

**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 must 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 must supply documentation for codes that require it.

## SPECIFIC INSTRUCTIONS

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

1. The PQAS is quarter specific. The labeler must complete a separate PQAS for each prior quarter reconciled.
2. Using the data definitions, enter the required information for each 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 must be provided.
5. Submit the completed PQAS with the payment/credit for all prior quarters.

### Examples for Completing the PQAS

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.

## Disclosure Statement

According to the Paperwork Reduction Act of 1995, no response is required for information collection unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0676. The time required to complete this information collection is estimated to average 37 hours per response, including reviewing instructions, searching existing data sources, gathering needed data, and completing and reviewing the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

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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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LABELER DATA DEFINITIONS

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

DATA DEFINITION: The rebate per unit reported on the original 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; no blanks.

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

DATA DEFINITION: The most recent 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 will always be 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, no blanks.

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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, but always enter the most recent.

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.

**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.**

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

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DATA ELEMENT NAME: Prior Units Paid (Column G)

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

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

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

DATA DEFINITION: The total units paid for this NDC, including those paid with this report. 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; no blanks.

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DATA ELEMENT NAME: Prior Units Disputed (Column I)

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

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

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

DATA DEFINITION: The total units disputed for this NDC, including those disputed with this report. 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; no blanks.

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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 ALL NDCs.

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 ALL NDCs.

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

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DATA ELEMENT NAME: Total Prior Units Paid

DATA DEFINITION: Total units in Column G for ALL NDCs.

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

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DATA ELEMENT NAME: Total Current Units Paid To Date  
DATA DEFINITION: Total units in Column H for ALL NDCs.  
SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled; no blanks.

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DATA ELEMENT NAME: Total Prior Units Disputed  
DATA DEFINITION: Total units in Column I for ALL NDCs.  
SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled, no blanks.

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DATA ELEMENT NAME: Total Current Units Disputed To Date  
DATA DEFINITION: Total units in Column J for ALL NDCs.  
SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified, zero filled, no blanks.

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DATA ELEMENT NAME: Total Original Amount Invoiced  
DATA DEFINITION: Total amount in Column K for ALL NDCs.  
SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers and 2 decimals, right justified, zero filled, no blanks.

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DATA ELEMENT NAME: Total Revised Invoice Amount  
DATA DEFINITION: Total amount in Column L for ALL NDCs.  
SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers  
and 2 decimals, right justified, zero filled,  
no blanks.

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DATA ELEMENT NAME: Total Prior Amount Paid  
DATA DEFINITION: Total amount in Column M for ALL NDCs.  
SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers  
and 2 decimals, right justified, zero filled,  
no blanks.

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DATA ELEMENT NAME: Total Current Amount Paid To Date  
DATA DEFINITION: Total amount in Column N for ALL NDCs.  
SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers  
and 2 decimals, right justified, zero filled,  
no blanks.

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DATA ELEMENT NAME: Total Amount Paid This Transaction  
DATA DEFINITION: Total amount in Column O for ALL NDCs.  
SPECIFICATIONS: Numeric values, 10 positions: 8 whole numbers  
and 2 decimals, right justified, zero filled,  
no blanks.

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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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