



NOV 26 1993

MEDICAID DRUG REBATE PROGRAM

Release Number 33

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

NOTE TO: All State Medicaid Directors

LATE SUBMISSION OF QUARTERLY PRICES

We continue to experience trouble with the drug labelers submitting their prices within 30 days after the end of every calendar quarter. By November 4th, we had received the prices for less than 75% of the National Drug Codes (NDCs) on the HCFA data base. Our telephone calls resulted in the final percentage being close to 94%.

Therefore, you should receive a minimum of NDCs with zeroes in the Unit Rebate Amount (URA) field. We mention this situation since data records containing zeroes in the URA are valid NDCs that are to be invoiced to the drug labelers. The drug labelers continue to be responsible for computing the correct URA for each of their NDCs and must perform this function even when their prices are not submitted timely to HCFA.

Failure to submit quarterly prices on time has resulted in the termination of almost 25 drug labelers. We are closely monitoring the submission of late price information and will take necessary action to improve the situation.

LABELER BANKRUPTCY

We are in receipt of a copy of a Chapter 7 bankruptcy filing by Trinity Technologies Corporation (Labeler Code 53020) in the United States Bankruptcy Court in the Eastern District of Michigan. Due to the nature of this filing, it appears that this labeler will be unable to pay rebates for its products. We will provide more information as it becomes available.

WEEKLY U.S. TREASURY BILL DISCOUNT RATE

Included with this release is a listing of the 90 day treasury bill auction rates for the period of February 22, 1993 through November 15, 1993.

NEW LABELER CODES

The following labelers have signed rebate agreements and will be joining the program effective January 1, 1994:

Reckitt & Colman Pharmaceuticals, Incorporated (Labeler Code 12496);

BioDevelopment Corporation (Labeler Code 59527);

Alphagen Laboratories, Incorporated (Labeler Code 59743);

Kerry Company, Incorporated (Labeler Code 60475);

Apotex USA, Incorporated (Labeler Code 60505).

Reminder: Genetco, Incorporated (Labeler Code 00302) signed a new rebate agreement; their next period of participation in the drug rebate program begins on January 1, 1994.

DRUG LABELER TERMINATIONS

The following terminations are effective for the quarter beginning January 1, 1994:

Mays Laboratories, Incorporated (Labeler Code 00853);

Ambix Laboratories, Incorporated (Labeler Code 10038);

Lane Pharmaceuticals, Incorporated (Labeler Code 54943).

STATE UTILIZATION DATA STUDY (SUDS)

For the past six months, we have been evaluating individual State utilization data that are aberrant or appear to be aberrant when compared to prior quarterly submissions. This exercise became necessary because, in preparing both the annual and the new

quarterly reports to the Congress, we discovered data that were clearly erroneous or did not match our data base on NDC. We presented our findings to members of a special State technical advisory group and asked for their opinions on developing edits to screen the data. At their suggestion, we tested data from several States using the following criteria:

- o The rebate amount must be at least \$1,000.00;
- o The reimbursement amount must be at least \$10,000.00;
- o Three standard deviations from the mean will be the tolerance used; and,
- o The mean(s) to be used will be extracted from data submitted for the previous 8 calendar quarters.

The results of our tests pointed to records that were clearly aberrant. If the records were rejected rather than alerted, the rejection rate would be about 1 percent.

Effective with our processing of State utilization tapes for the second calendar quarter of 1993, we are looking at the total units reimbursed, rebate amount claimed, number of prescriptions and the total amount reimbursed by the State. Records with data that fall outside of the criteria will be marked as alerts for the second, third and fourth calendar quarters of 1993 and will be rejected beginning with the first calendar quarter of 1994.

After comparing the NDCs from the State rebate invoices, effective with the second calendar quarter of 1993, any full 11 position NDC that does not match the HCFA data base will not be retained by HCFA nor used in the statistical compilation of utilization data in an effort to yield a more accurate quarterly and annual Congressional report. The non-matching records will be shown on the tape confirmation letter beginning with processing the State utilization tapes for the second calendar quarter of 1993.

HCFA has performed a quality review of the utilization database and has found NDCs submitted by the States that did not match the NDCs on the HCFA tapes. A listing of the unmatched NDCs was sent to the manufacturers for review and correction. Over 98% of the unmatched NDCs were confirmed as obsolete or erroneous by manufacturers.

The use of the data by us in this manner does not mean that States can exclude coverage of any valid NDC of participating labelers. Similarly, manufacturers must report all of their covered drugs by NDC number.

All States must provide coverage of any NDC belonging to a participating labeler, whether or not that NDC is on the HCFA data base. To assist in the clean-up of unmatched NDCs, if providers submit drug claims that do not match the HCFA pricing file on the full 11 position NDC, you should verify that the non-matching NDC is valid. If your investigation shows that the non-matching NDC is valid and the labeler needs to submit the necessary data to the HCFA, please notify us via the drug rebate hotline at (410) 966-3249.

In our Release Number 7 to manufacturers, we reminded all labelers of their responsibility for reporting product and pricing data for all of their drug products. HCFA does have the authority to impose penalties or terminate the rebate agreement of labelers that fail to comply. We plan to reiterate our policy in our next Program Release to all participating manufacturers.

A new value for the correction code field will be available and is to be used to "force" posting of rejected State records which are found to be correct for either of the above-mentioned situations. We will announce the new correction code value prior to processing the State data for the first calendar quarter of 1994.

IMPLEMENTATION OF THE DUPLICATE DISCOUNT/REBATE MECHANISM

With the enactment of section 602 of the Veterans Health Care Act of 1992, there is a potential for a drug purchased by a Public Health Service (PHS) covered entity at the statutory discount to be subject to a Medicaid rebate if the drug is reimbursed by the Medicaid program. PHS and HCFA have established a mechanism which prevents manufacturers from being charged the combination of a discount and rebate for the same drug purchase. On May 7, 1993, PHS published a notice with comment period in the Federal Register (58 FR 27293) which describes this mechanism. PHS sent you a letter dated May 25, 1993 discussing this mechanism and its options and published the final notice regarding this mechanism on June 23, 1993 (58 FR 340580).

A. Covered Entity File

PHS identifies participating entities which choose to participate in the program and bill Medicaid separately by including the entities' Medicaid provider number(s) on the PHS covered entity file. PHS sent this file, which included Medicaid provider numbers, to the States on June 26, 1993.

Effective July 1, 1993, updates to the covered entity file were available through the Office of Drug Pricing Program's electronic bulletin board called the "Electronic Data Retrieval System". PHS notified you in a letter dated June 30, 1993 that all updates to the file would be available through this system. The letter included instructions for accessing the bulletin board.

Monthly updates to the covered entity list with Medicaid numbers, where applicable, were available for July, August, and September, effective with the 1st day of each of these respective months. During fiscal year 1994, the PHS bulletin board will be updated on a quarterly basis effective October 1, 1993, and January 1 and April 1, 1994. These updates will be effective at the beginning of each quarter. Thereafter, updates will be made on an annual basis.

At the time PHS established this bulletin board, the capability to generate a separate file which contains only new additions and deletions did not exist. We discussed this problem with PHS and the problem it posed for States to update their exclusion files on a quarterly basis. To respond to State and manufacturer needs, PHS is modifying its system to include a separate file for additions and deletions. These additional files should be available through the bulletin board effective January 1, 1994.

To complete an exclusion file for the quarter ending September 30, 1993, however, States must use the file supplied them by PHS in June 1993 and update it using the July, August, and September 1993 files. This will ensure that all appropriate Medicaid provider numbers are included on the provider exclusion file for Quarter 93-3.

B. Precluding Duplicate Discounts/Rebates

There will be no change in how States handle claims from covered entities which bill Medicaid using an all-inclusive rate, e.g., per diem rates, since drug costs are included in the rates. These all-inclusive claims are excluded from drug utilization data used to calculate rebates due from manufacturers. Outpatient drug claims which are billed to Medicaid separately using an NDC-number are not considered all-inclusive rates.

The mechanism to prevent a duplicate discount/rebate applies to outpatient drug claims from covered entities which bill Medicaid separately for covered outpatient drugs. To implement the mechanism, States must create an exclusion file to apply to all outpatient drug claims from PHS covered entities for drugs dispensed on or after July 1, 1993. The exclusion file must screen drug claims to include only those claims for drugs dispensed on or after a covered entity's effective date of participation. Note that only those PHS

covered entities which bill Medicaid separately with a Medicaid provider number indicated on the PHS covered entity file have opted to participate in the PHS drug pricing program and are entitled to receive the statutory discounts from manufacturers.

Thus, States must only exclude from their Medicaid rebate invoices drug utilization data related to covered entities that appear, with their Medicaid number(s), on the PHS list. States are not to exclude claims from covered entities without a Medicaid number on the PHS covered entity file.

C. Billing at Actual Acquisition Cost

Participating covered entities are required to bill Medicaid for covered outpatient drugs using the actual acquisition cost of the drug plus a reasonable dispensing fee. This requirement was included in the PHS Federal Register Notice of May 7, 1993 (58 FR 27294). States should implement a procedure to verify that covered entities are billing for drugs at the actual acquisition cost. This procedure will assure that the discounts to the covered entities are passed on to the State Medicaid agencies.

Prior to the Veterans Health Care Act of 1992, some States limited reimbursement to certain entities, such as government institutions and tax-supported hospitals, to the actual acquisition cost which was verifiable by audit. In these cases, States have adequate procedures to assure that drug discounts to covered entities are passed on to the State Medicaid agencies.

D. Maintaining Exclusion File Data for Dispute Purposes

States should maintain a copy of the quarterly exclusion file, in either electronic or paper format, as evidence of a reduction in rebates billed to manufacturers for covered entity drug claims. We believe this documentation will be necessary in the event manufacturers dispute drug utilization data on the basis that they are being charged a duplicate discount/rebate for drugs dispensed to Medicaid beneficiaries by PHS covered entities. Note that unless a covered entity is on the PHS list with a Medicaid provider number, there is no duplicate discount/rebate even if discounted prices were given that entity. Disputes for the inclusion of these entities are to be rejected by the States.

E. Effective Date of Mechanism Using Exclusion File

The mechanism requiring the use of a provider exclusion file to prevent duplicate discounts/rebates must be applied to claims paid for covered outpatient drugs for the quarter ending September 30, 1993. States must include in their exclusion file those entities with Medicaid provider numbers from the comprehensive list consisting of entities on the June, July, August, and September files.

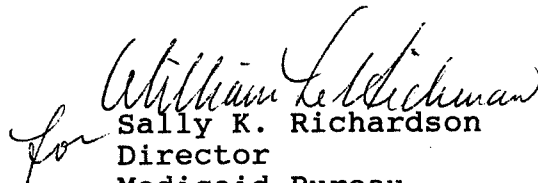
OTHER ATTACHMENTS

Copies of the topic index and the latest State Tape Status Report are attached.

STATE DATA VALIDATION EDITS

Several labelers mentioned that their disputes with selected States were settled after they reviewed zip code level drug claim data and were given detailed explanations of "up front" edits implemented by States. Since the "up front" edits appear to increase manufacturer confidence in State data, we ask that you share these edits with us so that we can let other States know what drug edits you find to be most useful in processing outpatient drug claims. We plan to publish a listing of useful State edits in a future Release.

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


Sally K. Richardson
Director
Medicaid Bureau

3 Attachments

CC:

All State Technical Contacts

All Regional Administrators

All Associate Regional Administrators for Medicaid

WEEKLY U.S. TREASURY BILL DISCOUNT RATE

The latest weekly 90-day treasury bill auction rates beginning with February 22, 1993, are as follows:

DATE OF AUCTION	TRUE DISCOUNT RATE
02/22/93	3.023
03/01/93	3.035
03/08/93	3.043
03/15/93	3.064
03/22/93	3.003
03/29/93	3.023
04/07/93	2.982
04/12/93	2.954
04/19/93	2.880
04/26/93	2.941
05/03/93	2.941
04/07/93	2.982
05/17/93	3.064
05/24/93	3.125
06/01/93	3.149
06/07/93	3.210
06/14/93	3.137
06/21/93	3.170
06/28/93	3.117
07/06/93	3.076
07/12/93	3.104
07/19/93	3.117
07/26/93	3.170
08/02/93	3.170
08/09/93	3.115
08/16/93	3.096
08/23/93	3.087
08/30/93	3.084
09/07/93	3.015
09/13/93	3.043
09/20/93	2.994
09/27/93	2.962
10/04/93	3.023
10/11/93	3.104
10/18/93	3.125
10/25/93	3.149
11/1/93	3.178
11/8/93	3.176
11/15/93	3.178

STATE TAPES STATUS REPORT

STATE	1/91	2/91	3/91	4/91	1/92	2/92	3/92	4/92	1/93	2/93	ALL QTRS
TX	X	X	X	X		X	X	X	X	X*	
UT	R	X	X	X	X	X	X	X	X	X*	
VA	X	X	X	X	X	X	X	X	X*	X*	X
VT	X	X	X	X	X	X	X	X	X		
WA	X	X	X	X	X	X	X	X	X	X*	X
WI	X	X	X	X	X	X	X	X	X	X*	X
WV	X	X	X	X	X	X	X	X	X	X*	X
WY	X	X	X	X	X	X	X	X	X	X*	X
TOTAL	47-45	49-49	49-49	50-49	49-49	50-50	50-50	50-50	47-47	38-38	33

* - Tapes received since last (10/4/93) Report.

X - Files processed; good data.

R - Files rejected and must be corrected.

U - State is unable to generate and submit tapes for this Quarter.

Second Total amount shown indicates number of usable tapes received.

STATE DISPOSITION STATUS REPORT

11/22/93

STATE	1/91	2/91	3/91	4/91	1/92	2/92	3/92	4/92	1/93	2/93
AK	4252	4894	5232	5305	5329	5471	5407	5518	5587	5309
AL	6745	11899	13893	14932	15542	15602	15355	15723	16191	15606
AR	14565	15852	15191	15171	14967	14470	14219	14663	14474	14374
CA	8142	11026	11500	11279	10871	10791	9207	9401	11830	
CO	7026	7837	9010	9019	9327	9909	10138	10382		
CT	9278	8330	11074	11669	11683	12123	12022	12338	12478	
DC	5451	6214	6584	6556	7337	7316	7853	6816	7465	7525
DE	5556	1887*	6800	7119	7417	8221	7345	7730	7851	
FL	19360	22136	21784	20985	21369	21295	21633	21289	21576	20993
GA	14603	17609	17781	18152	17741	18005	17345	16381	16724	16309
HI	7168	8012	8489	8471	8343	8260	8464	8279	8538	
IA	14040	15171	15396	15562	15977	15617	15704	15009	14794	13895
ID	15918	16944	17064	8981	9434	9541	9091	9116	8843	9302
IL		1370*	21498	22514	22050	21431	21258	21622		
IN	20237	22273	22506	23727	23526	23659	19742	19536	20118	20147
KS	9053	10514	11414		11870	12029	12190	12063	12084	11976
KY	12793	15926	16554	16898	17336	17539	17484	17624	17481	16735
LA	14680	16659	15555	15994	16013	15971	15699	15485	15868	15681
MA	11936	12641	4857	13977	14243	13889	14693	14224	14088	13038
MD	13192	14291		14530	15995	14537	14671	14340	15022	14044
ME	8172	8416	8470	8830	9115	9046	9042	9024	9387	9733
MI	2305*	16257	16554	17069	17205	17335	17637	17891	17501	17545
MN	13816	14459	14558	14857	14443	14663	14090	14496	14540	14492
MO	11955	17499	19716	20550	20304	21182	23179	20678	19361	20458
MS		5942	13878	12760	15166	15808	15807	15805	14783	14335
MT	7477	8644	8810	8918	9148	9316	9118	9133	9336	9367
NC	9866	10528	14705	15165	15658	15436	15814	15750	16222	15856
ND	6180	6743	6798	6854	7021	6980	6885	6786	6832	6630
NE	2349*	2514*	2513*	7488	11275	11694	11455	13524	13693	13845
NH	7740	7415	9509	9222	10626	9856	9470	9792	9746	9928
NJ	15918	16944	17064	16807	16321	16806	15309	15315		
NM			10471	10924	10869	10442	10206	10459	10576	
NV		7247	7039	7431	7635	7739	7609	7952	7320	
NY	17836	18723	20107	21445	21736	21469	14033	23710	26458	
OH	18484	20018	21435	21659	22213	21528	21517	21529	21243	20337
OK	11007	11590	12403		2037*	2304*	12791	13135	13129	13059
OR	11552	12579	12777	12936	13187	13178	14045	12907	12765	13213
PA	20848	23048	22976	23746	23324	21785	21874	21894	22122	
RI	8231	9064	9247	9135	9605	9590	9388	9316	9935	9483
SC	12917	13856	14090	13859	13332	13363	13353	13447	13278	13329
SD	5317	6815	7577	7346	7517	7550	7508	6920	7588	7566
TN	15997	17348	18398	18663	19223	19095	18161	18367	18593	

STATE DISPOSITION STATUS REPORT

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STATE	1/91	2/91	3/91	4/91	1/92	2/92	3/92	4/92	1/93	2/93
TX	13653	14502	14713	14039		15420	15279	15255	15693	15263
UT		10539	10309	10517	10853	10904	10876	9901	10003	9984
VA	17056	19116	18810	19392	19410	19200	19777	19470	18312	18472
VT	6255	6860	7005	7259	7356	7395	7324	7353	7437	
WA	12198	12869	12853	12761	13730		13519	13732	13782	13870
WI	6024	15380	15994	15986	16161	16198	16244	16406	16453	16154
WV	1352*	9122	11244	11405	11568	11444	11920	10885	11767	11977
WY	5322	6404	6293	6621	5436	6084	6334	6385	6630	6504
TOTAL	45	49	49	48	49	49	50	50	47	37

* - Indicates States submitting less than 5000 records in a Quarter.
Totals shown indicate number of States submitting usable tapes.