

August 9, 2018

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 109

For Participating Drug Manufacturers

Revision to the Line Extension Unit Rebate Amount Calculation

Effective January 1, 2010, the Affordable Care Act established a different rebate amount calculation under section 1927 of the Social Security Act (the Act) for new oral solid dosage formulations (line extensions) of brand name drugs. However, the original statutory language omitted an important component of the calculation, which was subsequently revised under the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115-123) that was signed into law on February 9, 2018. Section 53104 of the BBA of 2018 amended section 1927(c)(2)(C) of the Act to revise the rebate calculation for line extension drugs, effective for rebate periods beginning on or after October 1, 2018.

For rebate periods occurring after the enactment of the Affordable Care Act and prior to the enactment of the BBA of 2018, that is, drugs paid for by a state after December 31, 2009 and prior to October 1, 2018, the unit rebate amount calculation (URA) for a line extension drug is the greater of: 1) Standard URA = the basic rebate plus the additional rebate for the line extension drug or 2) Alternative URA = the product of the average manufacturer price (AMP) of the line extension drug (for each dosage form and strength) and the highest additional rebate (calculated as a percentage of AMP) under section 1927 of the Act for any strength of the original single source drug or innovator multiple source drug (“initial brand name listed drug”).

Effective for rebate periods beginning on or after October 1, 2018, the URA for a line extension drug will be the greater of: 1) Standard URA = the basic rebate plus the additional rebate for the line extension drug or 2) Alternative URA = the basic rebate plus the product of the quarterly AMP of the line extension drug (for each dosage form and strength) and the highest additional rebate (calculated as a percentage of AMP) under section 1927 of the Act for any strength of the original single source drug or innovator multiple source drug.

As a result of the new law, we plan to pursue future rulemaking in order to ensure that the regulatory text reflects the BBA of 2018 revised calculation of the rebate obligation for a line extension drug.

The Centers for Medicare & Medicaid Services (CMS) will modify the rebate system to incorporate the revised line extension URA calculation as part of the quarterly rebate files beginning with the fourth quarter 2018 file that will be sent to the states in early February 2019. CMS will provide additional operational instructions to manufacturers and states regarding the status of the system modifications. As always, while CMS provides states with URA information as a courtesy, in accordance with section 1927(c)(2)(C) of the Act, manufacturers remain responsible for calculating the revised line extension URA in accordance with the BBA of 2018 effective fourth quarter 2018.

To assist in those efforts, we are providing manufacturers with the following steps for the calculation of the URA for a line extension drug, along with an example of the calculation.

Step 1: Calculate Standard URA = Basic Unit Rebate Amount + Additional Unit Rebate Amount.

Step 2: Calculate Alternative URA = Basic Unit Rebate Amount + Product of the AMP of the line extension drug and the highest additional rebate (calculated as a percentage of AMP) under section 1927 for any strength of the initial brand name listed drug.

Step 3: Determine the URA = Greater of (1) Standard URA or (2) Alternative URA.

Step 4: Determine if the URA is greater than 100 percent of the Quarterly AMP

- a. If the URA is greater than or equal to 100 percent of the Quarterly AMP, then the URA = Quarterly AMP (consistent with section 1927(c)(2)(D) of the Act.)
- b. If the URA is less than 100 percent of Quarterly AMP, then use the URA.

Example:

Baseline AMP (line extension) = 100.00	Quarterly AMP (line extension) = 300.00
Best Price (line extension) = 250.00	Baseline CPI-U = 170.00
Quarterly CPI-U = 200.00	

Step 1: Calculate Standard URA

A. Basic Unit Rebate Amount is the greater of:

- a) Quarterly AMP \times 23.1% = 300.00 \times 23.1% = 69.30 or
- b) Quarterly AMP - Best Price = 300.00 - 250.00 = 50.00

The greater of the two results (69.30 or 50.00) is 69.30

Basic Unit Rebate Amount = **69.30**

B. Additional Unit Rebate Amount = Quarterly AMP - [(Baseline AMP/Baseline CPI-U) \times Quarterly CPI-U]

$$= 300 - [100/170 \times 200]$$

$$= 300 - 117.65 = 182.35$$

Additional Unit Rebate Amount = **182.35**

If the $[(\text{Baseline AMP}/\text{Baseline CPI-U}) \times \text{Quarterly CPI-U}]$ is equal to or greater than the Quarterly AMP, then the Additional Unit Rebate Amount is zero.

$$\text{Standard URA} = \text{Basic Unit Rebate Amount} + \text{Additional Unit Rebate Amount} = 69.30 + 182.35 = \mathbf{251.65}$$

Step 2: Calculate Alternative URA

$$\text{Quarterly AMP (line extension)} = 300.00$$

$$\text{Best Price (line extension)} = 250.00$$

- A. Basic Unit Rebate Amount is the greater of:
- Quarterly AMP \times 23.1% = $300.00 \times 23.1\% = 69.30$ or
 - Quarterly AMP - Best Price = $300.00 - 250.00 = 50.00$

The greater of the two results (69.30 or 50.00) is 69.30

Basic Unit Rebate Amount = **69.30**

- B. Alternative Additional Unit Rebate Amount:
Product of the Quarterly AMP of the line extension drug and the highest additional rebate (calculated as a percentage of AMP) for any strength of the initial brand name listed drug.

$$\text{Additional Unit Rebate Amount (initial brand name listed drug) strength A} = 200.00$$

$$\text{Additional Unit Rebate Amount (initial brand name listed drug) strength B} = 125.00$$

$$\text{Additional Unit Rebate Amount (initial brand name listed drug) strength C} = 110.00$$

$$\text{Quarterly AMP (initial brand name listed drug) strength A} = 280.00$$

$$\text{Quarterly AMP (initial brand name listed drug) strength B} = 275.00$$

$$\text{Quarterly AMP (initial brand name listed drug) strength C} = 270.00$$

$$\text{Additional rebate ratio strength A} = 200/280 = 0.7143$$

$$\text{Additional rebate ratio strength B} = 125/275 = 0.4545$$

$$\text{Additional rebate ratio strength C} = 110/270 = 0.4074$$

$$\text{Quarterly AMP of line extension drug} \times \text{highest additional rebate ratio for any strength of the initial brand name listed drug} = 300 \times 0.7143 = 214.29$$

Alternative Additional Unit Rebate Amount = **214.29**

Alternative URA = Basic Unit Rebate Amount + Alternative Additional Unit Rebate Amount = 69.30 + 214.29 = **283.59**

Step 3: **Determine the URA** = the greater of:

(Step 1) Standard URA = 251.65 or

(Step 2) Alternative URA = 283.59

URA = **283.59**

Step 4: **Determine if the URA is greater than or equal to 100 percent of the Quarterly AMP**

100 percent of Quarterly AMP = 100% × 300.00 = 300.00

URA = 283.59

If the URA is greater than or equal to 100 percent of the Quarterly AMP, then URA = Quarterly AMP.

If the URA is less than 100 percent of the Quarterly AMP, then use the URA

283.59 is less than 300.00

URA is equal to 283.59

We look forward to continuing our work together to implement this legislation. If you have any questions regarding the revised line extension URA calculation imposed by the BBA of 2018, please contact us at rxdrugpolicy@cms.hhs.gov.

Sincerely,

/s/

Michael Nardone
Director
Disabled and Elderly Health Programs Group