

December 23, 1996

MEDICAID DRUG REBATE PROGRAM

Release Number 65

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

NOTE TO: All State Medicaid Directors

EFFECTIVE DATE FOR DRUG EMPORIUM, INC. (LABELER CODE 62865)

In our latest release (number 64), we stated that Drug Emporium will be joining the drug rebate program effective January 1, 1997. That information continues to be correct. However, the information contained on our third quarter tape shows the effective date to be April 1, 1997. We have corrected that information to be January 1, 1997 on our data base, and you will receive the corrected date on the fourth quarter tape. We apologize for any confusion this may have caused.

MAINTAINING ACCURATE CONTACT INFORMATION

For the past year, there have been numerous instances where State drug programs change contact personnel, addresses, and/or telephone numbers and do not inform either us or participating drug companies. This can slow the dispute resolution process, and can also result in rebate checks being returned due to a bad address or expired forwarding time.

In order to maintain accurate data files and communication efforts, it is imperative that States send corrected information to HCFA whenever changes are made to the technical, policy, or rebate contact personnel information. We pass this information to participating drug companies with the expectation that it is correct at that point in time.

To ensure that we have the most current information, PLEASE COMPLETE THE ATTACHED FORM HCFA-368 AND RETURN VIA FACSIMILE TRANSMISSION TO HCFA AT (410) 786-0390. Please direct any questions regarding this requirement to Al Beachley at (410) 786-3276.

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. It is the State's responsibility to track the collection of 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, States should refer to the Medicaid Drug Rebate Operational Training Guide, section I.

INCORRECT SUBMISSION OF NATIONAL DRUG CODES (NDCs)

It was brought to our attention by a participating drug labeler, Golden State Medical (Labeler Code 60429), which began its participation effective July 1, 1996, that they received invoices from three States where no sales of their drug products occurred. The company is located in California and all three States are east of the Mississippi River. Investigation by one of the States involved revealed that the billing provider is a drug store chain that had used an incorrect NDC. We urge all State drug rebate programs to emphasize to their pharmacy communities the importance of correct NDC reporting.

We also note that where a manufacturer only sells its drug in a limited geographical area, it may enter into agreements with States outside that area to have the manufacturer's labeler code removed from the list of covered drugs.

UPDATE ON ALLSCRIPS

In Release Number 61, dated July 26, 1996, we notified all States of a situation involving ALLSCRIPS, a repackager not participating in the Medicaid program.

Recently, at the request of ALLSCRIPS, we met with the repackager's representatives and conducted a conference call with the Food and Drug Administration to clarify any misunderstanding. As a result, ALLSCRIPS voluntarily agreed to remove the original manufacturer's NDC from future repackaging. Additionally, ALLSCRIPS indicated that they are contemplating joining the Medicaid program. If ALLSCRIPS does enter into the Medicaid rebate agreement, we will advise all States regarding the effective date for coverage of ALLSCRIPS products.

DISPUTE RESOLUTION PILOT PROJECT - CONTINUATION

The Dispute Resolution Pilot Project (DRP) that started 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 resolution of disputes dating from 1991.

We are tentatively scheduling FY 1997 meetings in Denver sometime during the months of March, May, July and September. Any States in the Western Consortium and Kansas City Region, including those that participated last Fiscal Year, 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. You may also E-Mail her at ddunstan@hcfa.gov.

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 contains a directory of HCFA staff (section O). This

section lists each staff member along with 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
- 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 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 question 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 to obtain 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 timely submitted its pricing data to HCFA, 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.

ATTACHMENTS

In addition to the State Agency Contact Information form, copies of the topic index and the latest listing of the 90-day treasury bill auction rates for the period of May 6, 1996 through December 16, 1996 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.

/s/

Judith D. Moore
Acting Director
Medicaid Bureau

3 Attachments

cc:

All State Technical Contacts
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid