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 , CHIP, and Survey & Certification

SMDL#10-006
PPACA# 2
April 22, 2010

Re: Medicaid Prescription Drug Rebates
Dear State Medicaid Director:

This letter is one in a series to provide guidance on the health reform legislation, the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (HCERA), P.L. 111-152, enacted on March 30, 2010, together called the Affordable Care Act.

Specifically, this letter provides information on section 2501 of PPACA and section 1206 of HCERA concerning the increased rebate percentages for covered outpatient drugs dispensed to Medicaid patients, the extension of prescription drug rebates to covered outpatient drugs dispensed to enrollees of Medicaid managed care organizations (MCOs) and the rebate offset associated with the increase in the rebate percentages.

Increase in Rebate Percentages for Covered Outpatient Drugs
In general, manufacturers that participate in the Medicaid drug rebate program are required to pay rebates for covered outpatient drugs that are dispensed to Medicaid patients. The rebates are calculated based on formulas described in section 1927(c) of the Social Security Act (the Act).

Effective January 1, 2010, the changes are as follows:

Except as noted below, for single source and innovator multiple source (brand name) drugs, the minimum rebate percentage is increased from 15.1 percent of the average manufacturer price (AMP) to 23.1 percent of AMP (section 1927(c)(1)(B)(i)(VI), as added by section 2501(a) of PPACA).

For the following brand name drugs, the minimum rebate percentage is increased from 15.1 percent of AMP to 17.1 percent of AMP (section 1927(c)(1)(B)(iii), as added by section 2501(a) of PPACA):

- clotting factors for which a separate furnishing payment is made under Medicare Part B (section 1842(o)(5) of the Act) and which is included on a list of such factors specified and updated regularly by the Secretary; and

- drugs approved by the Food and Drug Administration exclusively for pediatric indications.

For non-innovator multiple source (generic) drugs, the rebate percentage is increased from 11 percent of AMP to 13 percent of AMP (section 1927(c)(3)(B)(iii), as added by section 2501(b) of PPACA).

For a drug that is a new formulation (line extension) of a brand name 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 brand name 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).

In addition, section 2501(e) of PPACA established a limit on the rebate amount for each brand name drug at 100 percent of the AMP.

We will issue additional guidance to manufacturers and other stakeholders concerning the process that will be used to identify clotting factors, drugs with pediatric indications, and line extensions of existing drugs.

Rebates for Medicaid MCO Drugs

The new legislation requires manufacturers that participate in the drug rebate program to pay rebates for drugs dispensed to individuals enrolled with a Medicaid MCO if the MCO is responsible for coverage of such drugs, effective March 23, 2010 (section 1927(b), as amended by section 2501(c) of PPACA). To facilitate the collection of these rebates, States must include utilization data reported by each Medicaid MCO to the States when requesting quarterly rebates from manufacturers as well as in their quarterly utilization reports to the Centers for Medicare & Medicaid Services.

This section also amends section 1903(m)(2)(A) of the Act, effective March 23, 2010, by adding new conditions for Federal financial participation for MCO contracts including that:
any covered outpatient drug provided by the MCO is eligible for the rebates authorized under section 1927 of the Act;

MCO capitation rates shall be based on actual cost experience related to rebates and subject to Federal regulations at 42 CFR 438.6 regarding actuarial soundness of capitation payments; and

The MCO shall report to the State information on the total number of units of each dosage form, strength and package size by National Drug Code of each covered outpatient drug dispensed to Medicaid MCO enrollees and such other data that the Secretary determines necessary for the State to access the rebates authorized by this provision.

Section 2501(c) also made a conforming amendment to section 1927(j)(1) of the Act, effective March 23, 2010, to specify that certain covered outpatient drugs in this section are not subject to the rebate requirements only if such drugs are both dispensed by health maintenance organizations, including Medicaid MCOs that contract under section 1903(m), and subject to discounts under section 340B of the Public Health Service Act.

Changes in Non-Federal Share of Rebates

Section 2501(a)(2) of PPACA added section 1927(b)(1)(C) that provides that, effective January 1, 2010, the amount of the savings resulting from the increases in the rebate percentages described above will be remitted to the Federal government.

Accordingly, we plan to offset the non-Federal share of the difference between the rebate percentages in effect on December 31, 2009, and the new rebate percentages in effect on January 1, 2010. For brand name drugs subject to the 23.1 percent minimum rebate, we plan to offset an amount equal to the non-Federal share of 8 percent of the AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP), regardless of whether States received a rebate amount based on the difference between AMP and best price. For brand name drugs subject to a rebate percentage of 17.1 percent of AMP, we plan to offset an amount equal to the non-Federal share of 2 percent of the AMP (the difference between 17.1 percent and 15.1 percent of AMP), regardless of whether States received a rebate amount based on the difference between AMP and best price. In both of the above instances, we do not plan to offset amounts attributable to the additional inflation-based rebates described in section 1927(c)(2)(A) or (B) of the Act. Further, we do not plan to offset the non-Federal share of any supplemental rebates States may receive above the increased Federal rebate percentages. For generic drugs, we plan to offset an amount equal to the non-Federal share of 2 percent of the AMP (the difference between 13 percent of AMP and 11 percent of AMP).

For a drug that is a line extension of a brand name drug that is an oral solid dosage form, we plan to offset the non-Federal share of 8 percent of the AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP for the line extension drug) as well as the additional rebate for those drugs.

For covered outpatient drugs that are dispensed to Medicaid MCO enrollees, we plan to offset the non-Federal share limited to the difference between the rebate percentages in effect outside of the MCO context on December 31, 2009 and the rebate percentages in effect on January 1, 2010, as described previously. Specifically, we plan for States to retain the non-Federal share of rebates below the 15.1 percent rebate percentage for brand name drugs and 11 percent for generic drugs as in effect on December 31, 2009. In addition, we plan for States to retain the non-Federal share of the amount above the 17.1 percent for clotting factors and drugs exclusively for pediatric indications, and 23.1 percent for all other brand name drugs.

We will issue additional guidance regarding the process that will be used to offset these amounts due to the increase in the rebate percentages.
We intend to issue additional letters to State Medicaid Directors and other guidance and regulations as necessary to assure the proper and timely implementation of these and related provisions, and we look forward to working with you as you implement PPACA and HCERA. In addition, some of the requirements addressed in this letter contain information collections that are subject to the Paperwork Reduction Act and we are working to obtain a valid Office of Management and Budget control number for these collections.

If you have general questions regarding Medicaid drug provisions in the new legislation, please send them to our drug policy e-mail box at RxDrugPolicy@cms.hhs.gov. If you have specific questions regarding the guidance described in this letter, please contact Larry Reed, Director, Division of Pharmacy at (410) 786-3325 or via e-mail at larry.reed@cms.hhs.gov.

Sincerely,
/s/
Cindy Mann
Director

cc:
CMS Regional Administrators
CMS Associate Regional Administrators
Division of Medicaid and Children's Health
Ann C. Kohler
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