[redacted]

From: CMS MDROperations [mailto:MDROperations@cms.hhs.gov]
Sent: Friday, April 14, 2017 10:08 AM
To: CMS MDROperations <MDROperations@cms.hhs.gov>
Cc: Bergin, Cindy D. (CMS/CMCS) <Cindy.Bergin@cms.hhs.gov>; Blatt, Ruth (CMS/CMCS) <Ruth.Blatt@cms.hhs.gov>; Bruce, Tamara L. (CMS/CMCS) <Tamara.Bruce@cms.hhs.gov>; Coster, John M. (CMS/CMCS) <John.Coster@cms.hhs.gov>; Du, Brian J. (CMS/CMCS) <Brian.Du@cms.hhs.gov>; Egwim, Emeka S. (CMS/CMCS) <Emeka.Egwim@cms.hhs.gov>; Ferrandi, Lisa (CMS/CMCS) <Lisa.Ferrandi@cms.hhs.gov>; Fine, Joseph L. (CMS/CMCS) <Joseph.Fine@cms.hhs.gov>; Hilliard, Renee M. (CMS/CMCS) <Renee.Hilliard@cms.hhs.gov>; Hinds, Christine M. (CMS/CMCS) <Christine.Hinds@cms.hhs.gov>; Khau, Meagan T. (CMS/CMCS) <Meagan.Khau@cms.hhs.gov>; Morgan, Mickey D. (CMS/CMCS) <Mickey.Morgan@cms.hhs.gov>; Rucker, Michele (CMS/CMCS) <Michele.Rucker@cms.hhs.gov>; Saddler, Kwan P. (CMS/CMCS) <Kwan.Saddler@cms.hhs.gov>; Simananda, Terry B.(CMS/CMCS) <Terry.Simananda@cms.hhs.gov>; Tuttle, Wendy L. (CMS/CMCS) <Wendy.Tuttle@cms.hhs.gov>; Vernon, Shannon M. (CMS/CMCS) <Shannon.Vernon@cms.hhs.gov>; Wellington, Andrea (CMS/CMCS) <Andrea.Wellington@cms.hhs.gov>; Williams, Yolanda (IHS/ABR) <Yolanda.Williams@ihs.gov>
Subject: Delay in the Implementation of the N Drug Additional Rebate Requirements
Importance: High

Dear Technical Contacts,

On February 16, 2017, we sent you the attached email, which provided operational guidance on the new additional rebate calculation for non-innovator multiple source (N) drugs. This guidance also outlined some related upcoming changes to the Drug Data Reporting for Medicaid (DDR) system. At that time, we indicated that we expected to implement both the revised Unit Rebate Amount (URA) for N drugs and the related DDR changes prior to calculating 1Q2017 rebates; however, we are writing to notify you of a temporary delay in that implementation. **As a result of this delay, the 1Q2017 URAs that CMS calculates for N drugs in early May will not include the new additional rebate portion of the calculation.** Instead, the 1Q2017 N drug URAs that are calculated by CMS, reflected in DDR, and provided to states on the quarterly rebate file will only reflect the "basic rebate amount" portion of the URA calculation (i.e., AMP x 13%).

As a reminder, per the terms of the national rebate agreement, labelers are responsible for calculating URAs. Therefore, although the 1Q2017 state rebate file will only reflect the basic rebate amount for N drugs, we expect labelers to correctly calculate 1Q2017 URAs for N drugs using the revised rebate methodology, which includes both the basic and the additional rebate amounts. In addition, because 1Q2017 state invoices will reflect the CMS-calculated URAs for N drugs that are based solely on the basic rebate amount, labelers should calculate and submit their 1Q2017 URAs to states using the OMB-approved Reconciliation of State Invoice (ROSI) form (i.e., form CMS-304). These URAs will subsequently be verified by state rebate invoices once DDR has been updated. For your convenience, a copy of the ROSI can be found in the Medicaid Drug Rebate Data Guide for Labelers, which is located in the "Guides and References" section of the "Documents" tab in DDR. Labelers that fail to report and pay rebates in accordance with the revised URA calculation for N

drugs beginning with 1Q2017 are responsible for interest in accordance with previous program guidance on any amount of rebate underpayment.

For more information regarding the upcoming DDR changes and the revised URA calculation for N drugs, please refer to the attached email. Also, we are aware that Step 2 of the URA calculation example included in the attached contained a typo (which slightly impacted the rounding throughout the rest of the calculation, but not the final URA); therefore, we have corrected the example and provided it again below for your convenience. We encourage you to share this information with your DDR Designees as appropriate.

We remain committed to the successful implementation of the system changes described in the attached, and anticipate that the revised URA calculation for N drugs and related DDR changes will be in place before 2Q2017 URAs are calculated in early August. At that time, we expect that states will receive Prior Period Adjustments (PPAs) for N drugs retroactive to 1Q2017. We will send another communication regarding the status of these system changes as we get closer to August. In the meantime, if you have any questions or concerns regarding the upcoming DDR system changes related to the BBA '15 Base AMP for N drugs, or the temporary delay in the revised URA calculation for N drugs, please feel free to contact us at mdroperations@cms.hhs.gov.

Sincerely,

CMS MDR Operations

Revised Unit Rebate Amount (URA) Calculation for N Drugs

Data Assumptions Used in the Example:

- Quarterly URA Being Calculated: 1Q2017
- NDC's Market Date = 1/1/2010 (i.e., on or before 4/1/2013)
- Baseline AMP (derived from 3Q2014) = 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 x 13% = 0.04652843 (round result to 7 decimal places)

= 0.0465284

Step 2: Additional Rebate Calculation

Formula: AMP – [(Baseline AMP/Baseline CPI-U) * Quarterly CPI-U]:

0.0465284 – [(0.244795 / 238.031) * 239.083] = 0.24587689412303034 (round final result to 7 decimal places)

= 0.2458769

Compare the result in Step 2 (0.2458769) to the Quarterly AMP (0.357911). If the value in Step 2 is less than the Quarterly AMP, subtract it from the Quarterly AMP to determine the additional rebate amount; if the value in Step 2 is equal to or greater than the Quarterly AMP value, the additional rebate amount is equal to zero.

In this example, the Quarterly AMP value (0.357911) is greater; therefore, the Additional Rebate Amount = 0.1120341 (round result to 7 decimal places).

Step 3: Total Rebate Calculation

Formula: Basic Rebate Amount (rounded to 7 decimal places) + Additional Rebate Amount = Total Rebate Amount

0.0465284 + 0.1120341 = 0.1585625 (round result to 7 decimal places)

Step 4: Comparison of Total Rebate Amount to Quarterly AMP

If the calculated Total Rebate Amount is greater than the Quarterly AMP, the URA is reduced to equal AMP:

- Total Rebate Amount = 0.1585625
- Quarterly AMP = 0.357911

Since the Quarterly AMP is greater than the Total Rebate Amount, the Total Rebate Amount does not change; therefore, the final URA is 0.1585625. This value will be rounded to 6 decimal places (0.158563) and then again to 4 decimal places (0.1586) to arrive at the final URA.