreement are required to report certain pricing information for all covered outpatient drugs. Also, in accordance with section 1927(b)(1)(A) of the Act, such manufacturers are required to make rebate payments for covered outpatient drugs dispensed after December 31, 1990, for which payment was made under the State plan for such a period. This includes drugs dispensed to Medicaid managed care organization (MCO) enrollees. Since the Centers for Medicare & Medicaid Services (CMS) issued Manufacturer Release #71, dated December 9, 2005, we have received inquiries on reporting inner national drug codes (NDCs) for various scenarios. States have reported that some manufacturers have been disputing rebate invoices for select inner NDCs in some situations. Additionally, states have reported that manufacturers have requested that the state modify the invoices to reflect the outer NDCs. Therefore, to ensure that manufacturers are complying with the applicable reporting and payment requirements, we are reminding manufacturers that they must report all of their NDCs that meet the definition of a covered outpatient drug as described in statute at section 1927(k)(2)-(4) of the Act, and regulation at 42 CFR §447.502. In addition, we are providing the following information regarding the required reporting of some specific types of NDCs that manufacturers may not have previously submitted for inclusion in the Medicaid Drug Rebate Program (MDRP) given the packaging of the drugs. This is not meant to address every concern regarding package size reporting, but we hope to address some of the broad issues that regularly arise.

Scenario 1: Outer package containing two or more inner packages
Some drugs are packaged such that the outer package contains two or more inner packages (e.g., packs of oral contraceptives, unit dose blister packs, vials of single dose injectable drugs). In these cases, there is typically one NDC on the outer package (i.e., the "outer" NDC) and a different NDC on the inner package (i.e., the "inner" NDC). If each of these individual NDCs meet the definition of a covered outpatient drug, then both the inner and the outer NDCs are to be reported to the MDRP. We understand that some manufacturers have only reported the

outer NDC using the rationale that they do not sell the inner NDC separately to wholesalers or retail community pharmacies, therefore, they only have sales on the outer NDC. However, even if the manufacturer does not sell the inner components separately and does not have sales price information for the inner NDCs, we would expect manufacturers to use reasonable assumptions, as addressed in the Medicaid National Drug Rebate Agreement (NDRA), when determining the pricing information to report for such NDCs, as we believe the manufacturers are required to submit pricing data at this level and are responsible to make rebate payments for all such covered outpatient drugs.

Scenario 2-Kit containing multiple inner package NDCs

Another scenario that correlates with this issue relates to a drug that is sold as a kit, in which the outer package may have one NDC, and the inner components of the kit each have a different NDC. Similar to the first example above, manufacturers should report the outer NDC as well as the inner NDC(s) that represents the individual components of the kit, so long as each separate component meets the definition of a covered outpatient drug. In this situation, even if the manufacturer does not sell the inner components separately and does not have sales price information for the inner NDCs, we would expect manufacturers to use reasonable assumptions, as addressed in the NDRA, when determining the pricing information to report for such NDCs, as we believe the manufacturers are required to submit pricing data at this level and are responsible to make rebate payments for all such covered outpatient drugs.

Scenario 3-Reporting of Certain NDCs as Covered Outpatient Drugs Absent Average Manufacturer Price (AMP)-Eligible Sales

Some manufacturers have not reported certain NDCs of some covered outpatient drugs to the MDRP because they believe they are not sold to entities which would result in AMP-eligible sales. For example, we have heard that certain NDCs are sold exclusively to hospitals or government programs. Regardless of how a manufacturer intends to distribute such NDCs, if the NDC represents a drug that meets the definition of a covered outpatient drug, all package sizes of the NDC should be reported to the MDRP. Similar to the scenario above, if there is no sales price information because of sales only to entities that do not generate AMP-eligible sales, then we would expect manufacturers to use reasonable assumptions, as addressed in the NDRA, when determining the pricing information to report for such NDCs, as we believe the manufacturers are required to submit pricing data at this level and are responsible to make rebate payments for all such covered outpatient drugs.

State Requirement to Bill Rebates on Inner NDCs of Covered Outpatient Drugs

Per 1927(b)(2)(A) of the Act, states are required to report to manufacturers at the end of each rebate period information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan, including information reported by each MCO. Therefore, if a state has reimbursed a provider for fee-for-service (FFS) claims for an inner NDC, or if an inner NDC was dispensed for an MCO claim, the state is required to report or invoice the total number of units of that inner NDC to the manufacturer, and the manufacturer is subsequently required to pay rebates in accordance with 1927(b)(1)(A) of the Act.

Some states have informed CMS of communications from manufacturers that ask the state to resubmit an invoice using the outer NDC, rather than the inner NDC appearing on the claim. If the claim is received from a provider using the inner NDC, representing that the drug paid for or dispensed was the inner NDC, it would be appropriate for the state to report units to

manufacturers using that inner NDC. As a reminder, a manufacturer should not dispute a rebate invoice on the basis that the manufacturer has not complied with reporting inner NDCs. Manufacturers should note that if a state includes an NDC on a rebate invoice that is a covered outpatient drug not previously reported by the manufacturer to CMS, the manufacturer will owe rebates and interest back to the quarter in which the state reimbursed a provider for an FFS claim, or when an NDC was dispensed for an MCO claim.

If you have any questions regarding the reporting of inner and outer NDCs, please email us at RxDrugPolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group