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

September 22, 2016

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 101**

For

Participating Drug Manufacturers

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

On April 15, 2016, the Centers for Medicare & Medicaid Services issued Manufacturer Release #97 (https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-097.pdf) to provide guidance on section 1927(c)(3) of the Social Security Act, as amended by 602 of the Bipartisan Budget Act (BBA) of 2015, which requires manufacturers to pay additional rebates on non-innovator multiple source (N) drugs if the average manufacturer prices (AMP) of an N drug increases at a rate that exceeds the rate of inflation. This provision of the BBA of 2015 goes into effect beginning with the Unit Rebate Amounts (URAs) that are calculated for the January 1, 2017 quarter. After Manufacturer Release #97 was issued, CMS received numerous requests for clarification regarding the additional rebate for N drugs that are marketed after April 1, 2013, and for which the baseline AMP is based on the AMP of the fifth full quarter after the drug's market date quarter. Specifically, some manufacturers questioned whether the additional rebate portion of the URA calculation applies prior to the baseline AMP quarter, especially for N drugs for which a baseline AMP is established from a quarter that falls after the first quarter of 2017.

If an N drug has a market date after December 31, 2015, the drug's baseline AMP will be established based on the AMP of the fifth full quarter after the market date, which will be a quarter that falls after the first quarter of 2017. CMS does not believe that section 1927(c)(3) of the Social Security Act, as amended by 602 of the BBA of 2015, supports requiring manufacturers to pay additional rebates for quarters prior to the baseline AMP. Therefore, CMS is clarifying in this release that, 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 URA calculation would only apply prospectively from the quarter in which the drug's baseline AMP is established.

Below are some examples outlining this clarification:

N Drug Market Date	Baseline AMP for N Drug	Quarter in Which the Additional Rebate Portion of the URA Calculation First Applies
3/1/2013	Equal to the AMP from 3Q2014 (this baseline AMP quarter is established by the law for drugs marketed on or before April 1, 2013)	1Q2017
7/1/2014	Equal to the AMP from 4Q2015 (this baseline AMP quarter is based on the 5th full quarter after the Market Date, which falls prior to first quarter 2017)	1Q2017
9/1/2016	Equal to the AMP from 4Q2017 (this baseline AMP quarter is based on the 5th full quarter after the Market Date, which falls after first quarter 2017)	4Q2017
4/1/2017	Equal to the AMP from 3Q2018 (this baseline AMP quarter is also based on the 5th full quarter after the Market Date, which falls after first quarter 2017)	3Q2018

Consistent with Manufacturer Release 90, a manufacturer that buys a drug product from another manufacturer is responsible for obtaining the baseline data of the drug. This includes obtaining the necessary data to report a baseline AMP consistent with section 1927(c)(1)(C) of the Act. Baseline data such as market date and baseline AMP must follow the new drug application (NDA)/abbreviated NDA (ANDA) of the product. To determine if drugs should have the same baseline data, manufacturers may access the FDA Online Label Repository at http://labels.fda.gov/, and enter each drug's NDC to determine if the drugs have the same NDA/ANDA.

If you have further 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