

**Memorandum**

JUL 22 1991

MEDICAID DRUG REBATE PROGRAM

Release No. 13

* * * IMMEDIATE ATTENTION REQUIRED * * *



NOTE TO: All State Medicaid Directors

We have a late addition to the list of drug labelers that are effective beginning July 1, 1991. Drug products marketed by Primus Pharmaceuticals, Incorporated (Labeler Code 55762), located in Macon, Georgia are covered beginning with the third quarter of 1991 (July 1, 1991). The names, addresses and telephone numbers of the personnel to contact are attached.

In my June 10 notice to participating drug manufacturers, a copy of which I sent to you on June 14 (Release No. 9), I noted that States would likely want to include a summary record with their quarterly utilization reports to manufacturers. I indicated that HCFA planned to recommend to the States a standard way to modify the prescribed magnetic media data record format in order to use it as a summary record. Several manufacturers and States had recommended we do this to promote uniformity in this area.

Attached is the standard summary record we have developed in consultation with the State Systems Technical Advisory Group (S-TAG). It reflects a minor modification of the magnetic media record format you are required to use in sending data to manufacturers and HCFA. I emphasize that you are not required to use this summary record format. However, we strongly encourage you to do so if you include a summary record with your quarterly utilization reports. We suggest that the summary record be placed at the end of the file rather than the beginning of the file. A copy of this summary record format will be sent to all participating manufacturers, for their information. Also, I am enclosing another copy of the mandated record format for electronic media since a prior release of this record format was incomplete for the Record Identification Field (Positions 1 - 4).

On May 24, I sent all States the methodology HCFA is using to calculate unit rebate amounts (Release No. 7). Section II of that methodology describes the calculation of an additional rebate for Single Source (S) and Innovator Multiple Source (I) drugs as specified in section 1927(c)(2) of the Social Security Act. Since new S and I drugs should not be subject to the additional rebate until the second quarter they are on the market, we have revised the rebate calculation methodology to make that fact clear. A copy of the revised methodology is attached and is being shared with all participating manufacturers.

On an ongoing basis, about 45 days after the end of each calendar quarter, HCFA will send you a data file for that quarter, including the unit rebate amounts for every drug product. These files are provided, in part, for your use in preparing the State utilization reports that must be sent to manufacturers within 60 days after the end of each quarter. Accordingly, while you are free to generate your utilization reports as soon after the end of a quarter as you wish, we would suggest that you not do so prior to receiving and using the HCFA update file for the subject quarter. Remember that unit rebate amounts change each quarter, and unit types are still being changed to accurately reflect how the drug products are marketed.

We remind you that the utilization data you report should be based on the date paid, not the date of service. Please ensure, however, that claims with service dates prior to the January 1, 1991 effective date of the drug rebate program are excluded, even if paid during 1991.

The process for handling prior period adjustments is being finalized and will be shared with you in a future release of information.

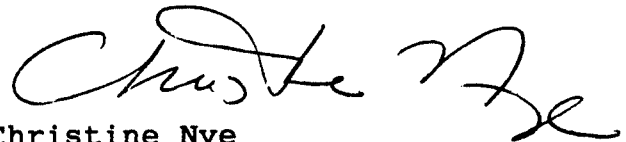
Two drug labelers have requested that they be terminated from the Drug Rebate Program. Effective October 1, 1991, delete Chester Labs Incorporated (Labeler Code 12462) and Can-Am Care Corporation (Labeler Code 08189) from the list of active participants. Both companies are being notified in writing of their termination and responsibilities for the first three calendar quarters of 1991.

Lastly, two drug labelers have changed their company names. ICI Pharmaceuticals P.R., Incorporated (Labeler Code 54921) is now listed as IPR Pharmaceuticals, Incorporated. Personal contact names, addresses and telephone numbers remain the same. On August 1, 1991, Russ Pharmaceuticals, Incorporated (Labeler Code 50474) will begin operating under the name of Whitby Pharmaceuticals, Incorporated. The persons shown as the legal, financial and technical contacts are unchanged but the following telephone numbers and address are to be used:

Telephone: (800) 477-7877
(804) 254-4400

Whitby Pharmaceuticals, Inc.
P. O. Box 85054
Richmond, VA 23261-5054

Please continue to refer your questions to us by using the Drug Rebate Hotline number at (301) 966-3249.



Christine Nye
Director
Medicaid Bureau

Attachments: 4

cc:
All State Technical Contacts
All Regional Administrators
All Associate Regional Administrators for Medicaid

CONTACT INFORMATION

Primus Pharmaceuticals, Incorporated

Legal Contact: W. H. Wells, Jr.
P.O. Box 123
1950 Canton Street
Macon, GA 31202
(912) 743-2123

Financial Contact: W. H. Wells, Jr.
P.O. Box 123
1950 Canton Street
Macon, GA 31202
(912) 743-2123

Technical Contact: Ralph M. Glovier
103 Shiloh Place
Warner Robbins, GA 31088
(912) 923-4829

**HCFA RECORD SPECIFICATIONS
 MEDICAID DRUG REBATE DATA
 RECORD FORMAT**

OMB #
 0 938-0582

SOURCE: STATE AGENCIES
 TARGET: HCFA & MANUFACTURERS

FIELD	SIZE	POSITION	REMARKS
RECORD ID	4	1-4	CONSTANT "01**"
STATE CODE	2	5-6	P.O. ABBREVIATION
LABELER CODE	5	7-11	NDC #1
PRODUCT CODE	4	12-15	NDC #2
PACKAGE SIZE CODE	2	16-17	NDC #3
PERIOD COVERED	3	18-20	QYY
FDA REG NAME (1ST 10)	10	21-30	1ST 10 OF FDA NAME
REBATE AMT PER UNIT	11	31-41	99999V999999
TOTAL UNITS REIMB.	12	42-53	999999999V999
TOT REBATE AMT CLMD	9	54-62	9999999V99
NO. PRESCRIPTIONS	6	63-68	999999
TOTAL REIMB. AMT.	10	69-78	99999999V99
CORRECTION FLAG	1	79-79	SEE DATA DIC. DEF
FILLER	1	80-80	BLANK

**HCFA RECORD SPECIFICATIONS
 MEDICAID DRUG REBATE DATA
 RECORD FORMAT
 (SUMMARY RECORD)**

SOURCE: STATE AGENCIES

TARGET: HCFA & MANUFACTURERS

FIELD	SIZE	POSITION	REMARKS
RECORD ID	4	1-4	CONSTANT "01\$\$"
STATE CODE	2	5-6	P.O. ABBREVIATION
LABELER CODE	5	7-11	NDC #1
FILLER	6	12-17	LEAVE BLANK
PERIOD COVERED	3	18-20	QYY
FILLER	21	21-41	LEAVE BLANK
TOTAL UNITS REIMB. *	9	42-50	999999999
TOTAL AMT CLMD **	12	51-62	9999999999V99
FILLER	18	63-80	LEAVE BLANK

*** ENTER THE TOTAL NUMBER OF RECORDS (NDC'S) ON THIS FILE**

**** ENTER THE TOTAL AMT CLAIMED FOR ALL RECORDS (NDC'S) ON THIS FILE**

MEDICAID DRUG REBATE PROGRAM
CALCULATION OF PER UNIT DRUG REBATE AMOUNTS

7/91

NOTE: Per unit rebate amounts provided to the 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.

PER UNIT REBATE CALCULATION FOR NONINNOVATOR MULTIPLE SOURCE DRUGS

Calculation of Basic Rebate amount (per unit) for Noninnovator 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. $2.333335 \times .1 = 0.233333500$
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. $1.005635 \times .11 = 0.110619850$
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: I) the Basic Rebate Amount and II) the Additional Rebate Amount, which are added when calculating III) 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.

I. 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. $10.000000 \times .125 = 1.250000000$
2. $10.000000 - 7.000000 = 3.000000$
3. 3.000000 is larger than 1.250000000
4. $10.000000 \times .5 = 5.000000000$
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).

1. Multiply AMP \times .15 (15%).
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. $10.000000 \times .15 = 1.500000000$
2. $10.000000 - 2.500000 = 7.500000$
3. 7.500000 is larger than 1.500000000

7.500000 is the basic rebate amount.

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

NOTE: Do not calculate an Additional Rebate for any drug for which the Date Drug Entered Market is within the current quarter.

Example: If Current Quarter is 2/91 (Second Quarter) and Date Drug Entered Market is 04/01/91 or 05/01/91 or 06/01/91
Do not calculate an Additional Rebate Amount

- A. Calculate the AMP-I for quarters 1/91 through 4/93 for S and I category drugs.

1. Divide the Baseline AMP by the Baseline CPI-U.
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. $.075357950 \times 133.8 = 10.082893745$

The AMP-I is 10.082893745.

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

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:

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.

III. Calculate the Total Rebate Amount for S and I drugs.

A. This calculation applies to both the 1/91-1/93 and the 1/94 forward timeframes.

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 Per Unit Rebate Amount is 4.417106.

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