DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 106**

For

Participating Drug 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.

Continuing Guidance on the Additional Inflation-Adjusted Rebate Requirement for Non-Innovator Multiple Source Drugs

Section 602 of the Bipartisan Budget Act (BBA) of 2015 requires manufacturers to pay additional rebates on their non-innovator multiple source (N) drugs, if the average manufacturer prices (AMP) of the N drug increases at a rate that exceeds the rate of inflation, commonly referred to as the "generic inflation penalty." In order to perform the new additional rebate calculation, each N drug must have a base AMP (BBA '15 Base AMP) against which all subsequent quarterly AMPs will be measured to determine whether any price increase from one quarter to the next exceeds the rate of inflation. Manufacturer Release #97 and 101, issued in 2016, provided guidance regarding the generic inflation penalty, including a description of how BBA '15 Base AMP values will be established for N drugs. This new release continues our series of guidance on this topic by providing responses to some frequently asked questions regarding the BBA '15 Base AMP and the additional rebate calculation.

Question: When a manufacturer's covered outpatient N drug is discontinued/terminated and re-activated at a later time, would the base AMP be established based upon the original market date of the N drug, or the new re-activated date?

Answer: If an NDC is terminated and then later reactivated, the BBA '15 Base AMP quarter and corresponding BBA '15 Base AMP will be established based upon the NDC's original market date.

Question: If a drug has a market date of December 1, 2016, the base AMP will be based upon the AMP in the 1st quarter 2018 (i.e., five full calendar quarters after the N drug's market date). Since the AMP and Consumer Price Index for All Urban Consumers (CPI-U) will not be defined for the rebate periods between the market date and the 1st quarter of 2018, which quarter should the manufacturer use as a base AMP for the period January 1, 2017 until 1st quarter 2018?

Answer: Once the 1st quarter 2018 AMP has been reported, the Drug Data Reporting for Medicaid (DDR) system will automatically populate the BBA '15 Base AMP field with that reported quarterly AMP value. For N drugs with market dates after April 1, 2013, for which the baseline AMP is established in second quarter 2017 or later, the additional rebate portion of the unit rebate amount (URA) calculation would only apply prospectively from the quarter in which the drug's baseline AMP is established, so there would be no additional rebates due from January 1, 2017 until 1st quarter 2018. Please see Manufacturer Release #101 for more information.

Question: Will the quarterly CPI-U value used for N drugs be from the month prior to the reported quarter, just as it is for S or I drugs?

Answer: Yes, the quarterly CPI-U for N drugs will equal the CPI-U for the month immediately prior to the quarter being calculated (e.g., if the quarter being calculated is 1st quarter 2018, the quarterly CPI-U will equal the CPI-U for December 2017). Further, in accordance with section 1927(c)(3) of the Social Security Act (the Act) (as revised by section 602 of the Bipartisan Budget Act of 2015), for N drugs with market dates on or before April 1, 2013, the base CPI-U will equal the CPI-U for September 2014. For N drugs with market dates after April 1, 2013, the base CPI-U will equal the CPI-U for the last month of each drug's BBA '15 Base AMP quarter.

Question: What is the BBA '15 Base AMP when the manufacturer purchases a series of generic products that were launched very early on (e.g., during the 1990s), and the manufacturers from which the products were purchased did not have a drug rebate agreement in place during each drug's base AMP quarter per 1927(c)(3)? In other words, these products do not have a reported AMP for each of those periods, therefore, which AMP should the purchasing manufacturer use?

Answer: In such cases, consistent with Manufacturer Release #90 and 101, a manufacturer that buys a product from another manufacturer is responsible for obtaining the baseline data of the drug. This includes obtaining the necessary data to report a base date AMP consistent with section 1927(c)(1)(C) of the Act. Therefore, the manufacturer must attempt to obtain the required AMP(s) from either the selling manufacturer or any manufacturer that previously owned the products.

Question: Sometimes a single manufacturer owns an ANDA for a product and licenses a secondary manufacturer/labeler to sell the product under the same ANDA. In those instances, which base AMP for the product should be used?

Answer: If the secondary manufacturer/labeler has already reported the licensed product in the DDR system, and has also already reported the quarterly AMP required to establish the NDC's BBA '15 Base AMP, CMS will auto-populate the BBA '15 Base AMP field using that AMP value. However, upon the implementation of the BBA '15 Base AMP field in DDR in Spring 2017, if a manufacturer reports a new product in the DDR system and that product has been licensed from another manufacturer that is allowing the product to be sold under the same ANDA, the licensed product's Market Date, and subsequently, the base AMP, should reflect the same information as that of the originating manufacturer's product. Consequently, secondary manufacturers in these instances will be required to obtain the baseline information, including (but not limited to) FDA Approval Date, Market Date and Base AMP, from the originating manufacturer. This is similar to our current policy regarding reporting the base AMP for authorized generics.

Question: When manufacturers change their product's drug category from innovator to non-innovator, which quarter should be used when establishing a baseline AMP for the non-innovator? For example, if a manufacturer launched a product in March 1995, and CMS recognized in December 2015 that the product should be a non-innovator, should the Base AMP for that product come from third quarter 2014 or first quarter 2017?

Answer: For the example given, third quarter 2014 would establish the BBA '15 Base AMP for the NDC now classified as a non-innovator. For products that are classified as single source or innovator multiple source for one period of time and as non-innovator for another period of time, the DDR system will be coded to pull the appropriate Base AMP for each drug category period. This results in establishment of:

1. An Omnibus Budget Reconciliation Act of 1993 (OBRA '93) Base AMP using the quarterly AMP for second quarter 1995 (i.e., the first full quarter after the Market Date quarter) and apply that Base AMP in the URA calculation for first quarter 1995 through third quarter 2015.

2. A BBA '15 Base AMP using the quarterly AMP for third quarter 2014 (because the Market Date of March 1995 falls on or before April 1, 2013) and apply that Base AMP in the URA calculation from first quarter 2017 onward. There would be no additional rebate calculated for fourth quarter 2015 through fourth quarter 2016 since the additional rebate for N drugs was not implemented until first quarter 2017.

If you have further questions regarding the additional rebate requirements, please submit your questions to rxdrugpolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group