

MEDICAID DRUG REBATE PROGRAM Release No. 15

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

REMITTANCE ADVICE REPORT (RAR)

The proposed RAR developed by the Dispute Resolution Workgroup is finalized. The RAR functions as a reconciliation report to reduce disputes by standardizing data exchange and improving communication between manufacturers and States.

Pending the publication of the drug rebate regulation mandating the RAR, all manufacturers are encouraged to voluntarily begin using the draft RAR to report the remittance of rebate payments, adjustments to previous rebate payments, and disputed rebate amounts. Attached are copies of the proposed RAR, instructions, data definitions, automated reporting format, and a listing of the adjustment and dispute codes. At this time, we do not anticipate any changes to the proposed RAR.

DESI CODE FIELD CHANGES

Effective with data submitted for calendar quarter 1-95, changes to the DESI Code field must be submitted to HCFA on paper. We will no longer allow this field to be changed via telecommunications or diskette transmissions. This change is being made to eliminate the many errors in this field that continue to be submitted by labelers even when the Food and Drug Administration (FDA) has declared a drug to be less than effective (LTE). In those instances where you have received notice from the FDA that one or more of your drug products have been declared LTE, we ask that you review your records to ensure their correctness.

BASELINE CHANGES

In order to make a Baseline change, both on diskette and through the Ordernet option, EVERY field MUST be included on all three records, the CORRECTION FLAG MUST be set to "1" and only the CHANGED field is to contain data different from that contained on the current Baseline record.

We have been receiving a large number of Baseline change records where the MARKET DATE and/or FDA APPROVAL DATE is/are missing. These dates may already be included on your file and you may have already established them on our master MDRI file; however, if you do NOT include them on the change record, the record WILL REJECT and will be sent to you as invalid changes, due to missing date(s).

Please assure that, whenever you submit a Baseline change, ALL FIELDS, including MARKET AND FDA APPROVAL DATES, are contained on the record.

BEST PRICE (BP) vs. AVERAGE MANUFACTURER PRICE (AMP)

When doing your calculations for quarterly AMP, charge-backs, discounts, returns, etc., are all subtracted from the gross sales dollars BEFORE dividing that field by total units sold. It is possible that, due to large numbers of returns not affecting BP, this calculation can cause the AMP to be LESS THAN the BP for that product for that quarter. If and when this condition ever occurs, please make sure you adjust the BP DOWN so that it is EQUAL TO the AMP. BP, by its very nature, CANNOT BE more than AMP.

TOLERANCE THRESHOLD FOR INTEREST

In those instances where the administrative cost of recovering interest payment(s) exceeds the interest payable to the State, the State may apply the \$50 tolerance level per labeler to interest payments. Application of this tolerance is optional for States; that is, any State may choose to invoice a labeler for interest amounts at or below the tolerance level. In all cases where a State chooses to apply tolerance levels, adequate documentation should be maintained by both the States and the labeler.

WEEKLY U.S. TREASURY BILL DISCOUNT RATES

Attached is the latest listing of the 90-day treasury bill auction rates from July 5, 1994 through February 13, 1995. These rates are to be used to calculate interest owed States on overdue rebates.

TOPIC INDEX

For your convenience, also attached is a topic index of all items covered in prior releases.

Please continue to contact us with your drug rebate questions by using the Drug Rebate hotline at (410) 966-3249.

Sally K. Richardson Director Medicaid Bureau

3 Attachments

cc:

All Regional Administrators

All Associate Regional Administrators Division of Medicaid

The Medicaid Drug Rebate Remittance Advice Report (RAR) is the mandatory form developed to maintain uniformity in the remittance of rebate payments to States from drug manufacturers participating in the program. Each participating manufacturer must complete and submit the RAR within 30 days of receiving State drug utilization information on the number of units paid, by NDC number. The RAR is available in two formats, paper and electronic, depending on the needs of the user. The electronic format consists of four 80-character records which may be incorporated into a PC database or telecommunications system (e.g., Ordernet). These instructions are provided as an aid in developing the data contained in the report.

The following information must accompany each rebate payment made to a State:

- I.For every Labeler Code:
 - 1.Period Covered
 - 2. Invoice Number
 - 3.State
 - 4.Labeler Code
 - 5. Company Name and Address
 - 6.Contact Name
 - 7.Phone Number
 - 8. Phone Extension (if applicable)
- 9. Contact Fax Number
- II.For every NDC:
 - 1.Product Code
 - 2.Package Size Code
 - 3. Product Name
 - 4. Rebate Amount Per Unit
 - 5.Units Invoiced
 - 6. Units Paid
 - 7. Rebate Amount Invoiced (if available)
 - 8.Rebate Amount Paid
- III. For every NDC where an adjustment has occurred:
 - 1.All data from II above
 - 2.Adjusted Rebate Per Unit
 - 3.Adjustment Code(s)
 - 4.Credit/Debit Indicator
 - 5. Invoice Adjustment Amount

- IV. For every NDC where a dispute has occurred:
 - 1.All data from II above
 - 2.Dispute Code(s)
 - 3. Withheld Invoice Amount

Please refer to the accompanying data dictionary for detailed information on each field.

INSTRUCTIONS FOR PAPER REPORTING:

- 1. Prepare a separate report for each quarter.
- 2. Include information for each NDC submitted on the State invoice for the quarter.
- 3. Provide grand totals for the Units Invoiced, Units Paid, Rebate Amount Invoiced, and the Rebate Amount Paid. If applicable, also provide grand totals for the Invoice Adjustment Amount and the Withheld Invoice Amount.
- 4. Include this form with all rebate payments made to a State.

INSTRUCTIONS FOR ELECTRONIC REPORTING:

- 1.Transmit one Record 1 for each quarter.
- 2. Transmit one Record 2 for each NDC submitted on the State invoice for the quarter.
- 3. Transmit one Record 3 for each NDC if:
 - a.an adjustment has been made to the Rebate Amount Per Unit or Rebate Amount Invoiced; or,
 - b.there is a dispute in the Units Invoiced and all, or a portion, of the Rebate Amount Invoiced is being withheld.
- 4. Transmit Record 4 (Totals record) for each quarter.
- 5. Transmit a Remittance Advice Report file for all rebate payments made to a State.

INSTRUCTIONS FOR PREPARING PRIOR PERIOD ADJUSTMENTS:

- 1. Complete a separate report for each quarter in which an adjustment has occurred.
- 2. The Rebate Amount Invoiced and the Rebate Amount Paid will reflect the data for the period for which the invoice and payment were made (not the current quarter).
- 3. Provide the Adjusted Rebate Per Unit only for the NDCs affected.
- 4.Enter "4" as the Adjustment Code for each NDC.
- 5. Use the Credit/Debit Indicator (C or D) to designate the adjustment action taken.
- Example: C -Manufacturer has overpaid. Subtract this amount from the Rebate Amount Invoiced.
- D Manufacturer has underpaid. Add this amount to the Rebate Amount Invoiced.
- 6. Provide the Invoice Adjustment Amount for each affected NDC.
- 7. Calculate the Total Invoice Adjustment Amount for all affected NDCs combined.
- 8.If it is determined that the Total Invoice Adjustment Amount is a credit to the manufacturer, it may be applied to the Rebate Amount Paid for the current quarter. If the Total Invoice Adjustment Amount is a debit, it must be paid to the State with the payment for the current quarter.
- 9. Submit the RAR to the State with the adjusted rebate payment. If the adjustment is applied to the Rebate Amount Paid for the current quarter, the RAR and the current quarter report must accompany the payment.
- 10. If the period involved is closed-out, use dispute code I.

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DATA ELEMENT NAME: Company Name
DATA DEFINITION: Name of company as it appears on the signed rebate agreement.
SPECIFICATIONS: Alpha-numeric values, first twenty-five positions of company name, left justified, blank filled.
DATA ELEMENT NAME:Labeler Code
DATA DEFINITION:First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug.
$\begin{tabular}{ll} {\tt SPECIFICATIONS:Numeric\ values\ only,\ 5\ positions\ right\ justified,\ zero\ filled;} \\ & \underline{\tt no\ blanks}. \end{tabular}$
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DATA ELEMENT NAME:Period Covered
DATA DEFINITION: Calendar quarter and year covered by this report.
SPECIFICATIONS: Numeric values, 3 position field, QYY; no blanks
Valid values for Q:
1 = January 1 - March 31 2 = April 1 - June 30
3 = July 1 - September 30 4 = October 1 - December 31
Valid values for YY: Last two digits of calendar year covered.

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DATA ELEMENT NAME: Contact DATA DEFINITION: Labeler's contact person receiving the State invoice. SPECIFICATIONS: Alpha-numeric values, twenty positions, left justified, first name and last name separated by 1 blank. DATA ELEMENT NAME: Phone DATA DEFINITION: Telephone number of contact person. SPECIFICATIONS: Alpha-numeric values, ten positions, area code and phone number. DATA ELEMENT NAME: Fax DATA DEFINITION: Telephone Fax number of contact person. SPECIFICATIONS: Alpha-numeric values, ten positions, area code and phone number. DATA ELEMENT NAME: State DATA DEFINITION: State postal abbreviation. SPECIFICATIONS: Alpha values, 2 position field; no blanks DATA ELEMENT NAME: Invoice Number DATA DEFINITION: Identification number of invoice submitted by State and associated with this report. If invoice contains no identification number, this field will be blank. SPECIFICATIONS: Alpha-numeric values, 10 position field, right justified.

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DATA ELEMENT NAME: Produc	ct Code
DATA DEFINITION:Second :	segment of National Drug Code.
SPECIFICATIONS:Alpha-nur	meric values, 4 position field, right justified, zero filled; no blanks.
DATA ELEMENT NAME:	Package Size Code
DATA DEFINITION: Third	segment of National Drug Code.
SPECIFICATIONS:Alpha-nur	meric values only, 2 digit field, right justified, zero filled; no blanks.
DATA ELEMENT NAME:Produc	ct Name
DATA DEFINITION:First te	en positions of product name as it appears in the product description submitted to HCFA.
SPECIFICATIONS:Alpha-num	meric values, 10 positions, left justified; blank filled.
DATA ELEMENT NAME:Rebate	e Amount Per Unit
DATA DEFINITION: HCFA-ca	lculated rebate amount per unit as shown on the State invoice (if present).
SPECIFICATIONS:Numeric v	ralues, 11 positions: 5 whole numbers and 6 decimals, right justified. If not available, this field will be zero filled; no blanks.

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DATA ELEMENT NAME: Units Invoiced DATA DEFINITION: State-calculated number of units paid for. If the number of units has been adjusted through correspondence or telephone contact between the State and the manufacturer, the Units Invoiced will reflect the adjusted number. SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks. DATA ELEMENT NAME: Units Paid DATA DEFINITION: Manufacturer-calculated number of units paid for. SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks. DATA ELEMENT NAME: Rebate Amount Invoiced DATA DEFINITION: State-calculated rebate amount invoiced by the State per NDC. SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified. If not available, this field will be zero filled; no blanks. DATA ELEMENT NAME: Rebate Amount Paid DATA DEFINITION: Amount per NDC that the manufacturer is remitting to the State with this report. SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified; No blanks.

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DATA ELEMENT NAME: Adjusted Rebate Per Unit DATA DEFINITION: Rebate amount per unit if different than the rebate amount per unit as shown on the State invoice (if present). SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers and 6 decimals, right justified. Calculate to 7 decimals and round to 6; blanks. DATA ELEMENT NAME: Adjustment Codes DATA DEFINITION: Reason(s) manufacturer has adjusted the rebate per unit or the number of units invoiced. Refer to the page 3 of the automated reporting format or the RAR form for values. SPECIFICATIONS: Alpha-numeric, 3 positions. Valid values: 1 through 6. Maximum: 3 Adjustment Codes per NDC DATA ELEMENT NAME: Credit/Debit Indicator DATA DEFINITION: Indicator to determine if the Invoice Adjustment Amount is added to or subtracted from the Rebate Amount Invoiced. SPECIFICATIONS: Alpha-numeric, 1 position, blank filled. Valid values: C =Credit (Subtract this amount from the rebate amount invoiced.) D =Debit to manufacturer (Add this amount to the rebate amount invoiced.)

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DATA ELEMENT NAME: Invoice Adjustment Amount DATA DEFINITION: Amount of the credit or debit resulting from the adjustment to the Rebate Amount Invoiced by the State for the period covered by this report. SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers and 6 decimals, right justified. DATA ELEMENT NAME: Dispute Codes DATA DEFINITION: Reason(s) manufacturer has disputed the invoice submitted by the State. Refer to page 3 of the automated reporting format or the RAR form for values. SPECIFICATIONS: Alpha-numeric, 3 positions. Valid values: A through I. Maximum: 3 Dispute Codes per NDC DATA ELEMENT NAME: Withheld Invoice Amount DATA DEFINITION: The rebate amount invoiced by the State that the manufacturer is disputing for the period covered by this report. SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified. DATA ELEMENT NAME: Total Units Invoiced DATA DEFINITION: Total number of State-calculated units invoiced. SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified.

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DATA ELEMENT NAME:	Total Units Paid	
DATA DEFINITION: Total nu	umber of manufacturer-calculated units paid.	
SPECIFICATIONS: Numeric v	values, 10 positions: 8 whole numbers and 2 decimals, right justified.	
DATA ELEMENT NAME:Total	Rebate Amount Invoiced	
DATA DEFINITION: Total re	ebate amount the State invoiced the labeler for all NDCs for the period covered by this report.	
SPECIFICATIONS: Numeric v	alues, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks.	
DATA ELEMENT NAME:Total	Rebate Amount Paid	
DATA DEFINITION: Total am	ount of rebate the labeler paid to the State for all NDCs for the period covered by this report.	
SPECIFICATIONS: Numeric v	values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks.	
DATA ELEMENT NAME:Total	Invoice Adjustment Amount	
DATA DEFINITION: Total am	ount of adjustments the labeler made to the rebate amount invoiced by the State for all NDCs for the period covered by this report.	
SPECIFICATIONS: Numeric v	alues, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks.	

DATA ELEMENT NAME: Total Withheld Invoice Amount

DATA DEFINITION: Total amount the labeler is withholding from the rebate amount

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invoiced by the State for all NDCs for the period covered by this report.

SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled; no blanks.