DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

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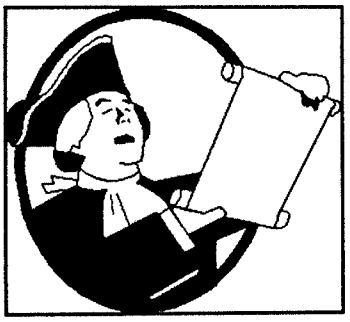

MEDICAID DRUG REBATE PROGRAM

Release No. 19

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

NOTE TO: All State Medicaid Directors

DISPUTE RESOLUTION ISSUES

We have had ongoing discussions with States and manufacturers on dispute resolution. On February 19, we also hosted a dispute resolution conference with representative of manufacturers, pharmaceutical associations, and Medicaid State agencies. Following are our policy positions as a result of these discussions.

Unit Rebate Amount

As stated in the law and the rebate agreement, the manufacturer is responsible for calculating the correct amount of rebate per unit of drug. If the manufacturer calculates an amount that differs from the unit rebate amount the HCFA calculated and provided to the State, the manufacturer must notify the HCFA of the basis for its calculation. This type of disagreement is not subject to the dispute resolution process, which is used to resolve disputes between States and manufacturers.

Payment of Undisputed Amounts

Neither a State nor a manufacturer may request that the undisputed amount of the rebate not be paid until the disputed amount is resolved. The undisputed amount of the rebate must be paid within 30 days of the manufacturer's receipt of State utilization data.

Minimum Rebate Tolerance

In any quarter, States should not invoice a manufacturer for rebate amounts that do not exceed their administrative costs associated with preparing the invoice. We consider rebate amount requests of $10 or less to meet this tolerance. States could set a smaller tolerance, but it should be greater than zero.

Steps in the Dispute Resolution

The following instructions are the steps that the dispute shall follow to reach a resolution.

1. Within 30 days of receipt of State utilization data, the manufacturer must pay rebates on all undisputed data. Within the same timeframe, if a manufacturer disputes specific utilization data, the manufacturer must identify by individual national drug code (NDC) the utilization data in question, specific reasons why that data is in question, and notify the State in writing, also within 30 days of receipt of the data.

2. Within the 30-day period, we encourage the manufacturers to distinguish between data inconsistencies and legitimate disputes. For inconsistencies involving, for example, unit types and incorrect NDCs the manufacturers should contact the State as soon as possible to determine the proper corrective action and attempt to resolve the dispute without further dispute resolution procedures (the disputed resolution timeframes and procedures apply, however, if informal negotiations do not resolve the problem).

3. The State must take steps to resolve the questionable data. The State may provide zip-code level data which the manufacturer will compare with its records to identify discrepancies. When pharmacy level data is requested the State may submit its State pharmacy data for comparison with the manufacturer's pharmacy data or, if State confidentiality laws prohibit the release of such information, request that the manufacturer make its data available to the State for comparison. If requested by the manufacturer, a State may opt to conduct sampling of a particular drug's utilization data to detect and resolve problems.

4. States must ensure that any exchange of data protects the confidentiality requirements of Section §1927(b)(3)(D) of the Social Security Act. That is, a particular manufacturer's identity and pricing data must not be disclosed by the State to outside parties, including resource information services.

Under section VII(b) of the rebate agreement, data released to the manufacturer by the State shall also be held confidential by the manufacturer.

5. Provided the State makes available zip-code data, pharmacy specific data, or other suitable data in response to the manufacturer, the State may consider cost effectiveness in deciding to pursue any remaining items in dispute.

   In any quarter, States need not enter into further dispute resolution processes with a manufacturer if the disputed amount is: under $10,000 per manufacturer and under $1,000 per product code.

   States maintain discretion to enter into the dispute resolution process in cases that fall below these thresholds.

We are continuing to work on issues involving dispute resolution and unit standardization which require additional development. We will address these further in release letters, the rebate agreement, and the regulations.

EXCLUSION OF VACCINES FROM REBATE PROGRAM

We were notified by E.R. Squibb & Sons, Incorporated (Labeler Code 00003) that some States are submitting rebate invoices for their influenza vaccine, Fluzone (NDC 00003-1341-10), which is marketed in a 5 ML vial from which 10 shots of .5 ML each can be given. There are two problems that need to be addressed by States. First, vaccines are not subject to rebates per Section §1927(k)(2)(B) of the Social Security Act. Second, even if the drug was covered, our review of State invoices for this product indicates either incorrect billing by pharmacies or incorrect invoicing by States. In most cases, the number of scripts equals the number of units. This should actually be a ratio of 2 to 1. We believe this problem exists for many covered outpatient drug products since some pharmacies may not have the electronic capability to bill for decimal value units but must bill whole numbers. (e.g. .5 ML being billed as 1 ML). Your review of drug claims and invoices may indicate additional drug products in this category. We plan to identify all vaccines and will send a listing to you when we complete this initiative.

STATE COVERAGE OF UNIT-DOSE PACKAGED DRUGS

UDL Laboratories, Incorporated (UDL) recently informed us that several States appear to be refusing reimbursement to pharmacies that dispense UDL's unit-dose packaged prescription drugs. UDL (Labeler Code 51079), which has been participating in the drug rebate program since its inception, is a distributor of unit-dose packaged generic drugs. We are, therefore, clarifying our policy as it relates to State coverage of unit-dose packaged drugs.

States may continue to exclude package sizes of participating manufacturers if they find that drugs packaged in smaller sizes are less cost efficient when the same drug is available from the manufacturer in larger sizes. However, the Omnibus Budget Reconciliation Act of 1990 requires coverage of all non-excludable or non-restricted drugs of a participating manufacturer. To comply with the drug rebate program requirements, a State cannot exclude the package size of a particular drug if this exclusion would result in that manufacturer's drug not being covered at all under the Medicaid program. Therefore, States must cover UDL's unit-dose packaged drugs if those drugs are not available from UDL in other package sizes.

Some of UDL's larger package sizes have been discontinued over the past couple of years but may still remain in pharmacies because the shelf life has not expired. In these cases, States that are not covering unit-dose packaging because a larger package size still exists should instruct pharmacies to dispense drugs from the larger, discontinued package size until its supply is depleted. After the discontinued product's supply is exhausted and no other package sizes exist, States must cover the unit-dose package size of the drug.

States still have the option, however, to prior authorize any or all package sizes of a manufacturer's drugs provided that their prior authorization program meets the provisions of Section §1927 (d)(5) of the Social Security Act.

SUBMITTING INVOICES TO DRUG LABELERS

When submitting invoices to drug labelers, we instructed you in Release Number 15 to send all invoices to the technical contacts unless advised by HCFA to submit the invoices to one of the other two contacts for any drug labeler. Likewise, the drug labelers were advised to submit contact changes to HCFA if they wanted the invoices submitted to someone not listed as one of their three contacts. This continues to be the HCFA policy.

Please note the following changes requested by drug labelers when submitting invoices:

- McGaw, Incorporated (Labeler Code 00264) - submit all invoices to the financial contact.
- Wyeth-Ayerst Laboratories (Labeler Codes 00008, 00031, 00046 and 00641) - submit all invoices to the financial contact.
- IOLAB Corporation (Labeler Code 00058) - submit all invoices to the new financial contact, Peggy S. Thomas. The new contact information for IOLAB is included on the enclosed diskette.

STATE RESPONSIBILITY ON TERMINATED DRUGS

There have been numerous questions regarding what the State's responsibilities are for maintaining and processing data for terminated drugs. **Please ensure that your processing system can correctly handle terminated drugs based on the following:**

1. The "termination date" **is the actual date the shelf life ends** (for any NDC). It is not the date the drug labeler stops making or selling the drug product.
2. The termination date (by NDC) is included on the pricing tape/data cartridge sent to you quarterly.
3. You **MUST** maintain this date and **ASSURE** that claims submitted by pharmacists are **NOT** for drugs dispensed **AFTER** the termination date. These should be rejected as invalid since these drugs cannot be dispensed after this date. If you find that the manufacturer's termination date is incorrect (e.g., a pharmacist has stock with an expiration date later than what the manufacturer stated), please notify us.
4. We will continue to supply a record with the same Unit Rebate Amount (URA) for an additional **FOUR QUARTERS** beyond the termination date to allow you to process all claims where the dispensing date is **ON OR BEFORE** the termination date.
5. The terminated drug product(s) are deleted by HCFA after these additional four quarters have elapsed.

BANKRUPTCY FILINGS BY DRUG LABELERS

Recently, we learned that three drug labelers are currently undergoing bankruptcy proceedings.

American Preferred Pharmaceutical, Incorporated, (Labeler Code 53445) - we are unable to establish contact with this company since their telephone numbers are disconnected. They did not submit pricing data for the fourth quarter but have been sent notice that it is overdue. We anticipate that their rebate agreement will be terminated but would appreciate knowing whether they are paying rebates.

Major Pharmaceuticals (Labeler Code 00904) - we are in receipt of a notice of their Chapter 11 filing with the United States Bankruptcy Court for the Southern District of New York. We were told by a company spokesperson that they are being purchased by another company which required them to file for Chapter 11 in order to ascertain their creditors. No unique rebate problems are anticipated by that drug labeler.

Vitarine Pharmaceuticals, Incorporated (Labeler Code 00185) - on May 24, 1991, Vitarine Pharmaceuticals, Incorporated filed for protection under Chapter 11 of the bankruptcy code. On March 21, 1992, the court approved the sale of the assets of Vitarine Pharmaceuticals to an investor group which will operate under the name of **EON Labs Manufacturing Incorporated.** This change of ownership was completed during April. No rebate problems are anticipated.

NEW DRUG LABELER CODES

The following new drug labeler codes will be effective for the quarter beginning July 1, 1992 and are included on the enclosed diskette:

- **Beiersdorf, Incorporated (Labeler Code 10356)**
- **Dr. Rose, Incorporated (Labeler Code 42037)**
- **Laboratorios Atral, S.A. (Labeler Code 53862)** - This company is located in Lisbon, Portugal but qualifies under current FDA regulations. We were told that they will be opening an office in New Jersey later this year, probably before October 31.
- **Huffman Laboratories, Incorporated (Labeler Code 54252)**

- **Snuva Incorporated (Labeler Code 58291)**
- **Otsuka America Pharmaceutical, Incorporated (Labeler Code 59148)**
- **We Pharmaceuticals, Incorporated (Labeler Code 59196)**
- **Nature's Bounty, Incorporated (Labeler Code 74312)**

The following labeler code is an addition to an existing rebate agreement and will be effective retroactively to October 1, 1991:

- **United States Trading Corporation (Labeler Code 58653)**

DRUG LABELER INFORMATION CHANGES

Due to the large number of changes to contact information, we are enclosing an updated diskette. We will continue to highlight the reasons for the changes.

ER Squibb and Sons, Incorporated (Labeler Code 00003) - change to the technical contact.

Mead Johnson and Company (Labeler Code 00015) - change to the technical contact.

Kabi Pharmacia (Labeler Code 00016) - change to financial and technical contact.

Sanofi Winthrop Pharmaceuticals (Labeler Code 00024) - the name of the company was changed from Winthrop Pharmaceuticals; individual contact data remain unchanged at this time.

Miles, Incorporated (Labeler Code 00026) - change to financial and technical contact.

Warner-Lambert Company - Warner Chilcot (Labeler Code 00047) - change to the technical contact.

Armour Pharmaceutical Company (Labeler Code 00053) - change to the financial contact.

Iolab Corporation (Labeler Code 00058) - change to financial contact.

Ortho Pharmaceutical Corporation (Labeler Code 00062) - all contacts are changed.

Dermik Laboratories (Labeler Code 00066) - change to the financial contact.

Rhone-Poulenc Rorer Pharmaceuticals, Incorporated (Labeler Code 00067) - change to the financial contact.

Warner-Lambert Company - Park-Davis (Labeler Code 00071) - change to the technical contact.

Westwood Squibb Pharmaceuticals (Labeler Code 00072) - change to the technical contact.

Rhone-Poulenc Rorer Pharmaceuticals, Incorporated (Labeler Code 00075) - change to the financial contact.

Bristol-Myers Squibb Company (Labeler Code 00087) - change to the technical contact.

3M Pharmaceuticals (Labeler Code 00089) - change to the technical contact.

Hollister-Stier Miles, Incorporated (Labeler Code 00118) - all contacts are changed.

Cutter Biological Miles, Incorporated (Labeler Code 00161) -all contacts are changed.

EON Labs Manufacturing Incorporated, formerly Vitarine Pharmaceuticals, Incorporated (Labeler Code 00185) - change to financial contact.

Purepac Pharmaceutical Company (Labeler Code 00228) - all contacts are changed.

Fluoritab Corporation (Labeler Code 00288) - change to the financial contact.

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

Bausch & Lomb Pharmaceuticals, Incorporated (Labeler Code 00303) - all contacts are changed.

Parmed Pharmaceuticals, Incorporated (Labeler Code 00349) - change to financial contact.

Calgon Vestal Laboratories (Labeler Code 00519) - all contacts are changed.

Lannett Company, Incorporated (Labeler Code 00527) - change to the financial and technical contacts.

Cetus Corporation (Labeler Code 00702) - all contacts are changed.

Pharmaceuticals Basics, Incorporated (Labeler Code 00832) - change to technical contact.

Sherwood Medical Company (Labeler Code 08880) - change to the technical contact.

Warner-Lambert Company (Labeler Code 11370) - change to the technical contact.

Bristol-Myers Squibb Company (Labeler Code 19810) - change to the technical contact.

Pharmafair, Incorporated (Labeler Code 24208) - all contacts are changed.

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

Baxter Healthcare Corporation (Labeler Code 47679) - change to the technical contact.

Sidmak Laboratories, Incorporated (Labeler Code 50111) - change to the financial and technical contacts.

Genderm (Labeler Code 52761) - change to all addresses plus the name of the technical contact.

Adams Laboratories, Incorporated (Labeler Code 53014) - change to the financial and technical contacts.

Warner-Lambert Company (Labeler Code 53592) - change to the technical contact.

Cetus Corporation (Labeler Code 53905) - all contacts are changed.

Makoff R and D Laboratories, Incorporated (Labeler Code 54391) - all contacts plus the telephone area code are changed.

Econolab, Incorporated (Labeler Code 55053) - address change for all contacts.

Genderm (Labeler Code 57284) - all addresses plus the technical contact are changed.

Caraco Pharmaceutical Laboratories, Limited (Labeler Code 57664) - change to financial and technical contacts plus an address change for all contacts.

Bristol-Myers Squibb Company (Labeler Code 57783) - change to the technical contact.

MGI Pharma, Incorporated (Labeler Code 58062) - change to financial contact.

CIBA Vision Ophthalmics (Labeler Code 58768) - all contacts are changed.

Coats Aloe International, Incorporated (Labeler Code 58826) -all contacts are changed.

Pioneer Pharmaceuticals, Incorporated (Labeler Code 60104) - change to financial and technical contacts.

UTILIZATION DATA SET NAMING REQUIREMENTS

Many States are not using the correct data set naming requirements when submitting Drug Rebate Utilization data tapes or cartridges to HCFA. The correct name to use is:

DRUG.REBATE.Uqyy.xx

where **qyy** should be a one position quarter (1 - 4) and two position year (e.g. 91), and **xx** should be the State's two position postal abbreviation. For example, the fourth quarter tape/cartridge for 1991 from Maryland should be named:

DRUG.REBATE.U491.MD

Please ensure that the State entity responsible for the creation of these tapes/cartridges is aware of this requirement.

TAPE/CARTRIDGE RETURN POLICY

When your State agency has completed processing the drug rebate data sent to you by HCFA, do not return the tape/cartridge to HCFA. Please be aware that when HCFA completes processing the utilization data that your State agency sent, the tape/cartridge will not be sent back to you.

UNITS PER PACKAGE SIZE (UPPS) LESS THAN 1.0

The drug product, ACTIMMUNE, marketed by Genentech, Incorporated, is sold in two sizes. One of them (NDC 50242-0052-23) is packaged as a 6 milliliter carton containing 12 doses while the other size (NDC 50242-0052-14) is a 0.5 milliliter package (one dose). By definition, the AMP must be the price per milliliter, which in the case of the one dose (0.5 ML) package, is twice the quantity for that package size. The Unit Rebate Amount is also reflective of the unit type (ML) and is double the rebate amount due for each 0.5 ML package. Therefore, you should be alert to pharmacy billing practices for this drug product and ensure that your invoice for these NDCs reflects the correct amount of milliliters dispensed.

ENTERAL PRODUCTS

Recently, we received a report from a manufacturer that a State is inappropriately invoicing for rebates on the utilization of enteral products. In the situation reported, the State was reporting the utilization of the enteral product by creating an NDC using the manufacturer's labeler code and product stock number.

We are taking this opportunity to reiterate our policy on enteral products that we previously set forth in our Release #14 dated August 15, 1991. Enterals are not covered outpatient drugs; therefore, they are not subject to the Medicaid drug rebate program. While a State may choose to cover enterals under other services in its Medicaid program, they are not subject to rebates under the Medicaid drug rebate program.

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

Christine Nye
Director
Medicaid Bureau

Attachment

Enclosure: Diskette

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

HCFA RECORD SPECIFICATION
MFR INFORMATION
ASCII FLAT FILE FORMAT

Field	*Size*	*Position*	*Remarks*
LABELER CODE	5	1 - 5	
LABELER NAME	39	6 - 44	
EFFECTIVE DATE	6	45 - 50	YYMMDD
LEGAL CONTACT NAME	39	51 - 89	
LEGAL CORPORATION	39	90 - 128	
LEGAL STREET 1	39	129 - 167	
LEGAL STREET 2	39	168 - 206	
LEGAL STREET 3	39	207 - 245	
LEGAL CITY	27	246 - 272	
LEGAL STATE	2	273 - 274	
LEGAL ZIP	9	275 - 283	
LEGAL PHONE NUMBER	14	284 - 297	
FINANCIAL CONTACT NAME	39	298 - 336	
FINANCIAL CORPORATION	39	337 - 375	
FINANCIAL STREET 1	39	376 - 414	
FINANCIAL STREET 2	39	415 - 453	
FINANCIAL STREET 3	39	454 - 492	
FINANCIAL CITY	27	493 - 519	
FINANCIAL STATE	2	520 - 521	
FINANCIAL ZIP	9	522 - 530	
FINANCIAL PHONE NUMBER	14	531 - 544	
TECHNICAL CONTACT NAME	39	545 - 583	
TECHNICAL CORPORATION	39	584 - 622	
TECHNICAL STREET 1	39	623 - 661	
TECHNICAL STREET 2	39	662 - 700	
TECHNICAL STREET 3	39	701 - 739	
TECHNICAL CITY	27	740 - 766	
TECHNICAL STATE	2	767 - 768	
TECHNICAL ZIP	9	769 - 777	
TECHNICAL PHONE NUMBER	14	778 - 791	
CARRIAGE RETURN/ LINE FEED	1	792 - 792	