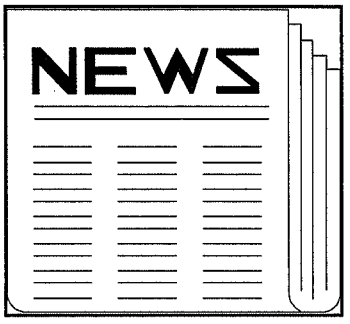
DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Memorandum

FEB 27 1997



MEDICAID DRUG REBATE PROGRAM Release No. 26

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All Participating Drug Manufacturers

FAILURE TO PAY INTEREST

We continue to receive reports from States regarding manufacturers failing to pay interest on late rebate payments. It has also come to our attention that some manufacturers allege no obligation to pay interest unless the State invoices for the interest due. While we have intervened on the States' behalf in a few of these situations, we believe it is once again necessary to remind manufacturers and States of their obligations regarding interest under the rebate program.

For all rebates not paid in a timely manner, to wit, within 38 calendar days after the postmark date of the State's invoice, interest accrues on the unpaid rebates until the date the manufacturer mails the check to the State. The obligation for calculating interest due to the States on late rebate payments rests with the manufacturer, just as does the obligation to calculate the rebate amounts. It is also the State's responsibility to collect interest due, and report those amounts to HCFA. However, whether or not a State invoices for interest has no bearing on the manufacturers' responsibilities to calculate and pay the amount(s) of interest due.

For more detailed information on interest, manufacturers should refer to the Medicaid Drug Rebate Operational Training Guide.

DISPUTE RESOLUTION PILOT PROJECT - CONTINUATION

The Dispute Resolution Pilot Project (DRP) that was initiated in the Boston Region in 1994 was expanded in 1996 to the Denver Region. States from the Western Consortium, as well as Missouri and Nebraska from the Kansas City Region, took part in the two weekly meetings during August and September. There were some very successful results from these meetings, including the resolution of disputes from as far back as 1991. Western Consortium States include: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, South Dakota, Oregon, Utah, Washington and Wyoming.

We are tentatively scheduling FY 1997 meetings in the Denver Regional Office during the months of March, July and September. Any Drug Companies interested in possible participation are encouraged to consider attending some or all of these meetings. If you are interested or would like some additional information, please contact Diane Dunstan, Denver R.O. DRP contact. Her number is (303) 844-6149, ext. 222. She can be contacted through E-Mail at ddunstan@hcfa.gov.

ADJUSTMENTS THAT CAUSE REBATE CORRECTIONS

We continuously receive phone calls from States complaining that they receive Prior Period Adjustment (PPA) records from us, but the actual adjustment (from labelers) may not be made for (up to) two years. Once again, it is the responsibility of THE LABELER to make monetary adjustments to State invoices caused by prior period Unit Rebate Amount (URA) changes. If you make a correction to an AMP or BP from a prior quarter, it is your responsibility to recalculate the URA and make adjustments to any affected State's remittance. This must be done IN THE QUARTER YOU MAKE THE ADJUSTMENT. Likewise, if you make a change to Baseline AMP or Market Date which causes ALL prior URAs to change, you MUST make proper adjustments when remitting payment to all affected States IN THE QUARTER YOU MAKE THE ADJUSTMENT.

Please refer to Section J (Prior Period Adjustments) of the Drug Rebate Operational Training Guide for complete instructions on how this process works.

BUYING INNOVATOR PRODUCTS FOR RESALE

We have had several questions regarding the purchase and repackaging of innovator products and how they must be reported to HCFA. Baseline information, such as Market Date and Baseline AMP MUST follow the NDA of the product. It does NOT follow the

NDC of the product. If your company purchases an innovator product and repackages it under your NDC for sale, you MUST establish this new NDC with the Market Date and Baseline AMP equal to that of the innovator. Your Drug Category, likewise, must be set to "I"; NOT "N". When you purchase this product, it must be with the understanding that the innovator will provide you with the Market Date and Baseline AMP that follows the NDA. Also, Therapeutic Equivalency, Product Name, Drug Type and Unit Type must be the same for multiple package sizes of the same product. That is, you cannot have "ML" as the Unit Type for one package size and "GM" for another. Nor can you have one package size being designated as Rx and another as OTC.

Please remember that you are responsible for having this data supplied by the innovator to you before you can establish it under your NDC.

THERAPEUTIC EQUIVALENCY CODE - UPDATE

In release #25, dated November 26, 1996 we discussed the new three-position Therapeutic Equivalency (TE) code for some, select "AB"-rated drugs. You were instructed to use the "A" always in position one, drop the "B", and code the numeric value "1" through "9" in position two. We changed the system to allow for these new values, but forgot that diskette users CANNOT put these codes in their system. The TE code field must pass an internal edit which has the valid codes hard coded. Any diskette user launching a new drug that is to be rated "Abx" must do the following: enter the baseline data on your MDRI diskette system with a TE rating of "AB", submit the actual TE to us in writing along with the diskette that contains the new NDC, and keep a record of the new TE for future updating. When a new version of the diskette program is released, it will allow you to enter your TE codes correctly. We apologize for this error. If you have any problems or questions regarding this change, please contact Vince Powell at (410) 786-3314.

REVISION TO INSTRUCTIONS FOR FORM HCFA-304 (RECONCILIATION OF STATE INVOICE (ROSI))

In our original instructions there was an exception to the requirement for completion of the ROSI. That exception being that if there are no zero rebate per unit (RPU) amounts reported on the State's invoice, and the labeler is remitting, in full, the rebate amount claimed for the current quarter utilization, there is no requirement to complete and submit a ROSI report.

Because there are several reasons why a State invoice may contain zeros in the RPU field, some of which are not the fault of the labeler, we have expanded the exception for completion and submission of the ROSI. Our revised exceptions have been approved by the Office of Management and Budget. The following list shows the circumstances under

which the ROSI is and is not required.

1.	Labeler is NOT paying, in full, the rebate amount due for the current quarter utilization, i.e., the labeler is disputing any units invoiced.	ROSI IS REQUIRED
2.	State invoice contains zeros in the RPU field because no dollar figure has been made available via the HCFA tape (due to the labeler's lack of data submittal), AND the labeler is remitting the rebate amount due, in full, for the current quarter utilization.	ROSI IS REQUIRED
3.	State invoice contains zeros in the RPU field where a dollar figure has been made available via the HCFA tape, AND the labeler is remitting the rebate amount due, in full, for the current quarter utilization. (In lieu of the ROSI, a copy of the State invoice must be returned with the full remittance. Labelers may optionally pen/ink the RPU field on the invoice copy, however, it is not a requirement.)	NO ROSI REQUIRED
4.	State invoice contains zeros in the RPU field due to HCFA data edits, AND the labeler is remitting the rebate amount due, in full, for the current quarter utilization. (The labeler must make pen/ink changes to a copy of the State invoice and return it with the full remittance.)	NO ROSI REQUIRED
5.	State invoice contains no zeros in the RPU field, AND the labeler is remitting, in full, the rebate amount due for the current quarter. (In lieu of the ROSI, a copy of the State invoice must be returned with the full remittance.)	NO ROSI REQUIRED

NOTE: Labelers have the option of always completing/submitting the ROSI regardless of the circumstances listed above.

The above revisions to the ROSI instructions are effective immediately and incorporated into the Medicaid Drug Rebate Operational Training Guide with the issuance of this release.

UPDATES TO THE MEDICAID DRUG REBATE OPERATIONAL TRAINING GUIDE

This is our first update to the operational training guide. Below is a list of those pages which should be replaced in your guide and the reason for the page revision. Please keep your guide updated to assure that your program is operating under the most recent instructions and guidelines. You may continue to direct your comments/suggestions on the guide to Sue Williams (410-786-3334) or Vince Powell (410-786-3314).

PAGE	REVISION
F7a	New form style.
F11b	Revised example; addition of omitted calculation step.
F14	Typographical error corrected.
F32 - F32a	Revised instructions for ROSI form (Page F32a is new).
F38 - F40	Revised instructions for ROSI form (Pages F39-F40 - pagination only).
G11 - G14	Revised to further clarify instructions.
M3 - M6	New form style.
M7	New form style; additions to option 2.
M10 - M11	New form style; rebate contact added.
O6	New coordinator for Kansas City Regional Office.
P3	Correction to Best Price definition.
Q2	AMP acronym corrected.
R2-R3	Page references revised.

QUESTIONS AND ANSWERS (Q&As)

From time to time, HCFA releases will contain a new section titled "Q&As." This section was created as a way for HCFA to share its responses to inquiries which may be helpful to

all program participants. The Q&A section will contain questions which are program-specific, as well as those frequently asked. This release contains our first set of Q&As.

Q & As

Q1. How do I know which HCFA person to contact for any given area of responsibility in the drug rebate program?

A: In State release number 53 and labeler release number 18, HCFA attached a list of its drug rebate staff, their major areas of responsibilities, and their telephone numbers. More recently, the "Medicaid Drug Rebate Operational Training Guide" contained a directory of HCFA staff (section O). This section lists each staff member and their telephone number, in addition to a list of the primary program functions and the staff member responsible. If your area of concern is not listed, you may contact one of the Technical Directors listed and they will direct your inquiry to the appropriate staff member. Our mailing address(es) and regional offices/coordinators also are listed in the directory.

Q2. How can drug rebate information on the Internet be accessed and what is currently available on HCFA's drug rebate home page?

A: HCFA's home page on the Internet can be accessed via http://www.hcfa.gov. At this time, the following drug rebate information is available on the Internet:

-Memoranda to State Medicaid Directors;
-Memoranda to participating drug labelers;
-Consumer Price Index-Urban values;
-91-day Treasury bill (T-bill) rates;
-State drug utilization for 1991-1995;
-Drug product baseline data (excluding prices);
-Participating drug labeler contact information;
-National drug rebate agreement;
-Interest calculation methodology;
-Formula for calculating unit rebate amounts;
-Listing of drugs subject to the Federal upper limit; and
-Quarterly listing of less-than-effective/identical, related or similar drugs.

Questions regarding HCFA's home page should be referred to Al Beachley at (410) 786-3276 or via email at abeachley@hcfa.gov.

Q3. Can HCFA add names to the drug rebate mailing list to receive the program releases?

A: Because there are over 500 drug labelers and 51 State agencies receiving drug rebate program releases, HCFA can accommodate only one name per labeler and State agency. HCFA has designated the Technical Contact person in the drug companies and States as the person to receive the releases. Because this is a frequent inquiry, Technical Contacts are asked to share information in the program releases with all staff involved in the drug rebate program.

Q4. I have called HCFA's drug rebate hotline number but never get an answer. Why?

A: This question usually comes from people new to drug rebate who are reading material issued early in the program, but a few veterans of the program also have asked about the non-response from the hotline number. Labeler release number 18 and State release number 53 reference the discontinuation of the Medicaid Drug Rebate Hotline because of the low volume of inquiries over the past several years. The discontinuation of the Hotline occurred at the same time HCFA's physical move took place. HCFA's relocation did not allow for the conversion of the Hotline number to our new phone exchange, which would have enabled a forwarding message to be heard. HCFA is working to have the Hotline number disconnected completely.

Please refer to section O of the "Medicaid Drug Rebate Operational Training Guide" for the name and telephone number of a drug rebate staff member to assist in answering your questions.

Q5. Why don't the ROSI and the PQAS forms provide for an entry by NDC for interest payments?

A: The column entries required for reconciliation of actual rebate payments currently exhaust the entire space available on the forms. In order to include interest payments without using two lines per NDC or further condensing the forms, it was decided that interest would be incorporated as a total for the quarter. Labelers optionally may attach a separate listing of interest payments per NDC to the ROSI and/or the PQAS, if needed.

Q6. It is not clear what is meant by Adjustment Code I for the ROSI or PQAS forms. Can you explain?

A: HCFA has received calls from labelers stating that the rebate per unit (RPU) reported on the State's invoice does not agree with any computation of RPU by HCFA or the labeler. Some States do not use the information on the HCFA tape when completing the invoice, but rather the RPU from the prior quarter. In addition, it appears that sometimes the RPU amount is an assumption on the State's part, and other times there is no explanation for the number used as the RPU on the invoice. In these instances, it is noted that the labeler submitted its pricing data to HCFA on time, the RPU calculation on the HCFA tape was not used on the State's invoice, and the labeler did not experience any product pricing changes. Because Adjustment Code A is not applicable for this situation, Adjustment Code I was developed.

Q7. On occasion, the quarterly rebate amount due to a State is a "negative" dollar amount. How should a labeler handle a "negative" rebate amount due to the State?

A: There is no hard and fast rule regarding this situation. When a "negative" rebate dollar amount is calculated, the labeler and State together should decide which method of payment is best. Some States may prefer to remit a check to the labeler for the balance due, while other States prefer that the labeler apply a credit to its next quarterly rebate payment. Either method is acceptable to HCFA.

OTHER ATTACHMENTS

Copies of the State Contact Listing, topic index and the latest listing of the 90-day treasury bill auction rates for the period of July 1, 1996 through February 24, 1997 are attached.

Please remember to direct your drug rebate questions to a staff member listed in Section O of the Medicaid Drug Rebate Operational Training Guide.

for Albert C. Beachley
Judith D. Moore
Acting Director
Medicaid Bureau

4 Attachments
cc:
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid