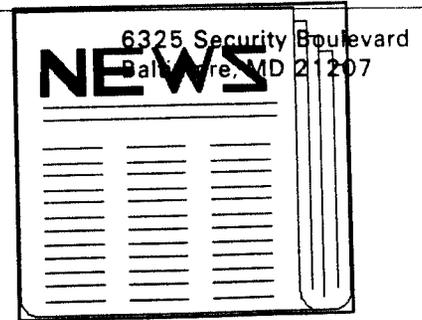




APR 29 1993



MEDICAID DRUG REBATE PROGRAM Release No. 7

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

50% REBATE CAP - TECHNICAL AMENDMENT PASSED

In Release Number 6 to manufacturers, we notified you that a strict legal reading of section 601(c) of the Veterans Health Care Act of 1992 (VHCA) removed the 50-percent rebate cap of average manufacturer price (AMP) for the October 1, 1992 - December 31, 1992 quarter. However, based on requests from Congressional members, we implemented the Medicaid provisions of the VHCA as though the 50-percent cap remained in effect for this quarter pending a technical correction.

On April 12, 1993, the Veterans Health Care Act of 1992-- Technical Corrections, (Pub. Law 103-18), was signed into law. Section 2(a) of Pub. Law 103-18 amended section 601(c) of VHCA to restore the 50 percent cap for that quarter. This amendment is effective as if it were included in the enactment of section 601(c) of the VHCA. Thus, section 1927(c)(1)(B)(ii)(II) of the Social Security Act has been amended to provide that for the quarter beginning after September 30, 1992 and before January 1, 1993, the amount of the rebate may not exceed 50 percent of the AMP. For all quarters beginning after December 31, 1992, the cap is removed.

MINIMUM REBATE PERCENTAGES MANDATED BY THE VETERANS HEALTH CARE ACT (VHCA) OF 1992 (P.L. 102-585)

Per section 601(c) of the VHCA, the following minimum percentages are to be used when computing the unit rebate amount for single source and innovator multiple source drugs:

<u>PERIOD</u>	<u>PERCENTAGE</u>
10/01/92 - 12/31/93	15.7 *
01/01/94 - 12/31/94	15.4
01/01/95 - 12/31/95	15.2
01/01/96 forward	15.1

* FOR THE QUARTER 10/01/92 THROUGH 12/31/92, THE AMP CAP OF 50% IS IN EFFECT. EFFECTIVE 01/01/93, THERE IS NO CAP USED IN THE CALCULATION.

The rebate percentages for non-innovator multiple source drugs remain 10 percent through 12/31/93 and 11 percent beginning 01/01/94.

AVERAGE MANUFACTURER PRICES (AMPs) FOR TERMINATED DRUGS

There continues to be confusion regarding the difference between what AMP to report for four quarters beyond shelf life for a terminated, specific package size of a drug, as opposed to an entire product line of a drug.

Terminated Product: When you stop selling a product, please use the calculated AMP based on sales for the last quarter you had sales. This AMP is submitted to HCFA, quarter by quarter for all package sizes, until four quarters beyond shelf life have elapsed.

Terminated Package Size: In the case where only a specific package size of a product is terminated, but other package sizes continue to be active, please use the AMP of the active package sizes as the AMP for the terminated package size until four calendar quarters beyond shelf life for that package size have elapsed. At that point, you may stop reporting that package size. Any deviation from this procedure is incorrect and may result in different AMPs for different package sizes of the same drug product.

CALCULATING AMP AND BEST PRICE (BP) FOR DIFFERENT QUARTERS

In a discussion with personnel at a drug company, we were consulted about calculating the correct AMP and BP when sales are limited.

Situation: This example involves a single source drug only sold during the first quarter of the year. For the remainder of the year, there are no recorded sales. During the first quarter of the next year, the only sale for the drug is a special sale to an HMO on a one-time basis only.

Background: The drug rebate agreement states that "Best Price means....., the lowest price,..... in the same quarter for which the AMP is computed." Does this mean that the Best Price continues to be the one from last year or should it be the new Best Price?

For the second, third and fourth quarters of the first year, the AMP and BP from the first quarter are used. Because of the special sale during the first quarter of the next year, the BP is calculated from that quarter (and reflects the special lower price given to the HMO). The AMP is not changed since the sale is to a non-retail entity.

Solution: The BP should be changed to reflect the New Best Price even though the AMP is still the one from the first quarter of last year. The reasoning behind this decision is that the AMP is calculated EACH QUARTER without regard to the fact that circumstances may cause it to revert back to a previous quarter for Unit Rebate Amount calculations (as in this example). Thus, manufacturers must report AMP and BP data, if applicable, each quarter regardless of whether there are no changes from the previous quarter.

BEST PRICE EXCLUSIONS

In our Release Number 6 to manufacturers, we noted that effective October 1, 1992, you must exclude from the best price calculation any prices charged to Public Health Service (PHS) covered entities listed under section 340B(a)(4) of the PHS Act. Several manufacturers have questioned if they can exclude from best price all drug prices charged to those disproportionate share hospitals (DSHs) that qualify as a covered entity under 340B(a)(4)(L). Manufacturers may only exclude from their best price calculation those prices charged for outpatient drugs sold to a DSH covered entity. All prices charged for inpatient drugs sold to a DSH must be included in a manufacturer's best price calculation.

Manufacturers have raised concerns that they may not be able to identify if discounted outpatient drugs are used in the inpatient portion of the DSH which does not qualify for the mandated discount. On March 9, 1993, the PHS sent a letter to its covered entities containing guidelines explaining how the program works and the responsibilities of covered entities. In that PHS letter under section IV, Drug Diversion and Entity Guidelines, PHS states the following:

Covered entities are required not to resell or otherwise transfer an outpatient drug purchased at the statutory price to an individual who is not a patient of the entity. If the entity fills prescriptions for individuals, other than patients of the covered entity, the entity must develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to facilities that are not eligible for the discount.

Further, covered entities must only utilize the discounted outpatient drugs in the eligible outpatient clinics and not in other clinics that may be only housed within a larger entity. Section 340B(a)(6) of the PHS Act recognized that a covered entity may be part of a larger facility and states that the larger facility will not be considered eligible for the discounted drug prices unless it is listed as a covered entity.

Thus, a DSH covered entity must have in place separate inventories for its inpatient and outpatient drugs and may not transfer its outpatient drugs purchased at a discount to the inpatient portion of the hospital. Therefore, for purposes of the Medicaid rebate program, these prices for outpatient drugs would be excluded in their entirety.

DATA REPORTING REQUIREMENTS

We are reminding all labelers that quarterly pricing data must be submitted by labelers and received by HCFA within 30 days after the end of each quarter. Some manufacturers have failed to comply with this requirement, and in some cases, action has been taken against them.

We are taking this opportunity to cite section 1927(b)(3)(C)(i) of the Social Security Act (the Act) regarding HCFA's authority to impose penalties in these cases.

(C) PENALTIES.-

(i) FAILURE TO PROVIDE TIMELY INFORMATION.-

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) [that is, pricing information to HCFA] on a timely basis, the amount of the penalty shall be increased by \$10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the date of such 90-day period and until such information is reported (but in no case shall such suspension be for a period of less than 30 days).

Additionally, section 1927(b)(4)(B)(i) of the Act provides HCFA with the authority to terminate a rebate agreement for violations of the agreement or other good cause. Section 1927(b)(4)(B)(iii) of the Act specifies the requirement that there must be a delay for reentry into the agreement of one calendar quarter after termination.

These statutory provisions are incorporated in the rebate agreement at section IV(c) and sections VIII(d) and (e), respectively.

These reminders are intended to strongly encourage compliance with the reporting requirements of the program. While it is not the desire of HCFA to impose penalties on manufacturers, it is a statutory requirement and a contractual obligation to provide the pricing information as specified on a timely basis. Non-compliance with the requirements puts you at risk for possible civil monetary penalties, suspension from the program and/or termination. We request your attention to this issue and ask your cooperation in complying with these requirements.

REMITTANCE ADVICE REPORT

Included with this release is the Remittance Advice Report (RAR) and instructions for its use. We plan on mandating the use of the report by manufacturers in upcoming regulations; however, in response to strong interest shown by some manufacturers and States to begin using the RAR now, we are providing the RAR at this time and encouraging its use by manufacturers when submitting rebate payments and/or disputes to States.

We believe the use of the RAR will be beneficial to both manufacturers and States in identifying rebates paid or disputed, adjustments, and reasons for any disputed or adjusted amounts. Furthermore, since the RAR has not been approved as a mandatory reporting form as of yet, there may be changes to it when it is mandated by regulations in the future. One of the potential changes we are considering is to use the RAR as a turnaround document; that is, States would complete a portion of the RAR and submit it to manufacturers with the rebate invoice and manufacturers would complete the RAR and send it back to States along with any rebate payments.

For now, we are simply encouraging manufacturers to use the RAR as instructed in the attached material. As indicated earlier, it is our intention to require its use after publication of the regulations regarding the Medicaid drug rebate program.

DISKETTE USERS

All diskette users are reminded here that we are now BEYOND all 92-4 data submissions. Based on the information supplied with the version 2 diskette, WE WILL NO LONGER ACCEPT DISKETTES FROM THE OLD (1.1) VERSION. ALL DATA NOW MUST AGREE WITH THE NEW VERSION 2 FORMAT AND CONTENT. ALL DATA FOR PAST, PRESENT OR FUTURE QUARTERS NOT MEETING THE NEW FORMAT REQUIREMENTS WILL BE REJECTED AND RETURNED TO THE SENDER.

CHANGES TO UNIT TYPE FIELD

After considering suggestions from various drug industry organizations, we have agreed to modify the allowable entries in the UNIT TYPE data field to be consistent with the standards used throughout the industry and to closely resemble the standards set by the National Council for Prescription Drug Programs.

These changes will include the addition of "EA," the conversion of "CC" to "ML," the conversion of "MG" to "GM" and the condensing of the remaining allowable entries to "AHF," "CAP," "SUP," "TAB" AND "TDP." With this release, we have included a list of the 8 unit types and explanations of their values.

NOTE: The conversion of milligrams to grams will result in the need to change the AMPs and BPs (for all quarters) for any drug products affected by this change. HCFA will convert milligrams to grams. LABELERS ARE RESPONSIBLE FOR COMPUTING AND SUBMITTING CHANGES TO THE AMP, BP AND UNITS PER PACKAGE SIZE FIELDS.

HCFA WILL SEND A LISTING OF CONVERTED UNIT TYPES, AMPs AND BPs TO ANY LABELER AFFECTED BY THIS CHANGE. THE LABELER WILL HAVE 30 DAYS TO NOTIFY HCFA OF CHANGES AND ANY CORRECTIONS THAT ARE NEEDED.

POLICY CLARIFICATION FOR THE CALCULATION OF INTEREST UNDER SECTION V(b) OF THE REBATE AGREEMENT

The following is an overview of the interest provisions of the Medicaid Drug Rebate program. For purposes of section V(b) of the rebate agreement, the interest rate as specified in section 1903(d)(5) of the Act is used. The interest rate is based on the yield of the weekly 90-day Treasury bill auction rates. The investment yield is considered the bond equivalent rate or the true discount rate.

Auctions of 90-day Treasury bills are generally held each Monday. If Monday is a holiday, the Treasury Department decides whether to hold the auction on the preceding Friday or the following Tuesday. Information on the rates will be provided by HCFA to the manufacturers and State Medicaid Agencies periodically in the State Medicaid Director/Manufacturer letters to assure both parties are using the same interest rates in their calculations.

Interest is applied to disputed or unpaid amounts and late rebate payments but not to prior period adjustments of unit rebate amounts or State utilization adjustments. Interest will begin accruing on disputed or unpaid amounts 38 calendar days from the date the State mails the State utilization data, as evidenced by the postmark by the United States Postal Service or other common mail carrier on the envelope (not a postage meter stamp). Note that this is a revision to the policy described in our Release Number 15 to States. In that release, we specified that interest on unpaid amounts accrues beginning on the 31st day after the manufacturer receives utilization data from a State. We are now including 7 additional days to allow time for receipt by the manufacturer of the mailing.

This revised policy allows sufficient time for the mailing and receipt of the State utilization data while reducing costs previously associated with return receipt requests. For documentation purposes, States must maintain a record of the date of mailing and manufacturers must maintain the envelope bearing the postmark from the State.

Interest accrues on the disputed portion of the rebate amount or on the total amount of the late rebate payment for all quarters beginning January 1, 1991 and only stops accruing on the date the check is disbursed. We consider the date of disbursement to be the date the check is mailed by the manufacturer. Interest must be collected and may not be disregarded as part of the dispute resolution process by the State or manufacturer.

The interest calculation is based on a 365-day year with simple interest applied to the average of the yield of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged. (For purposes of this calculation, include the rate for the entire week if the beginning and/or ending date fall within that week.) To calculate the interest rate to be applied to disputed rebate amounts, use the following formula:

1. Total the yield of each weekly auction of 90-day Treasury bills during the period for which interest will be charged.
2. Divide the total from Step 1 by the number of rates to determine the average interest rate.

3. Multiply the average interest rate from Step 2 by the unpaid rebate amount that is outstanding to obtain the amount of interest due.
4. Divide the amount of interest due from Step 3 by 365 days to obtain the daily amount of interest due.
5. Multiply the daily amount of interest due from Step 4 by the number of days that the unpaid rebate amount is outstanding to obtain the total interest due. Interest is applied to disputed or unpaid amounts and late rebate payments but not to prior period adjustments of unit rebate amounts or State utilization adjustments. The first day of interest starts on the 38th day after the State mails the State utilization data to the labeler(s), as evidenced by the postmark.

Example:

The State sends a manufacturer utilization data postmarked 01/25/93, resulting in rebates due totalling \$5,400 for the 4th quarter of 1992. Within 30 days after receipt of the data, the manufacturer pays \$4,400 of that amount and disputes the remaining \$1,000. Interest starts accruing on 3/4/93, which is the 38th day after the State mailed the data. Subsequently, the manufacturer decides that the State data are correct and pays the remaining \$1,000 by check mailed on 4/2/93. In this example, interest is accrued for the period 3/4/93 through 4/1/93. The check from the manufacturer must include the principal of \$1,000 plus interest calculated as follows:

Obtain yield rates (bond equivalent rates) for period involved:

AUCTION DATES AND YIELD RATES	
3/01/93	3.035%
3/08/93	3.043%
3/15/93	3.064%
3/22/93	3.003%
3/29/93	3.022%

- Step 1. Total the yield rates of each weekly auction of 90-day Treasury Bill.
Total: 15.167%
- Step 2. Divide the total from Step 1 by the number of rates to determine the average interest rate.
15.167% divided by 5 = 3.0334% Average Interest Rate.

- Step 3. Multiply average interest rate by amount of unpaid rebate. $\$1,000 \times 3.0334\% = \30.33 Amount of Interest Due.
- Step 4. Divide the amount of interest due by 365 days to obtain the amount of interest due per day. $\$30.33$ divided by 365 days = $\$.08309$ = Amount of Interest Due Per Day.
- Step 5. Multiply daily amount of interest due per day by the number of days the unpaid rebate amount is outstanding. $\$.08309 \times 29$ days (3/4/93-4/1/93) = $\$2.41$ Total Interest Due

THEREFORE, THE AMOUNT OF THE CHECK SHOULD BE \$1,002.41.

To reiterate, when a manufacturer pays the State for disputed rebate amounts or late rebate payments, the manufacturer must also pay all interest due. If a manufacturer fails to reimburse the State for the interest due, the interest calculations described above will apply to the unpaid balance. The unpaid interest will be treated as principal due, and interest will begin accruing as of the date the manufacturer paid the original disputed invoice amount. Interest will continue accruing on the unpaid balance of the principal for all quarters and stop accruing the date the check is mailed by the manufacturer.

DESI CODES

We are beginning to receive incorrect DESI Code values from certain drug labelers who have not corrected their data records. In our Manufacturer Letter Number 4 dated February 26, 1992, we advised you of the new DESI code values and elimination of the 0/1 values. Also, one labeler just submitted with its quarterly pricing data, product corrections to change the DESI code back to a 5 for all of its NDCs identifying dipyrindamole even though that drug is considered safe and effective based on a Department of Health and Human Services appeal board decision.

PLEASE ENSURE THAT YOU MAINTAIN CORRECT DESI CODE VALUES FOR YOUR NDCs. INCORRECT CODES CAN CAUSE YOUR DRUGS TO BE LISTED AS LESS THAN EFFECTIVE AND MAY RESULT IN LOST REVENUES FOR YOUR COMPANY.

Please continue to refer your questions to us by calling the drug rebate hotline at (410) 966-3249.


Rozann Abato
Acting Director
Medicaid Bureau

Attachments: 2

cc: Regional Administrators, HCFA

PROPOSED REVISED UNIT TYPES

AHF	Refers only to Anti-Hemophilic Factor injectables
CAP	Refers to all drugs dispensed in capsule form
EA	Refers to various drugs not identifiable by another unit type, such as powder-filled vials, powder-filled ampules, powder-filled packets, and kits containing two or more different items dispensed under one NDC and sold at a single price
GM	Refers to drugs measured in grams, such as ointments, gels, and inhalers, aerosols and topical drugs primarily labeled with gram measurements
ML	Refers to drugs measured in milliliters, such as liquid-filled vials, liquid-filled ampules, pre-filled syringes, all liquid ophthalmic products, reconstitutable ophthalmic drugs, reconstitutable oral drugs, and inhalers, aerosols and topical drugs primarily labeled with milliliter measurements
SUP	Refers to all suppositories, whether dispensed individually or in dosage packets
TAB	Refers to all drugs dispensed in tablet form, including oral contraceptives
TDP	Refers to all transdermal patches

MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER INSTRUCTIONS

The Medicaid Drug Rebate Remittance Advice Report (RAR) is the mandatory form that has been 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 from the State information on the number of units paid, by NDC number. The RAR is available in two media, paper and electronic, depending on the needs of the user. The electronic format consists of three records (Header, Invoice and Totals) in ASCII format which may be incorporated into a PC database. These instructions are provided as an aid in developing the data contained in the report.

Note: It is advisable for manufacturers to remit paper reports unless an electronic medium is specifically requested by a State. For those manufacturers preparing electronic reports, the computer generated output can be substituted for the paper RAR as long as it is the proper format and all data fields are present.

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
6. Contact Name
7. Phone Number
8. Phone Extension (if applicable)
9. Fax Number (if applicable)

II. For every NDC:

1. Product Code
2. Package Size Code
3. Product Name
4. Rebate Amount Per Unit
5. Units Invoiced
6. Rebate Amount Invoiced (if available)
7. Rebate Amount Paid

III. For every NDC where an adjustment has occurred:

1. All data from II above
2. Adjusted Rebate Per Unit
3. Units Adjusted (if applicable)
4. Adjustment Code(s)
5. Credit/Debit Indicator
6. Invoice Adjustment Amount

IV. For every NDC where a dispute has occurred:

1. All data from II above
2. Units Disputed (if applicable)
3. Dispute Code(s)
4. Withheld Invoice Amount

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

INSTRUCTION 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. These data are to be sorted in ascending order by NDC.
3. Provide grand totals for the 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 a separate report for each quarter. 
2. Transmit one Header Record for each labeler code.
3. Transmit one Invoice Record for each NDC submitted on the State invoice for the quarter. These data are to be sorted in ascending order by NDC.
4. Transmit one Totals Record for each labeler code.
5. Transmit a Remittance Advice Report for all rebate payments made to a State.

INSTRUCTIONS FOR PREPARING PRIOR PERIOD ADJUSTMENTS (PPA):

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 actual amounts for the quarter being adjusted, not the current quarter.
3. Provide the Adjusted Rebate Per Unit (if applicable) for the NDCs being adjusted.
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.
 D - Manufacturer has underpaid.
6. Provide the Invoice Adjustment Amount for each NDC.
7. Calculate the Total Invoice Adjustment Amount for all NDCs.
 - a. Add together all credits.
 - b. Add together all debits.
 - c. If the total credit is greater than the total debit, subtract the total debit from the total credit. The result is the Invoice Adjustment Amount that the manufacturer has overpaid for a prior quarter. Enter a "C" in the Total Credit/Debit Indicator.
 - d. If the total debit is greater than the total credit, subtract the total credit from the total debit. The result is the Invoice Adjustment Amount that the manufacturer has underpaid for a prior quarter. Enter a "D" in the Total Credit/Debit Indicator.
8. If it is determined that the Total Invoice Adjustment Amount is an overpayment by the manufacturer, the amount may be subtracted from the Rebate Amount Paid for the current quarter. If the adjustment results in an underpayment, it must be paid to the State by the due date of the next quarterly payment.
9. Submit the PPA report to the State with the adjusted rebate payment. If the adjustment will be applied to the Rebate Amount Paid for the current quarter, the PPA report and the current quarter report must accompany the payment.

INSTRUCTIONS FOR PREPARING ADJUSTMENTS TO A CURRENT QUARTER:

1. Include all information submitted on the State invoice.
2. For adjustments made to the Unit Rebate Amount (URA), enter the correct URA in the column for Adjusted Rebate Per Unit.
3. For adjustments made to the Units Invoiced, enter the number of units affected by the adjustment in the column for Units Paid.

Example: - State has invoiced manufacturer for 100,000 units.
- Manufacturer determines through contact with a State representative that an error was made. The actual number of units is 10,000.
- The Units Paid is 10,000.

4. Enter the appropriate Adjustment Code(s). Up to three codes may be used to explain each adjustment.
5. Calculate the Invoice Adjustment Amount. This will be the difference between the Rebate Amount Invoiced and the amount owed to the State after the adjustment to the URA or Units Invoiced.
6. Use the Credit/Debit Indicator to designate the adjustment action taken.

example: C - Rebate Amount Invoiced is greater than actual amount owed by manufacturer.

D - Rebate Amount Invoiced is less than the actual amount owed by the manufacturer.

Blank - No credit or debit action necessary (e.g., Invoice Amount or Units Invoiced adjusted through contact between manufacturer and State.)

7. If the adjustment is a credit (C above) to the manufacturer, subtract this amount from the Rebate Amount Invoiced and enter the result in the column for Rebate Amount Paid.
8. If the adjustment is a debit (D above) to the manufacturer, add this amount to the Rebate Amount Invoiced and enter the result in the column for Rebate Amount Paid.

MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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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; No blanks.

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DATA ELEMENT NAME: Adjustment Code

DATA DEFINITION: Reason(s) manufacturer has adjusted either
the rebate per unit or the number of units
invoiced. Refer to the Medicaid Drug Rebate
Remittance Advice Report for values.

SPECIFICATIONS: Alpha-numeric, 1 position.
Valid values: 1 through 6.
Maximum: 3 Adjustment Codes per NDC

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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.

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MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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DATA ELEMENT NAME: Contact Name

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.

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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 to manufacturer
(Subtract this amount from the rebate amount originally invoiced.)

D = Debit to manufacturer (Add this amount to the rebate amount originally invoiced.)

Blank = No credit or debit action necessary.

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DATA ELEMENT NAME: Dispute Code

DATA DEFINITION: Reason(s) manufacturer has disputed the invoice submitted by the State. Refer to the Medicaid Drug Rebate Remittance Advice Report for definition of values.

SPECIFICATIONS: Alpha-numeric, 1 position.
Valid values: A through H.
Maximum: 3 Dispute Codes per NDC

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MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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DATA ELEMENT NAME: Extension

DATA DEFINITION: Telephone extension (if any) associated with telephone number of contact person.

SPECIFICATIONS: alpha-numeric values, 4 positions, right justified; blank filled.

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DATA ELEMENT NAME: Fax Number

DATA DEFINITION: Telephone Fax number of contact person.

SPECIFICATIONS: alpha-numeric values, ten positions, area code and phone number.

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DATA ELEMENT NAME: Invoice Adjustment Amount

DATA DEFINITION: Amount resulting from the adjustment to the Rebate Amount Invoiced by the State for the period covered by this report. This will be the difference between the Rebate Amount Invoiced and the Rebate Amount Paid.

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified.

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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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MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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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.

.....

DATA ELEMENT NAME: Package Code

DATA DEFINITION: Third segment of National Drug Code.

SPECIFICATIONS: Alpha-numeric values, 2 position field, right justified, zero filled; no blanks.

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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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MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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DATA ELEMENT NAME: Phone

DATA DEFINITION: Telephone number of contact person.

SPECIFICATIONS: alpha-numeric values, ten positions, area code and phone number.

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DATA ELEMENT NAME: Product Code

DATA DEFINITION: Second segment of National Drug Code.

SPECIFICATIONS: Alpha-numeric values, 4 position field, right justified, zero filled; no blanks.

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DATA ELEMENT NAME: Product Name

DATA DEFINITION: First ten positions of product name as it appears in the product description submitted to HCFA.

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

.....

DATA ELEMENT NAME: Rebate Amount Invoiced

DATA DEFINITION: State-calculated rebate amount invoiced by the State per NDC (State option to submit to manufacturer.)

SPECIFICATIONS: Numeric values, 9 positions: 7 whole numbers and 2 decimals, right justified. If not available, this field will be zero filled; no blanks.

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MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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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: Rebate Amount Per Unit

DATA DEFINITION: HCFA-calculated 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. If not available, this field will be zero filled; no blanks.

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DATA ELEMENT NAME: State

DATA DEFINITION: State postal abbreviation.

SPECIFICATIONS: alpha-numeric values, 2 position field; no blanks.

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MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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DATA ELEMENT NAME: Total Credit/Debit Indicator

DATA DEFINITION: Indicator to determine if the Total Invoice Adjustment Amount is added to or subtracted from the Total Rebate Amount Invoiced.

SPECIFICATIONS: Alpha-numeric, 1 position, blank filled.

Valid values:

C = Credit to manufacturer
(Subtract this amount from the total rebate amount originally invoiced.)

D = Debit to manufacturer (Add this amount to the total rebate amount originally invoiced.)

.....

DATA ELEMENT NAME: Total Invoice Adjustment Amount

DATA DEFINITION: Total amount 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 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 Invoiced

DATA DEFINITION: Total amount of rebate the State invoiced the labeler 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.

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MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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DATA ELEMENT NAME: Total Rebate Amount Paid

DATA DEFINITION: Total amount of rebate the labeler paid to 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.

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DATA ELEMENT NAME: Total Withheld Invoice Amount

DATA DEFINITION: Total amount of this invoice that the labeler is withholding due to disputes with the State.

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

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DATA ELEMENT NAME: Units Adjusted/Disputed (FUTURE CHANGE)

DATA DEFINITION: Number of units invoiced by the State that the manufacturer is adjusting or disputing. These are the units for which the manufacturer is not paying a rebate for the period covered by this report.

SPECIFICATIONS: Numeric values, 12 positions: 9 whole numbers and 3 decimals, right justified.

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MEDICAID DRUG REBATE
REMITTANCE ADVICE REPORT
MANUFACTURER DATA DEFINITIONS

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DATA ELEMENT NAME: Units Invoiced

DATA DEFINITION: The number of units per NDC paid for by the State during the period covered by 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: 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.

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**MEDICAID DRUG REBATE REMITTANCE ADVICE
AUTOMATED REPORTING FORMAT**

HEADER RECORD

FIELD	SIZE	POSITION	REMARKS
RECORD ID	1	1 - 1	CONSTANT OF "1"
PERIOD COVERED	3	2 - 4	QYY
INVOICE NUMBER	10	5 - 14	CORRESPONDS TO STATE INVOICE NUMBER
STATE	2	15 - 16	TWO POSITION POSTAL ABBREVIATION
LABELER CODE	5	17 - 21	NDC #1
COMPANY NAME	25	22 - 46	FIRST 25 POSITIONS OF COMPANY NAME
CONTACT NAME	20	47 - 66	LABELER'S CONTACT PERSON
PHONE	10	67 - 76	AREA CODE AND PHONE NUMBER OF CONTACT
EXTENSION	4	77 - 80	PHONE EXTENSION OF CONTACT OR BLANK
FAX NUMBER	10	81 - 90	FAX NUMBER OF CONTACT OR BLANK

INVOICE RECORD

FIELD	SIZE	POSITION	REMARKS
PRODUCT CODE	4	1 - 4	NDC #2
PACKAGE SIZE CODE	2	5 - 6	NDC #3
PRODUCT NAME	10	7 - 16	FIRST TEN POSITIONS OF PRODUCT NAME
REBATE AMOUNT PER UNIT	11	17 - 27	99999V999999
UNITS INVOICED	12	28 - 39	999999999V999
REBATE AMOUNT INVOICED	9	40 - 48	9999999V99
REBATE AMOUNT PAID	9	49 - 57	9999999V99
ADJUSTED REBATE PER UNIT	9	58 - 66	9999999V99
UNITS PAID	12	67 - 78	999999999V999
ADJUSTMENT CODE	3	79 - 81	SEE LIST OF ADJUSTMENT CODES
CREDIT/DEBIT INDICATOR	1	82 - 82	"C", "D" OR BLANK
INVOICE ADJUSTMENT AMOUNT	11	83 - 93	99999V999999
DISPUTE CODE	3	106 - 108	SEE LIST OF DISPUTE CODES
WITHHELD INVOICE AMOUNT	9	109 - 117	9999999V99

TOTALS RECORD

FIELD	SIZE	POSITION	REMARKS
TOTAL INVOICED	10	1 - 10	TOTAL FOR ALL NDCs 99999999V99
TOTAL PAID	10	11 - 20	TOTAL FOR ALL NDCs 99999999V99
CREDIT/DEBIT INDICATOR	1	21 - 21	"C" OR "D"
TOTAL ADJUSTED	10	22 - 31	TOTAL FOR ALL NDCs 99999999V99
TOTAL WITHHELD	10	32 - 41	TOTAL FOR ALL NDCs 99999999V99

ADJUSTMENT CODES:

1. Rebate amount per unit has been revised by labeler and reported to HCFA.
2. Labeler has calculated rebate where none was provided to State by HCFA.
3. Units invoiced adjusted through correspondence or telephone contact with State Medicaid Agency.
4. Prior period adjustment. Attach supporting documentation.
5. Rebate amount paid adjusted for interest due. Attach supporting documentation.
6. Labeler/State unit discrepancy (e.g., MG vs ML.)

DISPUTE CODES:

- A. Discontinued/Terminated NDC for which the shelf life expired more than one year ago.
- B. Invalid/miscoded NDC.
- C. State units invoiced exceed expected unit sales.
Attach methodology and data source to support this reason.
- D. Utilization/quantity inconsistent with the number of prescriptions.
- E. Utilization/quantity is inconsistent with pharmacy reimbursement levels.
- F. Product not rebate eligible. Give details.
- G. No record of sales in this state. Attach data source.
- H. Other. Attach supporting documentation.