

Center for Medicaid and CHIP Services

April 15, 2016

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 97

For

Participating Drug Manufacturers

New Additional Inflation-Adjusted Rebate Requirement for Non-Innovator Multiple Source Drugs

On November 2, 2015, President Obama signed into law the Bipartisan Budget Act (BBA) of 2015. Section 602 of the BBA of 2015, amended section 1927(c)(3) of the Social Security Act (the Act), to require that manufacturers pay additional rebates when their covered outpatient drugs other than single source or innovator multiple source drugs (non-innovator multiple source (N) drugs) average manufacturer prices increase at a rate that exceeds the rate of inflation. In accordance with section 1927(c)(3), as revised by section 602 of the BBA of 2015, manufacturers must calculate these additional rebates for N drugs beginning with the January 1, 2017 quarter (i.e., first quarter of 2017).

Prior to enactment of the BBA of 2015, the basic quarterly unit rebate amount (URA) calculation for N drugs has been equal to 13 percent of a drug's quarterly average manufacturer price (AMP). However, section 602(a) of the BBA of 2015 amended section 1927(c)(3) of the Act by adding an inflation-based additional rebate requirement to the URA calculation for N drugs, which is similar to the additional rebate applied to single source (S) and innovator multiple source (I) drugs. In accordance with the statute, manufacturers are required to calculate an additional rebate amount when the AMP for the dosage form and strength of the N drug for a calendar quarter increases at a rate that is greater than the rate of inflation, based upon the consumer price index for all urban consumers (CPI-U) during the month before the month in which the rebate period begins.

In order to calculate the additional rebate portion of the URA calculation for N drugs, section 602(a) of the BBA of 2015 amended section 1927 of the Act to establish a "Base AMP" value for N drugs based, in part, upon each N drug's Market Date. In general, for N drugs marketed on or before April 1, 2013, the Base AMP is equal to the AMP for the third quarter of 2014 and the Base CPI-U is the CPI-U for September 2014. For N drugs marketed after April 1, 2013, the Base AMP is equal to the AMP for the fifth full calendar quarter after which the drug is marketed as a drug other than a single source or innovator multiple source drug and the Base

CPI-U is equal to the CPI-U for the last month of the Base AMP quarter (refer to the table below).

CMS will modify the Drug Data Reporting for Medicaid (DDR) system and Medicaid Drug Rebate (MDR) system to incorporate the new additional rebate portion of the URA calculation for N drugs. Upon implementation of the modifications to the MDR and DDR systems, CMS will include the URAs for N drugs as part of the quarterly rebate files to states beginning with the first quarter 2017. CMS will provide additional operational instructions to manufacturers and states regarding the status of the MDR and DDR system modifications. However, in accordance with section 1927(c)(3) of the Act, manufacturers will be responsible for calculating the additional rebates for N drugs effective first quarter 2017.

We look forward to continuing our work together to implement this legislation. If you have any questions regarding the additional rebate requirement on N drugs imposed by the BBA of 2015, please contact us at rxdrugpolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group

Attachment**Base AMP for N Drugs**

<i>N Drug Market Date</i>	<i>Base AMP for N Drugs</i>	<i>Base CPI-U for N Drugs</i>
On or before 4/1/2013	AMP for 3Q2014	9/2014 CPI-U
After 4/1/2013	AMP for the 5 th full calendar quarter after Market Date	CPI-U for the last month of the Base AMP quarter

Example of New URA Calculation for N Drugs

Assumptions in the Calculation Example:

- Quarterly URA Being Calculated: 1Q2017
- NDC's Market Date = 1/1/2010 (i.e., on or before 4/1/2013)
- Baseline AMP = 3Q2014 AMP = 0.244795
- 1Q2017 Quarterly AMP = 0.357911
- Baseline CPI-U = CPI-U Value for September 2014 = 238.031
- Quarterly CPI-U = 239.083

Step 1: Basic URA Calculation

Formula: Quarterly AMP * 13%:

$$0.357911 \times 13\% = 0.046528$$

Step 2: Additional Rebate Calculation

Formula: (Baseline AMP/Baseline CPI-U) x Quarterly CPI-U

- (Baseline AMP/Baseline CPI-U) x Quarterly CPI-U = $(0.244795/238.031) \times 239.083 = 0.2458769$
- Compare the resulting amount in step 2a (0.2458769) to the Quarterly AMP (0.357911): if the value in step 2a is less than the Quarterly AMP, subtract it from the Quarterly AMP to determine the additional rebate amount; if the value is equal to or greater than the Quarterly AMP, the additional rebate amount is equal to zero.
 - In this example, the Quarterly AMP (0.357911) is greater; therefore, the Additional Rebate Amount = 0.1120341

Step 3: Total Rebate Calculation

Formula: Total Rebate Amount = Basic Rebate Amount + Additional Rebate Amount

$$0.046528 + 0.1120341 = 0.1585621$$

Step 4: Comparison of Total Rebate Amount to Quarterly AMP

- If the Total Rebate Amount is greater than the Quarterly AMP, it is reduced to equal AMP
- Total Rebate Amount = 0.1585621
- Quarterly AMP = 0.357911
- Since the Quarterly AMP is greater than the Total Rebate Amount, the Total Rebate Amount does not change