

**MEDICAID DRUG REBATE
LABELER INSTRUCTIONS
for
RECONCILIATION OF STATE INVOICE
(FORM CMS-304)**

The Medicaid drug rebate Reconciliation of State Invoice (ROSI) is mandated for use by labelers to uniformly explain the adjusted rebate payments to states for the current quarter. The ROSI **MUST** accompany rebate payments made to states **if**:

1. The labeler is NOT paying the full rebate amount due for the current quarter, i.e., the labeler is disputing any units invoiced; or
2. The state invoice contains zeros (0s) in the RPU field due to the labeler's lack of data submittal, **AND** the labeler is remitting the full rebate amount due for the current quarter.

The ROSI is **not required**:

1. **If** the state invoice RPU field contains zeros (0s) but the CMS tape contains an RPU value, **AND** the labeler is remitting the full rebate amount due for the current quarter. Labelers **MUST** return a copy of the state's invoice with the rebate payment and may optionally pen/ink the RPU field on the invoice copy.
2. **If** the state invoice RPU field contains zeros (0s) due to CMS data edits, **AND** the labeler is remitting the full rebate amount due for the current quarter. Labelers **MUST** make pen/ink changes to the RPU on a copy of the state's invoice and return it with the full remittance.
3. **If** there are no zero (0) RPU amounts on the state's invoice, **AND** the labeler is remitting the full rebate amount due for the current quarter. Labelers **MUST** return a copy of the state's invoice with the rebate payment.

☛**NOTE:** Labelers may choose to complete and submit the ROSI each quarter regardless of the exceptions listed above.

The labeler's response (the ROSI or invoice copy) **MUST** be submitted within

30 days of receiving the state's current quarter invoice.

The labeler may complete and submit the ROSI in one of two media, paper or electronic, depending on the labeler's capabilities. Labelers may develop an automated system for the ROSI using the electronic field size listing attached as Appendix A. Labelers must submit the ROSI 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 ROSI. Please refer to these definitions for a complete explanation of the column headings whether completing the ROSI via paper or when developing an electronic medium.

Appendix C, Adjustment and Dispute Codes, lists the codes labelers may enter to explain any adjustments and/or disputes. The codes are comprehensive and accommodate any adjustment or dispute. (This list serves both current and prior quarter reporting (See form CMS-304a).) 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 ROSI is used for response to states' **CURRENT QUARTER UTILIZATION DATA ONLY**. (A separate form CMS-304a, the PQAS, has been developed for labelers to reconcile state utilization changes for prior quarters, prior disputed units, and PPAs.)

1. The ROSI is quarter and invoice specific. Therefore, only current quarter data is reported on this form.
2. Using the data definitions, enter the required information for **each** NDC reported on the state invoice. Each column is "lettered" for ease of reference.
3. Enter grand totals for columns E through H, and K through N. The grand total for column N for all NDCs listed, plus any interest being paid, should equal the remittance to the state.

However, **IF** a labeler completes and submits a PQAS simultaneously with the ROSI, the amount of the remittance should equal the Total Remittance as shown on the ROSI plus or minus the Total Remittance indicated on the PQAS.

4. Submit the ROSI with the rebate payment to the state.

Examples for Completing the ROSI

Appendix D to these instructions is a condensed ROSI sample showing column entries for four examples. The examples reflect situations such as adjusting the RPU, adjusting the invoiced units, and disputing units.

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 the 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, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
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 the current 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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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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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 Code

DATA DEFINITION: State postal abbreviation.

SPECIFICATIONS: Alpha values, 2 position field; no blanks.

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MEDICAID DRUG REBATE
ECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Invoice Number
DATA DEFINITION: Invoice identification number. 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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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Rebate Per Unit (Column C)

DATA DEFINITION: CMS-calculated rebate per unit as shown on the state invoice.

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 will be zero filled; no blanks.

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

DATA DEFINITION: Rebate per unit **IF** different than the amount entered in the Rebate Per Unit field. (The Adjustment Code field must be annotated.)

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: Units Invoiced (Column E)

DATA DEFINITION: This element will always be the state-calculated number of units reimbursed as shown on the invoice.

Please note that, upon completion of the ROSI, this element also acts as a compilation of the three elements which follow it (Adjusted Units, Labeler Disputed Units, and Units Paid).

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

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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Adjusted Units (+ or -) (Column F)

DATA DEFINITION: The number of units adjusted preceded by + or -, as a result of one of the following:

1. The actual Units Invoiced is adjusted through contact with the state prior to claims processing. (For example, if the actual Units Invoiced is 100,000 but the state agrees with the labeler that the figure should be 10,000 the Adjusted Units will be -90,000.)
2. The state permits the labeler to make routine adjustments to actual Units Invoiced, such as decimal rounding, or unit of measure conversions. Under this circumstance, no contact is necessary prior to claims processing.
3. The labeler adjusts actual Units Invoiced because an obvious non-routine error exists and the state has not responded to the labeler's contact.

The Adjustment Code field must be annotated if Adjusted Units are indicated for any NDCs.

SPECIFICATIONS: Numeric values, preceded by a + or - sign, 13 positions: 9 whole numbers and 3 decimals, right justified, blank filled if not applicable.

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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Labeler Disputed Units (Column G)
DATA DEFINITION: The number of Invoiced Units being
disputed,
OR
The number of the remaining units being
disputed after an adjustment has been
made.
SPECIFICATIONS: Numeric values, 12 positions: 9 whole
numbers and 3 decimals, right justified,
zero filled; no blanks.

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DATA ELEMENT NAME: Units Paid (Column H)
DATA DEFINITION: Labeler-calculated number of units paid.
This is calculated as follows:
+ or - Units Invoiced
- Adjusted Units
- Labeler Disputed Units
SPECIFICATIONS: Numeric values, 12 positions: 9 whole
numbers and 3 decimals, right justified,
zero filled; no blanks.

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DATA ELEMENT NAME: Adjustment Code(s) (Column I)
DATA DEFINITION: Reason(s) labeler has adjusted the rebate
per unit or the units invoiced.
SPECIFICATIONS: Alpha values only, 3 positions.
Valid values: Refer to Form
CMS-304, Appendix C
Maximum: 3 Adjustment Codes per NDC

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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Dispute Code(s) (Column J)
DATA DEFINITION: Reason(s) labeler is disputing any Units Invoiced.
SPECIFICATIONS: Alpha values only, 3 positions.
Valid values: Refer to Form CMS-304, Appendix C
Maximum: 3 Dispute Codes per NDC

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DATA ELEMENT NAME: Rebate Amount Invoiced (Column K)
DATA DEFINITION: State-calculated rebate amount as shown on the invoice.
SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified. If not available, this field will be zero filled; no blanks.

Please note that, upon completion of the ROSI, this element also acts as a compilation of the three elements which follow it (Invoice Correction Amount, Withheld Invoice Amount, and Rebate Amount Paid).

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DATA ELEMENT NAME: Invoice Correction Amount(+or-)(Column L)
DATA DEFINITION: Labeler-corrected invoice amount (+ or -) based on any Adjusted Units and/or the Rebate Per Unit or the Adjusted Rebate Per Unit.
SPECIFICATIONS: Numeric values, preceded by a + or - sign, 10 positions: 7 whole numbers and 2 decimals, right justified. If not applicable, this field will be zero filled; no blanks, unless the ROSI is manually completed.

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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Withheld Invoice Amount (Column M)

DATA DEFINITION: Portion of Rebate Amount Invoiced being withheld,
OR,
The portion being withheld of the remaining Rebate Amount Invoiced after correction.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified. If not applicable, this field will be zero filled; no blanks, unless the ROSI is manually completed.

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ATA ELEMENT NAME: Rebate Amount Paid (Column N)

DATA DEFINITION: Per NDC remittance for current quarter. This amount is calculated as follows:

Rebate Amount Invoiced
+ or - Invoice Correction Amount
- Withheld Invoice Amount

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

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DATA ELEMENT NAME: Total Units Invoiced

DATA DEFINITION: Total number of units invoiced for all NDCs.

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

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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Total Adjusted Units (+ or -)
DATA DEFINITION: Total number of Adjusted Units for all NDCs
(+ or -).
SPECIFICATIONS: Numeric values, preceded by a + or - sign,
13 positions, 9 whole numbers and
3 decimals, right justified, zero filled;
no blanks.

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DATA ELEMENT NAME: Total Labeler Disputed Units
DATA DEFINITION: Total number of disputed units 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 Units Paid
DATA DEFINITION: Total number of units paid 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 Rebate Amount Invoiced
DATA DEFINITION: Total rebate amount invoiced by the state
for all NDCs.
SPECIFICATIONS: Numeric values, 10 positions: 8 whole
numbers and 2 decimals, right justified,
zero filled; no blanks.

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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

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DATA ELEMENT NAME: Total Invoice Correction Amount (+ or -)
DATA DEFINITION: The total Invoice Correction Amount for all
NDCs (+ or -).
SPECIFICATIONS: Numeric values, preceded by a + or - sign,
11 positions: 8 whole numbers and
2 decimals, right justified, zero filled;
no blanks.

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DATA ELEMENT NAME: Total Withheld Invoice Amount
DATA DEFINITION: Total amount the labeler is withholding 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 Rebate Amount Paid
DATA DEFINITION: Total rebate amount the labeler is
remitting for all NDCs for current quarter.
SPECIFICATIONS: Numeric values, 10 positions: 8 whole
numbers and 2 decimals, right justified,
zero filled; no blanks.

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MEDICAID DRUG REBATE
RECONCILIATION OF STATE INVOICE
(Form CMS-304)
LABELER DATA DEFINITIONS

PAGE 11 OF 11

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DATA ELEMENT NAME: Plus Interest Payment

DATA DEFINITION: Total amount of any 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 Rebate Amount Paid 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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