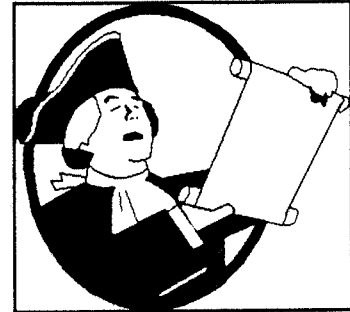




6325 Security Boulevard
Baltimore, MD 21207

AUG 11 1992



MEDICAID DRUG REBATE PROGRAM

Release No. 23

* * * IMMEDIATE ATTENTION REQUIRED * * *

NOTE TO: All State Medicaid Directors

REVISED EFFECTIVE DATE FOR DESI CHANGE

In Release Number 20 dated May 26, 1992, we advised you that September 1 would be the effective date for the States to be held accountable for using the new DESI codes to identify less-than-effective (LTE) and identical, related or similar (IRS) drugs.

Because drug labelers have been revising their initial self-reported DESI values and the changes will be included on the second quarter pricing tapes you receive in the middle of August, we are moving the effective date to October 1, 1992 to allow additional time for States to process any changes and to notify their pharmacy communities.

Section 4370 of the State Medicaid Manual (Less Than Effective and Identical, Related or Similar Drugs) will be amended to change existing Medicaid policy which holds States responsible for identifying LTE and IRS drugs, for purposes of determining Federal financial participation under the Medicaid program. HCFA will assume that responsibility on October 1.

Each quarter, HCFA will receive DESI data from the Food and Drug Administration (FDA). These data will update the HCFA data base and be passed to the States via the DESI code field present for each NDC on the quarterly pricing file. DESI changes submitted by labelers will be edited and passed to States using this same mechanism. Challenges to the DESI value of any drug product should be referred to HCFA by contacting us via the Drug Hotline at (410) 966-3249. If the challenged DESI value was generated by the FDA, it will be referred to the FDA for resolution. All other challenges will be referred to the reporting drug labeler for resolution. Changes to DESI code values will be reflected on each quarterly pricing file and will not be highlighted by HCFA via special notification.

HCFA will begin editing State invoices for LTE drugs effective with data submitted for the fourth calendar quarter of 1992. States will be notified by HCFA whenever payment for LTE drugs is discovered.

STATUS OF NEW REBATE AGREEMENT

As you are aware, we have been preparing a revised rebate agreement. We had originally planned to complete the new agreement and send it to manufacturers this summer, with an effective date of October 1, 1992. However, after further consideration, we have decided to proceed with the publication of the Medicaid drug rebate regulation first. Thus, we will not be sending the new agreement to manufacturers until the regulation is published.

We are taking this opportunity to remind you that the current agreement automatically renews at the end of each year, so there should be no disruption to the program.

In our next letter to manufacturers, we will advise them of the delay in sending out the new agreement and remind them of the automatic renewal provision in the current agreement.

CONSTANT DISPUTES BY DRUG LABELERS

In order to assist both States and drug labelers in settling invoice disputes, we want States to report to HCFA those drug labelers that are not paying rebates or are routinely disputing a majority of the rebate requests on your invoices. We will investigate to determine the problems causing the non-payment or disputes and attempt to assist both States and drug labelers in the resolution of the disputes.

NEW LABELER CODES

The following drug companies signed rebate agreements which are effective October 1, 1992:

Manufacturing Chemists, Incorporated (Labeler Code 00148) - contact information is attached.

~~50458~~ 00349
50458

Page 3 - Medicaid Drug Rebate Program - Release Number 23

Quality Formulations, Incorporated (Labeler Code 12225) - contact information is attached.

Niche Pharmaceuticals, Incorporated (Labeler Code 59016) - contact information is attached.

Topi-cana Specialty Products (Labeler Code 59197) - contact information is attached.

Wakefield Pharmaceuticals, Incorporated (Labeler Code 59310) - contact information is attached.

Altaire Pharmaceuticals, Incorporated (Labeler Code 59390) - contact information is attached.

DRUG LABELER INFORMATION CHANGES (Contact sheets attached.)

E.R. Squibb and Sons, Incorporated (Labeler Codes 00003, 00015, 00072, 00087, 19810 & 57783) - change to technical contact.

Lederle Laboratories (Labeler Codes 00005, 00205, 00206, 53124 & 57706) - all contacts are changed.

The Upjohn Company (Labeler Code 00009) - change to technical contact.

Schering Corporation (Labeler Codes 00085 and 00369) - all contacts are changed.

L. Perrigo Company (Labeler Codes 00113 and 70030) - change to financial and technical contacts.

Procter & Gamble Pharmaceuticals (Labeler Code 00149) - all contacts are changed.

Blaine Company, Incorporated (Labeler Code 00165) - all contacts are changed.

Goldline Laboratories, Incorporated (Labeler Code 00182) - change to the technical contact.

Tap Pharmaceuticals, Incorporated (Labeler Code 00300) - change to technical contact.

Calgon Vestal Laboratories (Labeler Codes 00519, 08237 and 55559) - change to financial and technical contacts.

Page 4 - Medicaid Drug Rebate Program - Release Number 23

Bioline Laboratories, Incorporated (Labeler Code 00719) - change to the technical contact.

Logen Pharmaceutical, Incorporated (Labeler Code 00820) - all contacts are changed.

Longs Drug Stores California, Incorporated (Labeler Code 12333) - all contacts are changed.

Marlop Pharmaceuticals, Incorporated (Labeler Code 12939) - change to financial and technical contacts.

Serono Laboratories, Incorporated (Labeler Code 44087) - change to financial and technical contacts.

Whitby Pharmaceuticals, Incorporated (Labeler Code 50474) - change to technical contact.

U.S. Pharmaceutical Corporation (Labeler Code 52747) - all contacts are changed.

Best Generics, Incorporated (Labeler Code 54274) - change to the technical contact.

CORRECTIONS

1. On page 10 of Release Number 19 dated May 18, we showed an incorrect labeler code (58062) for MGI Pharma, Incorporated. The correct labeler code is 58063.

2. Again, in release 19 on page 7, we correctly notified you that the United States Trading Corporation (Labeler Code 58653) had acquired another labeler code which would be effective retroactively to October 1, 1991. However, the diskette that we sent to you showed the effective date as January 1, 1992. Please ensure that your records reflect an effective date of 10/01/91 for labeler code 58653.

VACCINES

We are taking this opportunity to reiterate Medicaid coverage policy regarding vaccines. As we explained in Release No. 19 dated May 18, 1992, and as set forth in section 1927(k)(2)(B) of the Social Security Act, vaccines are excluded from the Medicaid drug rebate program and are not subject to the provisions of the rebate agreement. However, a State may choose to cover vaccines with Federal financial participation provided irrespective of the drug rebate program.

We continue to receive reports that some States are refusing to cover vaccines based on information provided by data sources that vaccines are not coverable under Medicaid. The most recent example was reported to us by SmithKline Beecham who indicated some States are denying coverage of a Hepatitis-B vaccine because First DataBank issued a notice that Medicaid coverage is unavailable. That information is erroneous because States' Medicaid coverage of vaccines is optional. We will contact the data services to clarify this policy for them.

Further, if a State decides to reimburse vaccines through the outpatient drug program, it must maintain adequate reporting mechanisms to separate pharmacy claims for vaccines from pharmacy claims for drugs which are subject to the drug rebate program.

In no case should a State delete any drug from its data base of drugs subject to the rebate program unless instructed to do so by HCFA.

VACCINES BEING DELETED

The following vaccines are being deleted since they are excluded from the drug rebate program per Section 1927(k)(2)(B) of the Social Security Act:

<u>NDC</u>	<u>Product</u>
00118-6700-01	9 South Grass Mix Treatment
00118-6701-01	7 Grass Mix Treatment
00118-6770-01	House Dust Mix Treatment
00118-9940-11	Honey Bee Venom Diagnostic Kit
00118-9940-12	Honey Bee Venom Maintenance Kit
00118-9941-11	White Faced Hornet Diagnostic Kit
00118-9941-12	White Faced Hornet Maintenance Kit
00118-9942-11	Yellow Hornet Diagnostic Kit
00118-9942-12	Yellow Hornet Maintenance Kit
00118-9943-11	Wasp Venom Diagnostic Kit
00118-9943-12	Wasp Venom Maintenance Kit
00118-9944-11	Yellow Jacket Diagnostic Kit
00118-9944-12	Yellow Jacket Maintenance Kit
00118-9945-45	Mixed Vespidae Maintenance Kit

MONTHLY CONSUMER PRICE INDEX-URBAN (CPI-U) VALUES

The latest CPI-U values are as follows:

09/90	132.7	05/91	135.6	01/92	138.1
10/90	133.5	06/91	136.0	02/92	138.6
11/90	133.8	07/91	136.2	03/92	139.3
12/90	133.8	08/91	136.6	04/92	139.5
01/91	134.6	09/91	137.2	05/92	139.7
02/91	134.8	10/91	137.4	06/92	140.2
03/91	135.0	11/91	137.8		
04/91	135.2	12/91	137.9		

WEEKLY U.S. TREASURY BILL DISCOUNT RATE

At the suggestion of several State representatives, we are furnishing the weekly 90 day treasury bill auction rates beginning with June 3, 1991. As you are aware, this rate is used in computing interest due on late rebate payments from drug labelers, pursuant to Section 1903(d)(5) of the Social Security Act as referenced in Section V (b) of the Rebate Agreement.

<u>DATE</u>	<u>RATE</u>	<u>DATE</u>	<u>RATE</u>	<u>DATE</u>	<u>RATE</u>
06/03/91	5.765	11/04/91	4.877	04/06/92	4.043
06/10/91	5.777	11/12/91	4.774	04/13/92	3.684
06/17/91	5.785	11/18/91	4.712	04/20/92	3.778
06/24/91	5.752	11/25/91	4.565	04/27/92	3.798
07/01/91	5.762	12/02/91	4.515	05/04/92	3.737
07/08/91	5.752	12/09/91	4.325	05/11/92	3.724
07/15/91	5.731	12/16/91	4.252	05/18/92	3.696
07/22/91	5.777	12/23/91	3.849	05/26/92	3.839
07/29/91	5.752	12/30/91	4.013	06/01/92	3.839
08/05/91	5.682	01/06/92	3.952	06/08/92	3.798
08/12/91	5.463	01/13/92	3.931	06/15/92	3.745
08/19/91	5.326	01/21/92	3.878	06/22/92	3.757
08/26/91	5.567	01/27/92	3.944	06/29/92	3.671
09/03/91	5.504	02/03/92	3.964	07/06/92	3.3
09/09/91	5.45	02/10/92	3.817	07/13/92	3.292
09/16/91	5.347	02/18/92	3.931	07/20/92	3.231
09/23/91	5.335	02/24/92	4.067	07/27/92	3.251
09/30/91	5.264	03/02/92	4.117		
10/07/91	5.19	03/09/92	4.117		
10/15/91	5.137	03/16/92	4.191		
10/21/91	5.19	03/23/92	4.178		
10/28/91	5.137	03/30/92	4.178		

MAGNETIC MEDIA SHIPMENTS

Recently, when questioned as to why quarterly tapes/data cartridges had not been sent to HCFA, several States indicated that the quarterly tapes had been mailed, as instructed, to the HCFA tape library. When the volume serial numbers were furnished for two missing tapes, their audit trails revealed that they had rejected and had been sent back to the States. Also, the audit trails uncovered a recordkeeping problem which we corrected.

However, the other tapes alleged to have been sent, were not located. When we checked our confirmation letters file, we could not find shipment confirmation letters for the missing tapes.

Please ensure that shipment confirmation letters are generated for every tape/data cartridge submitted to HCFA (include the volume/serial number(s)). This is necessary since the HCFA tape library and data center are at a separate location from the majority of HCFA offices. In this way, we can track the State utilization files that need to be processed.

Shipment confirmation letters should be generated every quarter and mailed to:

Health Care Financing Administration
2-A-1 Security Office Park Building
Attention: Karen Trudel
6325 Security Boulevard
Baltimore, Maryland 21207

Tapes and data cartridges should be mailed to:


Health Care Financing Administration
Attention: Tape Library, Lyon Building
7131 Rutherford Road
Baltimore, MD 21207

STATE CONTACT INFORMATION

Attached are the State contact data that we have in our data base. Please review this information and send any corrections to us via facsimile transmission at (410) 966-0390 or 966-3252.

Page 8 - Medicaid Drug Rebate Program - Release Number 23

Please continue to contact us by using the Drug Rebate Hotline number at (410) 966-3249.


for Christine Nye
Director
Medicaid Bureau

21 Attachments

CC:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators for Medicaid