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Center for Medicaid , CHIP, and Survey & Certification

August 11, 2010

MEDICAID DRUG REBATE PROGRAM **Release No. 81**

Bulletin

For
Participating Drug Manufacturers

AFFORDABLE CARE ACT OPERATIONAL GUIDANCE & FIRST QUARTER 2010 REBATE INFORMATION

In an effort to expedite this guidance, we previously provided interim guidance via email on May 24, 2010; however, we have since received questions requesting clarification on some of the provisions. Therefore, we have updated the language on the new rebate calculation for Single Source (S)/ Innovator Multiple Source (I) line extension drugs in an oral solid dosage form and on the limit of the rebate amount for S/I drugs under this section. This bulletin updates the initial guidance. We will continue to provide additional guidance as soon as it becomes available.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (HCERA), P.L. 111-152, together called the Affordable Care Act (ACA). Section 2501 of ACA, as amended by section 1206 of HCERA, include changes to certain Medicaid Drug Rebate (MDR) provisions, effective first quarter 2010. Several of these changes impact the Unit Rebate Amount (URA) calculation for all drugs covered under the MDR Program. Specifically, these sections increase the rebate percentages for S, I, and Non-Innovator (N) drugs and establish new requirements for calculating rebates for reformulated S/I drugs in oral solid dosage form. Additional details about these revised calculations may be found below.

In accordance with the national rebate agreement, labelers are responsible for calculating URAs. However, CMS usually provides States with calculated URAs for use on rebate invoices so that States can verify these URAs with any labeler-adjusted URAs that States may receive. CMS was not able to calculate a URA using the new rebate percentages or requirements for reformulated drugs in time for first quarter 2010 rebate processing. Therefore, until CMS' MDR systems (i.e., Drug Data Reporting for Medicaid (DDR) and MDR) are modified to reflect the URA changes implemented by ACA, CMS does not expect to be calculating these URAs.

In order to facilitate the data exchange between CMS and States, CMS did not send updated URAs to States on the first quarter 2010 tapes, along with the usual labeler contact and drug product data files. As a result, State invoices will not contain updated URAs, and labelers remain responsible for calculating these amounts. These uncalculated URAs will also be reflected in DDR beginning with the URAs for the first quarter of 2010 until system modifications are made. (Please note that this does not affect any prior period adjustments (PPAs) which are based on percentages in effect prior to ACA.) Therefore, labelers should update and submit their URAs to States using the OMB-approved Reconciliation of State Invoice (ROSI) form (Form CMS-304) that reflects the ACA amendments beginning with the first quarter 2010 drug rebate reporting period. A copy of the ROSI can be found in the MDR Data Guide for Labelers which is posted on the DDR website. Labelers that fail to report and pay the increased rebates beginning with first quarter 2010 may be responsible for interest in accordance with the terms of the national rebate agreement.

The URA calculation changes are summarized below:

Changes to the Basic URA Calculation

--Innovator (S/I Drug Category) drugs are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 23.1 percent.

--Innovator (S/I Drug Category) clotting factor drugs for which a separate furnishing payment is made under section 1842(o)(5) of the Social Security Act are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 17.1 percent. A list of these NDCs will be posted and updated in DDR in the near future for State and labeler use.

--Innovator (S/I Drug Category) drugs approved by the Food and Drug Administration (FDA) for exclusively pediatric indications are subject to an increase in the minimum rebate percentage used to perform the basic rebate calculation. The Basic URA of these products is now the greater of AMP minus best price or the product's AMP multiplied by 17.1 percent. A list of these NDCs will be posted on the internet in the near future for State and labeler use.

--Non-innovator (N Drug Category) drugs are subject to an increase in the minimum rebate percentage used to calculate rebates. To calculate the Basic URA of these products, the product's AMP is now multiplied by 13 percent.

New Rebate Calculation for S/I Line Extension (i.e., New Formulations) Drugs in Oral Solid Dosage Forms

For a drug that is a line extension (new formulation) of an S/I drug that is an oral solid dosage form, the rebate is the amount computed under section 1927 of the Act or, if greater, the product of:

- the AMP for the line extension drug,
- the highest additional rebate for any strength of the original S/I drug, and
- the total number of units of each dosage form and strength of the line extension drug (section 1206 of HCERA, which replaced section 1927(c)(2)(C) as added by section 2501(d) of PPACA).

Limit on Rebate Amount for S/I Drugs

--The total rebate obligation for all innovator drugs (S/I Drug Category) is capped at 100% of AMP.

Labelers are responsible for calculating rebates and URAs in accordance with the statute. CMS is currently working on systems updates and will promptly notify labelers and States when the changes are in place. At that time, States will receive PPAs retroactive, if applicable, to the first quarter 2010.

(Contact: mdroperations@cms.hhs.gov)

LIST OF PEDIATRIC AND CLOTTING FACTOR DRUGS AVAILABLE SOON IN DDR

The Affordable Care Act (ACA) establishes several new rebate calculations for those National Drug Codes (NDCs) covered under the Medicaid Drug Rebate Program, effective January 1, 2010. Under section 2501 of the ACA, most single source and innovator multiple source drugs are subject to a minimum rebate of 23.1 percent. Section 2501(a)(1)(B) of the ACA added a new section 1927(c)(1)(B)(iii) to the Social Security Act (the Act) to require a new minimum rebate of 17.1 percent of the average manufacturer price (AMP), effective January 1, 2010 for a drug approved by the Food and Drug Administration (FDA) exclusively for pediatric indications.

We plan to interpret this provision in accordance with Federal regulations published by the FDA regarding pediatric labeling requirements for prescription drugs, and plan to interpret in light of the FDA labeling and as the indications for pediatric use on the labeling. In accordance with regulations at 21 CFR 201.57, and 21 CFR 201.80, the FDA defines pediatric use for drugs use as for pediatric populations and pediatric patients. The FDA defines pediatric populations and pediatric patients as the pediatric age group from birth to 16 years. Accordingly, we plan to apply the 17.1 percent minimum rebate to those single source or innovator multiple source drugs approved by the FDA exclusively for pediatric indications meeting this FDA definition. Drugs that are not approved, or labeled, exclusively with indications for pediatric use will not qualify for the minimum rebate provisions in section 1927(c)(1)(B)(iii of the Act.

Until CMS's systems can be updated to include an identifier for these drugs and others specified in ACA, we have compiled an initial draft list of those pediatric drugs we have been able to identify that we believe to meet the above-mentioned definition. This list will be posted on the Bulletin Page in the Drug Data Reporting for Medicaid (DDR) application for State and labeler use. Additionally, this list will be posted on the Policy & Reimbursement's Spotlight web page at http://www.cms.gov/Reimbursement/02_Spotlight.asp. If you have concerns or are aware of other drugs that meet the pediatric definition specified above, please contact the policy email resource box at RxDrugPolicy@cms.hhs.gov and specify the drug(s) for which you have concerns or that you believe meet this definition as well as supporting documentation, including the FDA labeling, so that CMS can review this and, if appropriate, update the list accordingly.

Additionally, the ACA added a new section 1927(c)(1)(B)(iii) establishing a minimum rebate of 17.1 percent for clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by the Secretary. We expect that when products are included on the list, the minimum rebate of 17.1 percent of AMP will be used as a basis for rebate calculation. CMS has obtained this data from Medicare Part B and will post the list of clotting factor NDCs on the Bulletin Page

in DDR for State and labeler use. This list will also be posted on the Policy & Reimbursement's Spotlight web page. If you have any questions or corrections to this list, please contact the policy email resource box at RxDrugPolicy@cms.hhs.gov so that we can review this submission and, if appropriate, update the list accordingly.

CMS will issue additional guidance regarding changes to the Medicaid Drug Rebate Program as it becomes available.

REMOVAL OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) AND EXCIPIENTS AS COVERED OUTPATIENT DRUGS

We are providing policy clarification regarding the inclusion of APIs and excipients in the drug rebate program. An API is a bulk drug substance, which is defined by the FDA as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient of the drug product. 21 C.F.R. § 207.3(a)(4). APIs may be included in extemporaneously compounded prescriptions and may serve as the active drug component in a compounded formulation.

In accordance with the foregoing, APIs do not meet the definition of a covered outpatient drug as defined in section 1927(k)(2) of the Social Security Act (Act). As such, APIs are not subject to the requirements of the MDR program. In addition, excipient products used in compounds (*e.g.*, aquaphor, petrolatum, etc.) are non-drug products and, as a result, should not be reported to the MDR program. However, FFP may be available for these products if the State plan allows for their coverage as incident to another service category (*e.g.* Home Health, Nursing, Other Practitioner).

To the extent possible, CMS has identified the APIs and excipients that are listed in the MDR system. We are notifying manufacturers that the NDCs do not qualify as covered outpatient drugs and, as a result, will be deleted from the MDR product file of covered outpatient drugs effective January 1, 2011. As with all deletions, we will notify the States regarding the removal of these products. The list of identified API and excipient NDCs can be found on the Policy & Reimbursement's Spotlight Webpage. Please note that this is not a definitive list. If additional API and/or excipient NDCs are identified, please notify MDROperations@cms.hhs.gov to have them removed from the MDR Program.

Manufacturers are reminded to comply with the terms of the national rebate agreement by submitting NDCs to CMS for only those products that meet the definition of a covered outpatient drug.

(Contact: RxDrugPolicy@cms.hhs.gov)

FAILURE TO SUBMIT MONTHLY & QUARTERLY AMP TIMELY

We would like to remind all manufacturers that manufacturers are required to report pricing information to CMS on a timely basis in accordance with Section 1927(b)(3)(A) of the Social Security Act (the Act). Specifically, manufacturers must submit price information no later than 30 days after the last day of each month and each quarter of a rebate period. Section 1927(b)(3) provides that the penalty for "fail[ing] to provide [required AMP and best price] information . . . on a timely basis" is "increased by $10,000 for each day in which such information has not been provided." In addition, "if such information is not reported within 90 days of the deadline imposed, the [Rebate] agreement shall be suspended for services furnished after the end of such

90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days)."

We have identified manufacturers that do not report their AMP data best price on a timely basis to CMS. Therefore, to ensure that CMS receives AMP and best price data on timely basis, we plan to report to the Office of Inspector General (OIG) a list of manufacturers that do not submit AMP and best price data within the timeframe established by the statute.

Lastly, CMS's receipt of documentation relating to a manufacturer's AMP submission is not, and may not be, considered to be, CMS approval of the delay or an otherwise inaccurate or incomplete submission of pricing data. Furthermore, any acknowledgment of such receipt is not, and may not be considered to be, an advisory opinion under Section 1128D (b) of the Social Security Act. Only the Inspector General of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under that section. Further, as discussed above, CMS' receipt of such documentation (or any acknowledgement of such receipt) is not a release of any liability.

(Contact: RxDrugPolicy@cms.hhs.gov)

CHANGE TO THE DISPUTE RESOLUTION PROGRAM

CMS is in the process of replacing the Central Office Dispute Resolution Program (DRP) Team Lead, who recently retired. Therefore, as DRP issues arise for which a State and/or labeler would like to request CMS's assistance, please follow the established practice of contacting the appropriate Regional Office DRP Coordinator. The contacts may be found on the web at: www.cms.gov/MedicaidDrugRebateDispR/Downloads/rodrpcoordinators.pdf

The Denver Regional Office's DRP/Drug Coordinator continues to serve as the Lead RO for DRP issues and should be copied on all dispute-related communications to other Regional Office DRP Coordinators.

Please direct your drug rebate data questions to mdroperations@cms.hhs.gov and your drug policy questions to the Division of Pharmacy at RxDrugPolicy@cms.hhs.gov.

Rick Friedman /s/ for

Penny R. Thompson
Acting Director
Data and Systems Group

cc:
Regional Administrators

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