DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration
Center for Medicaid and State Operations

November 10, 1998

MEDICAID DRUG REBATE PROGRAM - RELEASE #85
TODAY'S NEWS
for State Medicaid Directors

ADDITIONAL UNIT REBATE AMOUNTS (URA) IN 3/1998 FILE

As part of our continual efforts to ensure that the data contained in our master MDRI file is as accurate as possible, we are making several system enhancements over the next 2 or 3 quarters, some of which will be evident when you receive the quarterly files. We have become aware, for example, of the condition in which URAs are missing although pricing data was reported, in a timely manner, so that they should have been available at the time we released the quarterly tapes to you. Included on the quarter 3/1998 file, there will be an increased number of URA records (about 33,500 additional) that will "fill the gaps" (missing URAs) from previous quarters. Some are sporadically interspersed throughout the file, while others will fill an entire quarter for a given labeler code (example is Geneva - Labeler #00781 for qr.. 4/1996). A coding error, causing this condition, was found while doing a thorough "walk-through" of our MDRI programs by our combined operations and systems staffs. Also, beginning with this 3/1998 quarter, URAs will be calculated using fixed decimal (calculate to 7, round to 6) rather than floating-point decimal calculations. This should assist in the problem where some of our URAs may differ from some of the labelers' URAs by a few thousandths of a cent.

As we have more changes for next quarter, we will put them in a state release before the tape goes out. If you have any questions or comments, please contact Vince Powell on (410) 786-3314.

GENENTECH (Labeler 50242) NEW PRODUCT HERCEPTIN (0134-60)

From time to time, new products are introduced to the Drug Rebate Program and, due to specific packaging or dosage reasons, CANNOT be carried and priced through the Medicaid Drug Rebate Initiative (MDRI) master file in accordance with the National Council of Prescription Drug Programs (NCPDP) or the pricing compendia First Data bank/Medi-Span and RedBook. This new product from Genentech, Herceptin, is one of these products.

The "official" Unit Type is ONE (EA)ch Powder-Filled (multi-dose) Vial (PFV) and is priced accordingly. However, because it is not dispensed to one patient only, the dispensing must be reported on a patient-by-patient basis. In order to (CORRECTLY) report the product this way, the units reported would be in Milligrams (MG) which is NOT a valid Unit Type in the Drug Rebate Program.

This product is packaged as a 440 MG PFV with 30 ML of Bacteriostatic water and will be used primarily in a physicians office/clinic or hospital outpatient setting. After discussions with physician groups about this product, it was indicated that physicians would schedule their Herceptin patients on the same day and use the vial on multiple patients to avoid any waste of this expensive medication. The physicians are reluctant to "earmark" a vial for one patient only, as these patients are often extremely sick and may either discontinue therapy or expire before the entire vial could be used on them.

Therefore, ALL Oncologists questioned about their use of this product agree that they will bill Medicaid on the number of milligrams administered for each patient. Considering this and in order to make the pricing and rebate process as simple as possible, we have instructed Genentech to use "EA" (each) as the Unit Type for this product and report prices to us on a PER MG basis, thus 1 EA would = 1 MG. The Units Per Package Size (UPPS) field would equal 1 and the state would multiple the number of "eachs" reported on the script by the UPPS (which is 1) and would report the correct number of units (Milligrams) in its utilization field.

Any questions or comments may be directed to Vince Powell on (410) 786-3314. If you wish to speak to a Genentech representative, please call Linda Schock at (800) 626-3553 x-52115.

STATE PHARMACY POINT-OF-SALE (POS) SYSTEM

Over the past several months, we have been hearing more and more about states putting in (or getting ready for) POS systems. There is much excitement about this upgrade in the pharmaceutical community, as it will assist in decreasing costs, increasing accuracy and speeding service to the Medicaid Recipients. It has come to our attention, however, that some of these may be outside of the guidelines set forth by HCFA at the inception of the Drug Rebate Program and continue to be used today with no changes. This is causing us some concern and, in cases where your POS system may fall outside these guidelines, you will be responsible for making system changes to bring it back in line within our minimum standards.

When a state makes a utilization correction for a prior quarter, it MUST be able to identify and adjust the utilization from that quarter. There are POS systems that only make adjustments in the current quarter (using signed fields) and do NOT have the ability to identify the quarter in question nor the actual correct number of units the correction is for. HCFA policy has stated, from the beginning, that signed fields may ONLY be used between the state and labeler when it is acceptable by BOTH parties and used uniformly each and every quarter between that state and that labeler only and that correction records must have an audit trail back to the original utilization claim (and URA value) that it is correcting. Signed fields may NEVER be used when reporting utilization corrections to HCFA. Utilization corrections also must indicate the quarter for which the correction is made and URA values from the corrected quarter in conjunction with the adjusted units.

An example that shows how an incorrect POS system works is as follows:

> In qr.. 1/98, the state received pharmacy claims and paid for 2 units, 2 units, 200 units and 2 units. The state invoiced (and received a rebate from) the labeler for 206 units. In qr.. 3/98, it was discovered that the 200 units (from 1/98) were wrong and should have been 2 units. Utilization for this quarter was 2 units, 2 units, 4 units and 2 units. The State, therefore, this qr.. invoices for a minus (-) 188 units (+2, +2, +4, +2 and the corrected +2 as well as the -200 from 1/98) and uses current qr.. URA only, making no corrections for the actual quarter that the adjustment is for. Also, because the state duplicates the NDC summary record for the file it supplies to HCFA, the HCFA file will now contain a signed field.

If you are in the process of installing, or already have, a POS system that fits the above incorrect example, please be aware that this is not within the framework of the Drug Rebate Program guidelines and is not acceptable by HCFA. Please contact Vince Powell on (410) 786-3314 if you have any questions or comments.

NEW SYSTEMS TECHNICAL ADVISORY GROUP (S-TAG)

Since the beginning of the Drug Rebate Program, we have sponsored an S-TAG which focused primarily on drug rebate issues. Meeting monthly in a teleconference mode, the S-TAG worked diligently in solving and resolving problems associated with "growing pains" of this gigantic program. Needless to say, over the years the S-TAG has been an overwhelming success. The appreciation of all of us here at HCFA goes to all that participated and persevered over the years. Your hard work and dedication made the S-TAG a complete success. It is with mixed emotions that we bring the current S-TAG to a close.

We are now ready to tackle the issues surrounding the Dispute Resolution Project (DRP) and are asking for volunteers to be part of a new S-TAG. We are seeking participants for this S-TAG who have experience with the DRP, but also would like a few members that as yet have not been able to participate in the DRP process. In addition to assisting in the resolution of DRP issues, all S-TAG participants will be expected to attend a monthly teleconference and keep the States in your "region" apprised of the DRP issues and any S-TAG decisions.

If you are interested in serving on the new S-TAG please contact Vince Powell at (410) 786-3314.

INTERNET DELETIONS

Effective immediately, we are deleting two items from our INTERNET site. The first is the State Technical Contact list. This list is no longer in a format compatible with the INTERNET. Please be sure that your invoices to the labelers contain the name, address, and telephone number of the contact person.

Second, the Drug Rebate Operational Training Guide is no longer available on the INTERNET. This material also has become incompatible with the INTERNET due to the graphics it contains. The guide is still in use and updates will continue to be issued through the drug rebate releases, as necessary.

TRAINING GUIDE UPDATES

Attached are the latest updates to the Medicaid Drug Rebate Operational Training Guide. Please share the updates with all staff involved in the program and replace these pages in your guide.

REINSTATED LABELER

Consolidated Pharmaceutical Group, Inc. (Labeler Code 61423) has submitted missing drug prices for all quarters and signed a new rebate agreement. They will be reinstated in the drug rebate program effective January 1, 1999.

NEW LABELER

The following labeler has entered into a drug rebate agreement and is joining the rebate program effective January 1, 1999:

Boca Pharmacal, Inc. (Labeler Code 64376).

TERMINATED LABELER

The following labeler is being terminated effective January 1, 1999:

Pharmaderm, Div. of Altana, Inc. (Labeler Code 00462).

OTHER ATTACHMENTS

A copy of the topic index and a current listing of the 90-day treasury bill auction rates beginning with the period September 15, 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.

/s/

Sally K. Richardson
Director

3 Attachments

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid