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

March 10, 2014

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 89

For Participating Drug Manufacturers

2012 STATE UTILIZATION DATA FOR BRANDED PRESCRIPTION DRUG (BPD) FEES

CMS issued its annual reminder to manufacturers to review the accuracy of utilization data submissions in order to prepare for the upcoming Branded Prescription Drug fee year calculations. A copy of CMS' guidance to manufacturers is available on our website, Medicaid.gov. Go to our BPD page at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Branded-Prescription-Drug.html, look under the BPD Disputes heading, and click on the "CMS Medicaid BPD Guidance to Manufacturers" link.

If you have any questions, please contact <u>MDROperations@cms.hhs.gov</u>, and please include "BPD" in the subject line.

<u>USING CMS FORM 304 (ROSI – RECONCILITION OF STATE INVOICE) AND CMS</u> FORM 304 A (PQAS – PRIOR QUARTER ADJUSTMENT STATEMENT) FORMAT

CMS would like to remind manufacturers that both the CMS Form 304 (ROSI) and CMS Form 304A (PQAS) are OMB-approved documents. Manufacturers should make sure to complete all the data fields specified below when sending these documents to the States:

CMS-304 (ROSI - Reconciliation of State Invoice):

- Record ID
- Labeler Code
- Product/Package Code

- Product Name
- FFS/MCO Record ID
- Rebate Per Unit
- Adjusted Rebate Per Unit
- Units Invoiced
- Adjusted Units (+/-)
- Labeler Disputed Units
- Units Paid
- Adjustment Code(s)
- Dispute Code(s)
- Rebate Amount Invoiced
- Invoice Correction Amount (+/-)
- Withheld Invoice Amount
- Rebate Amount Paid

CMS-304A (PQAS - Prior Quarter Adjustment Statement):

- Record ID
- Labeler Code
- Product / Package Code
- Product Name
- FFS/MCO Record ID
- Original Rebate Per Unit
- Current Rebate Per Unit
- Original Units Invoiced
- Current Units to Date
- Prior Units Paid
- Current Units Paid to Date
- Prior Units Disputed
- Current Units Disputed to Date
- Original Amount Invoiced
- Revised Invoice Amount
- Prior Amount Paid
- Current Amount Paid to Date
- Amount Paid this Transaction
- Adjustment Code(s)
- Dispute Codes(s)

If you have any questions, please contact MDROperations@cms.hhs.gov.

<u>CLARIFICATION OF POSTMARK DATES FOR PURPOSES OF CALCULATING INTEREST</u>

In accordance with section 1927(b)(1)(A) of the Social Security Act (the Act) and the terms of the National Medicaid Drug Rebate Agreement, manufacturers are required to pay a rebate to each state for all covered outpatient drugs of the manufacturer that were paid for in a quarterly rebate period. This section of the Act also states that such rebate payments are to be paid within 30 days of the manufacturer's receipt of the state invoice. For purposes of calculating interest on late rebate payments, previously issued guidance (e.g., Manufacturer Release #7 and State Release #29) has noted that manufacturers have 37 calendar days (as evidenced by the postmark by the U.S. Postal Service on the envelope) to pay rebates before interest begins to accrue. We have received various inquiries regarding the postmark date that should be used for state invoices received via alternate methods (i.e., other than the traditional paper format received via regular U.S. Postal Service). Therefore, as a follow-up to our release item titled "Clarification on Postmark Dates for Web Invoices" (Manufacturer Release #80), we believe it would be helpful to provide a list of scenarios that identifies different state invoice transmission methods, along with the appropriate "postmark date" manufacturers should use when determining when interest begins to accrue:

• If a state sends a paper invoice:

The postmark date equals the date the postmark is applied to the envelope which may not necessarily be the day that the envelope was mailed. For example, the envelope containing the paper invoice was mailed on 1/13/14; however, the envelope was postmarked 1/15/14. The date when interest begins to accrue is the postmark date of 1/15/14.

• If a state sends an email with the invoice attached:

The date when interest begins to accrue equals the date on which the email was sent. For example, if the email was sent 1/14/14, the date when interest begins to accrue is 1/14/14.

• Secure websites:

For states that use a secure website, (optional) the date when interest begins to accrue equals the date of an email notification that a web invoice is ready to be downloaded; however, these state emails should also include the invoice within the body of the email or, at a minimum, include the information on the number of units paid, by NDC. State email notifications that do not contain unit information (i.e., ones that only link to an invoice) do not meet the minimum invoice requirements; therefore, the date of such an email does not qualify as a postmark date.

• If a state sends an invoice in multiple formats:

The date when interest begins to accrue equals the date of whichever format is transmitted first.

<u>Note:</u> If a manufacturer sends a rebate payment that is missing the postmark date on the envelope, the state should use the date of the enclosed payment check to determine if any interest applies.

If you have any questions, please contact MDROperations@cms.hhs.gov.

RETIREMENT NEWS

Larry Reed has decided to retire after 37 years of Federal service effective January 3, 2014. Until the position of Director of the Division of Pharmacy is filled, we are pleased to announce that Kim Howell will serve as Acting Director.

/s/

Barbara Edwards Director Disabled and Elderly Health Programs Group