DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

NEWS

FEB 14 1994

MEDICAID DRUG REBATE PROGRAM Release No. 10

*** * * IMMEDIATE ATTENTION REQUIRED * * ***

NOTE TO: All Participating Drug Manufacturers

INVOICE/REMITTANCE ADVICE REPORT SURVEY

For the past 2 years, we have been attempting to design a standardized remittance advice report (RAR) to be used by all drug labelers when they send their rebate checks to the State Medicaid agencies (SMAs). In our quest to develop a usable form, we consulted with State and drug labeler personnel in addition to receiving recommendations from both a special technical group of State representatives and from attendees at two dispute resolution conferences held in Baltimore during 1993.

Currently, all SMAs report their utilization data for purposes of rebate to the drug labelers using a standard invoice record promulgated by Health Care Financing Administration (HCFA) and approved by the Office of Management and Budget. At the time the invoice record was introduced, we also issued standard record specifications for electronic media reporting. To date, only one State (Ohio) and one drug labeler (Glaxo) are utilizing electronic reporting.

Because we received several recommendations to alter both the invoice and the RAR and to consider incorporating both forms into one standard turn-around document, we are soliciting comments from SMAs and drug labelers as to what approach would be favored by them as they process the drug rebate requests and RARs. Attached is a short survey document that is intended to capture your preferences in this area. Copies of both the invoice and the latest draft version of the RAR are included with the survey document. We invite any additional comments you have that you believe are not being addressed by the survey document. We have included a return, pre-addressed, franked envelope to be used in returning your completed survey to us.

WE ASK THAT YOU RETURN THE COMPLETED SURVEY DOCUMENT TO US NO LATER THAN FEBRUARY 28, 1994.

WEEKLY U.S. TREASURY BILL DISCOUNT RATE

Attached is the latest listing of the 90-day treasury bill auction rates for the period of January 4, 1993 through January 31, 1994.

OMNIBUS BUDGET RECONCILIATION ACT OF 1993 (OBRA '93) ADDITIONAL REBATE CALCULATION (REVISION)

In our release number 9 dated December 9, 1993, we described in detail the changes brought about by OBRA '93. After careful consideration by government legal staff, we are issuing a revision to one item that we covered in release number 9.

We had stated that effective with the calendar quarter beginning October 1, 1993, additional rebate calculations for all 'S' and 'I' drugs would be based on a new set of values for the Baseline Average Manufacturer Price (AMP) and the Consumer Price Index-Urban. This new set of values would apply for those products where BOTH FDA APPROVAL DATE AND DATE DRUG ENTERED MARKET ARE AFTER OCTOBER 1, 1990.

This has been changed to include all products where the DATE DRUG ENTERED MARKET IS ON OR AFTER OCTOBER 1, 1990, REGARDLESS OF FDA APPROVAL DATE. All other areas of OBRA '93 covered in release number 9 are unchanged.

A copy of the revised unit rebate calculation instruction is attached.

DRUG REBATE DATA DEFINITIONS (ENCLOSURE C TO THE REBATE AGREEMENT)

Since the inception of the Drug Rebate program, there have been several legislative changes that caused revisions in the definition of many data elements covered in both the Drug Rebate Agreement (Enclosure A) and the Manufacturer Data Definitions (Enclosure C). The majority of the revisions were the direct result of the Veterans Health Care Act of 1992 and the OBRA '93.

Included with this note is an updated version of Enclosure C to the Drug Rebate Agreement which encompasses all data definition revisions through the end of calendar year 1993. Please note that the changes affect the AMP, Baseline AMP, Best Price, Unit Type, Market Date and FDA Approval Date.

FDA DATE SUBMISSION FOR OVER-THE-COUNTER (OTC) DRUGS

With the changes brought about by OBRA '93, we have been requesting that drug labelers supply the FDA approval dates for drugs marketed after October 1, 1990, even if they are OTC drugs. We received several inquiries from drug labelers regarding OTC drug products that do not have an FDA approval date.

Based on a discussion we had with personnel at the FDA, it was decided that, for OTC drug products not requiring an FDA approval date, the MONOGRAPH date is to be used in this field. This clarification is reflected in the attached data dictionary.

TOPIC INDEX

Again, we have included a topic index for the information covered in all prior releases to you.

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

for Sally K. Richardson
Director
Medicaid Bureau

5 Attachments

cc:
All Regional Administrators

All Associate Regional Administrators Division of Medicaid

* * NOTICE * *

TO ALL LABELER AND STATE AGENCY TECHNICAL CONTACTS

Attached is a survey containing questions formulated during the Dispute Resolution Workgroup Meeting, held at HCFA Headquarters on December 15, 1993. This workgroup is made up of representatives from private industry, state and federal government drug rebate operations.

Please complete the survey, adding comments where you deem appropriate. Please include your comments on a separate page, if needed. Return the survey, plus any additional comments, in the enclosed self-addressed, franked envelope, **NO LATER THAN**, Monday, February 28, 1994.

Albert C. Beachley

Albert C. Beachley, Chief
Drug Rebate Operations Branch
HCFA/MB/OMM/DPS

DISPUTE RESOLUTION WORK GROUP
TURNAROUND DOCUMENT QUESTIONNAIRE
FEBRUARY 1994

NOTE: IN YOUR REVIEW OF THE INVOICE AND THE DRAFT VERSION OF THE REMITTANCE ADVICE REPORT (RAR), WE ASK THAT YOU LIMIT YOUR COMMENTS TO THOSE AREAS/ITEMS THAT YOU DEEM TO BE CRITICAL TO THE DEVELOPMENT OF A STANDARD RAR OR A REVISED INVOICE FORM.

1. On the invoice submitted from States to labelers, would you like to see a separate field that would show the amount reimbursed (to pharmacies) that was paid by recipient co-payment or liable third parties (e.g., Blue Cross/Blue Shield)?

   ____ YES ____ NO

2. On the invoice submitted from States to drug labelers, is there a need for an indicator to identify rounded utilization data?

   ____ YES ____ NO

3. Of the following data elements, which would you like to have added to the RAR? Place an "X" next to **ALL** you are interested in.

   ____ Interest Element (Showing the interest due with the rebate payment)

   ____ Adjustment Indicator (Showing that you made adjustments to State reported data)

   ____ Close-out Indicator (Prior Period Adjustments)

   ____ Close-out Indicator (12-quarter limitation)

4. When States submit adjustments to utilization data, would you prefer:

   ____ Total Replacement of previous utilization data

   ____ Incremental Replacement showing changes from previous data reported (changed field only)

5. Which adjustment document should be used by States, for responses to the labelers?

   ____ Modified Invoice ____ Modified RAR

6. Do you have any proposals, comments, suggestions, etc., for uniform invoices and/or RARs?

____ YES ____ NO

If yes, please explain and include forms layouts, record layouts, etc., that will help describe your proposal.

QUESTIONS BELOW FOR STATES ONLY

7. How are you currently reporting adjustments to labelers?

8. Is a "response-to-the-response" document needed that would distinguish whether the adjustment is initiated by revised state utilization or an adjustment to the disputed utilization amount agreed to by the State and labeler?

____ YES ____ NO

9. Are you having any rounding problems with pharmacies that cannot, as yet, deal with decimal values when dispensing specific package sizes?

____ YES ____ NO

If yes, please explain the way pharmacies are handling this problem (ex., rounding up, rounding down, truncating, etc.)

08/19/92

MEDICAID DRUG REBATE REMITTANCE ADVICE REPORT

DRAFT

COMPANY NAME
LABELER CODE
ADDRESS

CONTACT
PHONE
FAX

STATE
QUARTER/YEAR
INVOICE No.

PRODUCT/ PACKAGE CODE	PRODUCT NAME	REBATE AMOUNT PER UNIT	UNITS INVOICED	UNITS PAID	REBATE AMOUNT INVOICED	REBATE AMOUNT PAID	ADJUSTED REBATE PER UNIT	ADJ. CODE	CREDIT/ DEBIT IND.	INVOICE ADJUSTMENT AMOUNT	DISPUTE CODE	WITHHELD INVOICE AMOUNT
TOTAL												

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 expire d 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 prescript ions.*
E. *Utilization/quantity is inconsistent with pharmacy reimburse ment levels.*
F. *Product not rebate eligible. Give details.*
G. *No record of sales in this state. Attach data source.*
H. *Other. Attach supporting documentation.*

DATE:

STATE OF

MEDICAID AGENCY

Form Approved
OMB No. 0938-0832

PAGE OF

SOURCE: STATE AGENCIES
TARGET: MANUFACTURERS

MEDICAID DRUG REBATE INVOICE

MANUFACTURER: _____ STATE CODE: _____ INVOICE #: _____

ADDRESS 1: _____ PERIOD COVERED: _____

ADDRESS 2: _____

CITY: _____ STATE: _____ ZIP: _____

NDC NUMBER	DRUG NAME	REBATE AMT. PER UNIT	TOTAL UNITS REIMB.	TOTAL REBATE AMT. CLAIMED	NO. OF SCRIPTS	TOTAL REIMB. AMOUNT	COR FLG

TOTALS: _____ * _____ _____ _____

Note:
NDC# = Labeler Code (5)
Product Code (4)
Pkg. Size Code (2)

* Please remit this amount to: _____ Medicaid Agency

Address: _____

_____

Attn: _____

Form HCFA-R-144

MEDICAID DRUG REBATE PROGRAM
CALCULATION OF PER UNIT DRUG REBATE AMOUNTS
OBRA '93

NOTE: Per unit rebate amounts provided to States by HCFA will be calculated as illustrated by the following examples. The HCFA rebate calculations are performed using full floating-point precision, with the final rebate amounts rounded to six decimal places. Values 5 or greater in the seventh decimal position round upward, and values less than 5 round down.

The examples below display intermediate calculations to nine decimal places, although actual calculations were performed and carried forward based on full precision. The limitation to nine decimal places in these illustrative examples is solely for clarity of presentation, and does not affect the accuracy of the final results. Calculations performed using lower levels of decimal precision may not reconcile with the HCFA numbers, due to rounding or truncation error.

PPER UNIT REBATE CALCULATION FOR NON-INNOVATOR MULTIPLE SOURCE DRUGS

I. Calculation of Basic Rebate amount (per unit) for Non-innovator Multiple Source (N) drugs as specified in section 1927(c)(3) of the Social Security Act.

A. Calculate the Basic Rebate Amount for calendar quarters 1/91 through 4/93 for N category drugs.

1. Multiply the AMP by .1 (10%).
2. Round the product of Step One to six decimals.

Example: AMP = 2.333335

1. 2.333335 x .1 = 0.233333500
2. 0.233333500 rounds to 0.233334

The Per Unit Rebate Amount is 0.233334.

B. Calculate the Basic Rebate Amount for calendar quarters 1/94 forward for N category drugs.

1. Multiply the AMP by .11 (11%).
2. Round the Product of Step One to six digits.

Example: AMP = 1.005635

1. 1.005635 x .11 = 0.110619850
2. 0.110619850 rounds to 0.110620

The Per Unit Rebate Amount is 0.110620.

PER UNIT REBATE CALCULATIONS FOR SINGLE SOURCE (S) AND INNOVATOR MULTIPLE SOURCE (I) DRUGS

NOTE: The Per Unit Rebate Amount for S and I drugs involves three separate calculations: 1) the Basic Rebate Amount and 2) the Additional Rebate Amount, which are added when calculating 3) the Total Rebate Amount. Each of these three calculations are taken to full available precision; the final step of rounding to six decimals takes place after the calculation of the Total Rebate Amount.

II. Calculation of Basic Rebate Amount for Single Source (S) and Innovator Multiple Source (I) drugs as specified in section 1927 (c)(1) of the Social Security Act.

A. Compute basic rebate for calendar quarters 1/91 through 4/91 for S and I categories (25% cap).

1. Multiply AMP x .125 (12.5%).
2. Subtract Best Price (BP) from AMP (AMP - BP).
3. Compare 1 and 2 and choose the larger.
4. Multiply AMP x .25 (25% cap).
5. Compare 3 and 4 and choose the smaller to get the Basic Per Unit Rebate Amount.

Example: AMP = 10.000000 BP = 7.000000

1. 10.000000 x .125 = 1.250000000
2. 10.000000 - 7.000000 = 3.000000
3. 3.000000 is larger than 1.250000000
4. 10.000000 x .25 = 2.500000000
5. 2.500000000 is smaller than 3.000000

2.500000000 is the Basic Per Unit Rebate amount.

B. Compute basic rebate for calendar quarters 1/92 through 4/92 for S and I categories (50% cap).

1. Multiply AMP x .125 (12.5%).
2. Subtract BP from AMP (AMP - BP).
3. Compare 1 and 2 and choose the larger.
4. Multiply AMP x .5 (50% cap).
5. Compare 3 and 4 and choose the smaller to get the Basic Per Unit Rebate Amount.

Example: AMP = 10.000000 BP = 7.000000

1. 10.000000 x .125 = 1.250000000
2. 10.000000 - 7.000000 = 3.000000
3. 3.00000. is larger than 1.2500000
4. 10.000000 x .5 = 5.000000000
5. 3.000000 is smaller than 5.000000000

3.000000 is the basic rebate amount.

C. Compute the basic rebate for quarter 1/93 forward for S and I categories (no cap).

Basic Rebate Rates by Period Covered:

01/01/91 - 09/30/92 = 12.5
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 - future = 15.1

Current Quarter = 1/93

1. Multiply AMP x .157 (15.7%).
2. Subtract BP from AMP (AMP - BP).
3. Compare 1 and 2 and choose the larger to get the Basic Per Unit Rebate Amount.

Example: AMP = 10.000000 BP = 2.500000

1. 10.000000 x .15 = 1.500000000
2. 10.000000 - 2.500000 = 7.500000
3. 7.500000 is larger than 1.500000000

7.500000 is the basic rebate amount.

III. Calculation of Additional Rebate for S and I drugs as specified in section 1927(c)(2) of the Social Security Act.

A1. Calculate the AMP-I for all quarters for S and I category drugs with a Date Entered Market before 10/1/90.

1. Divide the Baseline AMP (the AMP for quarter 3/90) by the Baseline CPI-U (i.e. 132.7, the CPI-U of September 1990).
2. Multiply the quotient of Step 1 by the current CPI-U to get the AMP-I.

Example:

Base CPI-U = 132.7

Base AMP = 10.000000
Current CPI-U = 133.8

1. 10.000000/132.7 = 0.075357950
2. .075357950 x 133.8 = 10.082893745

The AMP-I is 10.082893745.

A2. Calculate the AMP-I for quarters 1/91 - 3/93 for S and I category drugs with a Date Entered Market on or after 10/1/90.

1. Divide the Baseline AMP by the Baseline CPI-U (i.e. the CPI-U of the month before the product was marketed).
2. Multiply the quotient of Step 1 by the current CPI-U to get the AMP-I.

Example:

Date Entered Market = 07/21/91
First Full Month Drug was on the Market = 8/91

Base CPI-U (July '91) = 136.2
Per Unit Price on 08/01/91 = .003450
Current CPI-U (September '92) = 141.3

1. .003450/136.2 = .000025330
2. .000025330 X 141.3 = .003579185

The AMP-I is .003579185.

A3. Calculate the AMP-I for quarters 4/93 forward for S and I category drugs with a Date Entered Market on or after 10/1/90.

1. Divide the quarterly AMP for the first full quarter that the drug was marketed by the Baseline CPI-U. The Baseline CPI-U is the CPI-U of the month before the first full quarter that the drug was marketed.

2. Multiply the quotient of Step 1 by the current CPI-U to get the AMP-I.

Example:

Date Entered Market = 7/21/91
First Full Quarter Drug was on the Market = 4/91

Base CPI-U (September '91) = 137.2
Quarterly AMP for 4/91 = .003850
Current CPI-U (September '93) = 145.2

1. .003850/137.2 = .000028061
2. .000028061 X 145.1 = .004071684

The AMP-I is .004071684.

B. Calculate Additional Rebate Amount for S and I drugs.

NOTE: For drugs with a Date Entered Market on or after 10/01/93, the Additional Rebate Amount will not be calculated for the first reported quarter and for the first full quarter that the drug is on the market. Therefore, the first two Total Unit Rebate Amounts for these drugs will not include any Additional Rebate Amount.

1. Subtract AMP-I from current quarter AMP to get Additional Rebate Amount.
2. If the amount is 0 or a negative number, set the Additional Rebate Amount equal to 0.

Example 1:
Date Entered Market = 10/1/93
Current Quarter = 3/94
Current AMP = 12.000000
AMP-I = 10.082893745

1. 12.00000-10.082893745 = 1.917106255
2. The Additional Rebate Calculation results in a positive number.

The Additional Per Unit Rebate Amount is 1.917106255.

Example 2:

a) Date Entered Market = 1/15/94
Current Quarter = 1/94
Current AMP = .005260
AMP-I = Not applicable

Since the Date Entered Market falls within the Current Quarter, no additional rebate is calculated.

b) Date Entered Market = 1/15/94
Current Quarter = 2/94
Current AMP = .005260
AMP-I = Not applicable

Since the first full quarter that the drug is on the market is 2/94, no additional rebate is calculated.

c) Date Entered Market = 1/15/94
Current Quarter = 3/94
Current AMP = .005260
AMP-I = .004071684

1. .005260 - .004071684 = .001188316
2. The Additional Rebate Amount results in a positive number.

The Additional Rebate Amount is .001188316.

IV. Calculate the Total Unit Rebate Amount for S and I drugs.

A. This calculation applies to both the 1/91-3/93 and the 3/93 forward timeframes. However, for drugs with a Date Entered Market on or after 10/1/93, the first two quarterly Total Unit Rebate Amounts will not include an Additional Rebate Amount.

1. If the Additional Rebate Amount is a positive number, add to the Basic Rebate amount to get Total Rebate Amount.

2. Round the Total Rebate Amount to six digits.

Example:

Basic Rebate Amount (From Example II.A.) = 2.500000

Additional Per Unit Rebate Amount
(From Example III.B) = 1.917106255

1. 2.500000 + 1.917106255 = 4.417106255
2. 4.417106255 rounds to 4.417106

The Total Unit Rebate Amount is 4.417106.

Revised 2/2/94 by MB/OMM

ENCLOSURE C
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 digit field, right-justified and 0-filled for 4-digit labeler codes

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DATA ELEMENT NAME: Product Code

DATA DEFINITION: Second segment of National Drug Code.

SPECIFICATIONS: Alpha-numeric values, 4 digit field, right justified, zero filled

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DATA ELEMENT NAME: Package Size Code

DATA DEFINITION: Third segment of National Drug Code.

SPECIFICATIONS: Alpha-numeric values, 2 digit field, right justified, zero filled

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DATA ELEMENT NAME: Period Covered

DATA DEFINITION: Calendar quarter and year covered by data submission.

SPECIFICATIONS: Numeric 3-digit field, QYY; 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

For Baseline Data Submission, indicate third quarter of 1990 as 390.

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DATA ELEMENT NAME: Product Registration Name

DATA DEFINITION: Product name as it appears on FDA registration form.

SPECIFICATIONS: Alpha-numeric values, 63 characters, left justified

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DATA ELEMENT NAME: Drug Category

DATA DEFINITION: Classification of drug for purposes of rebate calculations.

SPECIFICATIONS: Alpha-numeric values, 1 character;
Valid Values: N = Non-innovator Multiple source
S = Single Source
I = Innovator Multiple Source

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DATA ELEMENT NAME: DESI Drug Indicator

DATA DEFINITION: A DESI (Drug Efficacy Study Implementation) drug is any drug that lacks substantial evidence of effectiveness (Less Than Effective/LTE) and is subject by the FDA to a Notice of Opportunity for Hearing (NOOH). This includes drugs which are identical, related or similar (IRS) to DESI drugs. Federal Financial Participation (FFP) funds are available to States for drugs with values 2, 3 and 4.

SPECIFICATIONS: Numeric value, 1 digit

Valid Values:
- 2 = Safe and Effective or non-DESI drug
- 3 = Drug Under Review (No NOOH Issued)
- 4 = LTE/IRS drug for some indications
- 5 = LTE/IRS drug for all indications
- 6 = LTE/IRS drug (withdrawn from market)

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DATA ELEMENT NAME: Therapeutic Equivalence Explanation Code

DATA DEFINITION: The classification as contained in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the FDA Orange Book) for the last day of the calendar quarter for which the rebate payment is being made.

SPECIFICATIONS: Alpha-numeric values, 2 character field

Valid Values:

AA	AB	AN	AO	AP	AT
BC	BD	BE	BN	BP	BR
BS	BT	BX			

NR - Not rated

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DATA ELEMENT NAME: Unit Type

DATA DEFINITION: Basic measurement that represents the smallest unit by which the drug is normally measured. The rebate amount will be calculated per unit. Refer to program instructions in the Medicaid Drug Rebate program releases for a more detailed explanation.

Example: For drugs that are dispensed in capsules or tablets, the Unit Type would be a capsule or tablet. The rebate amount would be calculated per capsule or tablet. For liquids, the Unit Type would be a milliliter. The rebate amount would be calculated per milliliter.

SPECIFICATIONS: Alpha-numeric values, 3 character field, left justified

Valid Values:

AHF = refers only to injectable Anti-Hemophilic Factor (AHF) units
CAP = Capsule
SUP = Suppository
GM = Gram
ML = Milliliter
TAB = Tablet
TDP = Transdermal Patch

* * NEW VALUE as of 10-01-93 * *

EA = EACH (Refers to drugs not identifiable by any other unit type as given in program instructions.)

Examples are:

.Powder-filled vials
.Powder-filled ampules
.Powder-filled packets
.Kits containing two or more items dispensed under one NDC

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DATA ELEMENT NAME: Units Per Package Size Code

DATA DEFINITION: Total number of units, as defined in the Unit Type field, in the smallest dispensable container or entity for the product defined by the full NDC.

SPECIFICATIONS: Numeric values, 10 digit field: 7 whole numbers and 3 decimal places.

Example 1: For a tablet, UPPS depends on whether the container of tablets must be dispensed "as packaged" or if tablets may be dispensed from it in smaller amounts. If the container is a bottle of 100 tablets and must be dispensed unbroken, the UPPS would be 100. If a smaller amount may be dispensed, always show "1" regardless of the amount under 100 that can be dispensed.

Example 2: For a powder-filled vial, the unit type would be EA and the units per package size would be 1.

Example 3: For a package of 12 suppositories that can be dispensed individually, the unit type would be SUP and the units per package size would be 1.

Example 4: For an unbreakable package of 6 transdermal patches, the unit type would be TDP and the units per package size would be 6.

Example 5: For a 100 ML ampule, the unit type would be ML and the units per package size would be 100.

Example 6: For a package containing a mix of different unit types such as a tube of ointment and 3 suppositories, the unit type would be EA and the units per package size would be 1.

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DATA ELEMENT NAME: AMP (Average Manufacturer's Price)

DATA DEFINITION: The Average Manufacturer's Price per unit per product code for the period covered, based on sales. If a drug is distributed in 3 package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. See Drug Rebate Agreement (Enclosure A) for more details.

SPECIFICATIONS: Numeric, 11 digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places.

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DATA ELEMENT NAME: Baseline AMP (Average Manufacturer's Price).

NOTE: This is required for Single Source and Innovator Multiple Source drugs. Baseline AMP is drug-specific; i.e., it follows the drug, regardless of changes in the drug's legal ownership.

DATA DEFINITION: The Average Manufacturer's Price per unit per product code. The calculation of the Baseline AMP is dependent upon the date of FDA approval and the date the drug is marketed. If a drug is distributed in 3 package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes.

EXAMPLES:
For drugs that are marketed before 10-01-90, the Baseline AMP is determined by the AMP for the quarter of 07-01-90 thru 09-30-90.

For **ALL** drugs marketed **AFTER** 09-30-90, **REGARDLESS OF FDA APPROVAL DATE**, the Baseline AMP is determined by the AMP for the first day of the first full month in which the drug was first marketed. **NOTE:** Effective for all quarters beginning with 10-01-93, the Baseline AMP for these products is determined by the AMP for the first full quarter **AFTER** the product is marketed.

SPECIFICATIONS: Numeric values, 11 digit field: five whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places. Zero fill for non-innovator drugs.

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DATA ELEMENT NAME: Best Price
NOTE: This is only required for Single Source and Innovator Multiple Source drugs.

DATA DEFINITION: The lowest price available from the labeler to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States (excluding depot prices and single award contract prices of any agency of the Federal Government). Effective 10/1/92, manufacturers must exclude any prices charged to the following entities: the Indian Health Service; the Department of Veterans Affairs; a State home receiving funds under section 1741 of title 38, United States Code; the Department of Defense; the Public Health Service or any entity described in section 340B(a)(4) of the PHS Act and as further specified in Federal Register notices; the Federal Supply Schedule; and, a State pharmaceutical assistance program. The Best Price is the lowest price, regardless of package size, for the same product code. Refer to program instructions for more detail.

SPECIFICATIONS: Numeric values, 11 digit field: five whole numbers and 6 decimal places.

Compute to 7 decimal places, and round to 6 decimal places. Zero fill for non-innovator drugs.

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DATA ELEMENT NAME: FDA Approval Date

DATA DEFINITION: Date of FDA Approval of the NDA, without regard to whether the drug has been sold or transferred to any entity, including a subsidiary or division of the original manufacturer. For OTC drugs, use monograph date.

SPECIFICATIONS: Numeric values, 6 digit field (MMDDYY)

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DATA ELEMENT NAME: Date Drug Entered Market

DATA DEFINITION: If Marketed prior to 10-01-90, first day of the first month that the drug was marketed for the entire month; otherwise, actual date the product is marketed.

SPECIFICATIONS: Numeric values, 6 digit field (MMDDYY)

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DATA ELEMENT NAME: Drug Termination Date

DATA DEFINITION: If drug is immediately withdrawn from the market, date of withdrawal. If drug is terminated because it is no longer being manufactured, this date is the shelf life of last lot.

SPECIFICATIONS: Numeric values, 6 digit field (MMDDYY)

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DATA ELEMENT NAME: Drug Type Indicator

DATA DEFINITION: Indicator to show whether this drug product can be acquired only by prescription or can be acquired Over-The-Counter (OTC).

1 = Rx
2 = OTC

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DATA ELEMENT NAME: Correction Record Flag

DATA DEFINITION: Indicator that this record corrects and replaces a record already submitted for the initial submission.

SPECIFICATIONS: Numeric one-digit field.

Valid Values: 0 = Original Record
1 = Correction Record

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