MEDICAID DRUG REBATE
LABELER INSTRUCTIONS
for
PRIOR QUARTER ADJUSTMENT STATEMENT
(FORM CMS-304a)

The Medicaid drug rebate PQAS is mandated for use by labelers to uniformly explain prior quarter actions/payments/credits to states. This form may accompany the ROSI or may be submitted separately. In either case, the PQAS <u>must</u> accompany rebate payments or payment adjustments for a prior quarter.

The labeler may complete and submit the PQAS in one of two media, paper or electronic, depending on the labeler's capabilities. Labelers may develop an automated system for the PQAS using the electronic field size listing attached as Appendix A. Labelers MUST submit the PQAS in the mandated format regardless of the media selected. No additional information should be entered on the form itself and no information should be omitted unless instructed in the data definitions.

The Labeler Data Definitions, Appendix B, fully explain the information required for each data element on the PQAS. Please refer to these definitions for a complete explanation of the column headings whether completing the PQAS via paper or when developing an electronic medium.

Appendix C, Adjustment and Dispute Codes, lists the codes you may enter to explain any adjustments and/or disputes. The codes are comprehensive and accommodate any adjustment or dispute. (This list serves both prior and current quarter reporting (see form CMS-304).) Codes A-I are generally considered Adjustment Codes, and codes N-W are generally considered Dispute Codes. Only use codes listed in Appendix C.

Labelers may choose up to three codes each for adjustments and disputes per NDC. Attach supporting documentation, as needed, to further explain the reason for the adjustment or dispute. Labelers <u>must</u> supply documentation for codes that require it.

SPECIFIC INSTRUCTIONS

The PQAS is used for reporting all <u>PRIOR QUARTER</u> actions, i.e., invoiced unit changes, prior disputed unit adjustments, and PPAs.

1.   The PQAS is <u>quarter specific</u>. The labeler must complete a separate PQAS for <u>each</u> prior quarter reconciled.

2.   Using the data definitions, enter the required information for <u>each</u> NDC reported to the state. Each column is "lettered" for ease of reference.

3.   Enter grand totals for columns E through O. The grand total for column O for all NDCs listed, plus interest being paid, should equal the remittance to the state.

    ✎NOTE: If the labeler completes and submits the PQAS with the ROSI, the amount of the remittance should equal the Total Remittance shown on the ROSI, plus or minus the Total Remittance on the PQAS.

4.   A brief explanation of any interest payment <u>must</u> be provided.

5.   Submit the completed PQAS with the payment/credit for all prior quarters.

<u>Examples for Completing the PQAS</u>

Appendix D to these instructions is a condensed PQAS sample showing column entries for five examples. The examples reflect situations such as invoiced unit changes, prior disputed unit adjustments, and PPAs.

MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form CMS-304a)
LABELER DATA DEFINITIONS

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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 25 positions of company name, left justified, blank filled.

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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.

SPECIFICATIONS: Numeric values only, 5 positions right justified, zero filled; no blanks.

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DATA ELEMENT NAME: Quarter Covered

DATA DEFINITION: This data element will always be a **prior** quarter and year.

SPECIFICATIONS: Numeric values, 5 position field, QYYYY; 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 YYYY: Four digit calendar year covered.

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DATA ELEMENT NAME: Labeler Contact

DATA DEFINITION: Labeler's contact person for questions
                    concerning this report.

SPECIFICATIONS: Alpha-numeric values, 20 positions, left
                    justified, first name and last name separated
                    by 1 blank.

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DATA ELEMENT NAME: Phone

DATA DEFINITION: Telephone number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 14 positions, area
                    code, phone number, and extension, if needed.

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DATA ELEMENT NAME: Fax

DATA DEFINITION: Fax number of labeler's contact person.

SPECIFICATIONS: Alpha-numeric values, 10 positions, area code
                    and phone number.

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DATA ELEMENT NAME: State

DATA DEFINITION: State postal abbreviation.

SPECIFICATIONS: Alpha values, 2 position field; no blanks

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DATA ELEMENT NAME: Invoice Number

DATA DEFINITION: Invoice identification number. Use the
                    invoice number for state unit changes
                    currently submitted, or the most recent
                    invoice number for the quarter you are
                    initiating PPAs or adjusting prior disputed
                    units. If invoice contains no identification
                    number, this field is left blank.

SPECIFICATIONS: Alpha-numeric values, 10 position field,
                    right justified, blank filled.

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DATA ELEMENT NAME: Date

DATA DEFINITION: Date this report was created (not mailed).

SPECIFICATIONS: Numeric values only, 8 position field;
                    no blanks.

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DATA ELEMENT NAME: Product/Package Code (Column A)

DATA DEFINITION: Second and Third segments of National Drug
                    Code.

SPECIFICATIONS: Alpha-numeric values, 6 position field, right
                    justified, zero filled; no blanks.

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DATA ELEMENT NAME: Product Name (Column B)

DATA DEFINITION: First 10 positions of product name as it
                    appears on the FDA listing form.

SPECIFICATIONS: Alpha-numeric values, 10 positions, left
                    justified; blank filled.

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DATA ELEMENT NAME: Original Rebate Per Unit (Column C)

DATA DEFINITION: The rebate per unit reported on the <u>original</u>
                    invoice for the quarter involved. This will
                    never change, even if it is "zero."

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers
                    and 6 decimals, right justified. Calculate
                    to five decimals and round to four, pad
                    positions 5 & 6 with zeros. IF NOT AVAILABLE
                    ON THE STATE INVOICE, this field is zero
                    filled; <u>no blanks</u>.

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DATA ELEMENT NAME: Current Rebate Per Unit (Column D)

DATA DEFINITION: The <u>most recent</u> calculated rebate per unit.
                    (The Adjustment Code field must be annotated
                    if this number is different from the Original
                    Rebate Per Unit.)

SPECIFICATIONS: Numeric values, 11 positions: 5 whole numbers
                    and 6 decimals, right justified. Calculate
                    to five decimals and round to four, pad
                    positions 5 & 6 with zeros; blank filled, if
                    not applicable.

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DATA ELEMENT NAME: Original Units Invoiced (Column E)

DATA DEFINITION: This element <u>will always be</u> the number of
                    units first reported for the quarter
                    involved. This number never changes.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                    and 3 decimals, right justified, <u>no blanks</u>.

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DATA ELEMENT NAME: Current Units To Date (Column F)

DATA DEFINITION: The most recent number of units reported by
                    the state or agreed upon under one of the
                    circumstances below. This number can be
                    more, less, or the same as the original, and
                    can change from time to time, <u>but always
                    enter the most recent</u>.

                    Unit adjustments agreed upon subsequent to
                    state invoicing may be the result of the
                    following:

                    1.   Contact with the state.

                    2.   The labeler and the state regard the
                          adjustments as routine. For example,
                          decimal rounding or unit of measure
                          conversions. Under this circumstance, no
                          contact is necessary.

                    3.   An obvious non-routine error exists and
                          the state has not responded to the
                          labeler's contact attempts.

                    <u>**The Adjustment Code field is annotated if the
                    units entered are different from the Original
                    Units Invoiced (Column E) or those currently
                    invoiced for the quarter involved**</u>.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                    and 3 decimals, right justified, <u>no blanks</u>.

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MEDICAID DRUG REBATE
PRIOR QUARTER ADJUSTMENT STATEMENT
(Form CMS-304a)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Prior Units Paid (Column G)

DATA DEFINITION: The total units paid for this NDC up to, <u>but not including</u>, the date of this report.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; <u>no blanks</u>.

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DATA ELEMENT NAME: Current Units Paid To Date (Column H)

DATA DEFINITION: The total units paid for this NDC, <u>including those paid with this report</u>. This can be more, less, or the same as the Prior Units Paid (Column G).

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; <u>no blanks</u>.

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DATA ELEMENT NAME: Prior Units Disputed (Column I)

DATA DEFINITION: The total units disputed for this NDC up to, <u>but not including</u>, the date of this report.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; <u>no blanks</u>.

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DATA ELEMENT NAME: Current Units Disputed To Date (Column J)

DATA DEFINITION: The total units disputed for this NDC, <u>including those disputed with this report</u>. This can be more, less, or the same as the Prior Units Disputed (Column I).

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; <u>no blanks</u>.

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DATA ELEMENT NAME: Original Amount Invoiced (Column K)

DATA DEFINITION: The number of ORIGINAL UNITS INVOICED
                     (Column E) times the ORIGINAL REBATE PER UNIT
                     (Column C). This number never changes, even
                     if it is "zero."

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

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DATA ELEMENT NAME: Revised Invoice Amount (Column L)

DATA DEFINITION: The number of Current Units To Date
                     (Column F) times the Current Rebate Per Unit
                     (Column D). This can be more, less, or the
                     same as the Original Amount Invoiced
                     (Column K).

PECIFICATIONS: Numeric values, 9 positions: 7 whole
                     numbers and 2 decimals, right justified, zero
                     filled, no blanks.

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DATA ELEMENT NAME: Prior Amount Paid (Column M)

DATA DEFINITION: The amount paid for this NDC up to, but not
                     including, the date of this report.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
                     and 2 decimals, right justified, zero filled,
                     no blanks.

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DATA ELEMENT NAME: Current Amount Paid To Date (Column N)

DATA DEFINITION: The amount paid to date for this NDC,
                    including any amount paid with this report.
                    This can be more, less, or the same as the
                    Prior Amount Paid (Column M), and is the sum
                    of Current Units Paid To Date (Column H)
                    times the Current Rebate Per Unit (Column D).

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
                    and 2 decimals, right justified, zero filled,
                    no blanks.

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DATA ELEMENT NAME: Amount Paid This Transaction (Column O)

DATA DEFINITION: The amount from Column N less the amount from
                    Column M (Current Amount Paid To Date minus
                    Prior Amount Paid). This amount can be a
                    positive or negative number.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers
                    and 2 decimals, right justified, zero filled,
                    no blanks.

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DATA ELEMENT NAME: Adjustment Code(s) (Column P)

DATA DEFINITION: Reason(s) labeler has:

                    1.   Entered a Current Rebate Per Unit that
                         differs from the Original Rebate Per
                         Unit,
                                   AND/OR

                    2.   Has entered a Current Units To Date
                         number that differs from the number of
                         units currently invoiced for the quarter
                         involved.

SPECIFICATIONS: Alpha values only, 3 positions.
                    Valid values: Refer to CMS-304a, Appendix C
                    Maximum: 3 Adjustment Codes per NDC

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DATA ELEMENT NAME: Dispute Code(s) (Column Q)

DATA DEFINITION: Reason(s) labeler is:

1.   Disputing any original units or current
     units invoiced for the quarter involved,

AND/OR

2.   Disputing the difference, or any part
     thereof, of the remaining units after
     adjustment.

SPECIFICATIONS: Alpha values only, 3 positions.
                    Valid values: Refer to CMS-304a, Appendix C
                    Maximum: 3 Dispute Codes per NDC

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DATA ELEMENT NAME: Total Original Units Invoiced

DATA DEFINITION: Total units in Column E for <u>ALL NDCs</u>.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                    and 3 decimals, right justified, no blanks.

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DATA ELEMENT NAME: Total Current Units To Date

DATA DEFINITION: Total units in Column F for <u>ALL</u> NDCs.

SPECIFICATIONS: Numeric values, 12 positions, 9 whole numbers
                    and 3 decimals, right justified, <u>no blanks</u>.

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DATA ELEMENT NAME: Total Prior Units Paid

DATA DEFINITION: Total units in Column G for <u>ALL</u> NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                    and 3 decimals, right justified, zero filled,
                    <u>no blanks</u>.
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DATA ELEMENT NAME: Total Current Units Paid To Date

DATA DEFINITION: Total units in Column H for <u>ALL</u> NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole
                    numbers and 3 decimals, right justified, zero
                    filled; <u>no blanks</u>.

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DATA ELEMENT NAME: Total Prior Units Disputed

DATA DEFINITION: Total units in Column I for <u>ALL</u> NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                    and 3 decimals, right justified, zero filled,
                    <u>no blanks</u>.

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DATA ELEMENT NAME: Total Current Units Disputed To Date

DATA DEFINITION: Total units in Column J for <u>ALL</u> NDCs.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers
                    and 3 decimals, right justified, zero filled,
                    <u>no blanks</u>.

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DATA ELEMENT NAME: Total Original Amount Invoiced

DATA DEFINITION: Total amount in Column K for <u>ALL</u> NDCs.

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

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DATA ELEMENT NAME: Total Revised Invoice Amount

DATA DEFINITION: Total amount in Column L for <u>ALL</u> NDCs.

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

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DATA ELEMENT NAME: Total Prior Amount Paid

DATA DEFINITION: Total amount in Column M for <u>ALL</u> NDCs.

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

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DATA ELEMENT NAME: Total Current Amount Paid To Date

DATA DEFINITION: Total amount in Column N for <u>ALL</u> NDCs.

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

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DATA ELEMENT NAME: Total Amount Paid This Transaction

DATA DEFINITION: Total amount in Column O for <u>ALL</u> NDCs.

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

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DATA ELEMENT NAME: Plus Interest Payment

DATA DEFINITION: Total amount of interest the labeler is
                    remitting.

SPECIFICATIONS: Numeric values, 8 positions: 6 whole numbers
                    and 2 decimals, right justified, zero filled,
                    no blanks.

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DATA ELEMENT NAME: Total Remittance

DATA DEFINITION: The Total Amount Paid This Transaction for
                    all NDCs plus any interest payment.

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

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