DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Center for Medicaid and State Operations

November 20, 1998

MEDICAID DRUG REBATE PROGRAM RELEASE #38

TODAY'S NEWS for Participating Drug Manufacturers

TENNESSEE BEHAVIORAL HEALTH PHARMACY BENEFIT

Tennessee's waiver-only demonstration of its Medicaid program was approved under the authority of section 1115 of the Social Security Act (the Act) on January 1, 1994. Under this waiver, Medicaid beneficiaries received drugs through capitated managed care settings and the cost of these drugs were included in the capitated payment. Therefore, a rebate under section 1927 of the Act was prohibited for these drugs.

Effective July 1, 1998, the Tennessee State Medicaid Agency will no longer administer the pharmacy benefit for TennCare Partners Program through the Behavioral Health Organization as part of the capitation payment system. The State will maintain the administration of their behavioral health drugs and payment will be on a fee-for-service basis. As a result of this change, beginning July 1, 1998, a rebate under section 1927 of the Act is required for the covered outpatient drugs provided under this program. [Reminder: Prices to capitated managed care entities are included in Best Price (BP) calculations, but not in Average Manufacturer Price (AMP) calculations. However, Medicaid rebates under section 1927 of the Act, including those rebates for the drugs paid for under Tennessee's fee-for-service arrangement described in this paragraph, are not included in either BP or AMP calculations.]

Questions concerning Tennessee's pharmacy benefit for TennCare Partners Program may be directed to the following State contacts:

Jeff Stockard (615) 532-3107
Billy Moates (615) 741-0213.

QUARTERLY PRICING DATA

Quarterly pricing data, including baseline data on new products, baseline changes to already established NDCs, and pricing corrections for previous quarters, is to be delivered to HCFA within 30 days after the end of each calendar quarter. It was not HCFA's intention to have this interpreted as postmarked by day 30 after the end of a quarter. When the data starts arriving at HCFA, there is a lot of work done to assure its accuracy. When errors are detected and data is rejected, edit reports are sent out as soon as possible to allow labelers to make corrections and turn them around before we "shut down" the system to generate unit rebate amounts (URAs) for the state tapes.

It appears that more and more labelers are waiting until the last minute to supply quarterly data to us. There are times when data gets to us late; however, these times should be the exception, rather than the norm. We do everything possible to get all the data in the quarterly run that we receive. Once we shut down, however, it is impossible to have data received after that time included on that quarter's tape.

It is the responsibility of the labeler to get the data to HCFA in a timely manner. If your data is not received in time and, therefore, missing from that quarterly run, it is the responsibility of the labeler to compute the URA for each NDC and update that field on every State invoice. When an invoice is received with zeros in the URA field, it DOES NOT mean that you do not owe rebates for that NDC. It means that you must calculate the URA and include the updated amount on the Reconciliation of State Invoice (ROSI) to the State and reflect the additional rebate payment in the check. Please do everything possible to assure that your quarterly data is reported to us no later than the statutory 30-day required time frame. This will cut down on the number of zero URAs we send to the states and will cause less confusion to both you and the states when attempting to reconcile rebate claims.

QUARTERLY PRICING - ZERO AND/OR NEGATIVE AMOUNTS

Due to the recent questions we've received on this topic, we are reiterating information on quarterly AMP pricing when the calculation for the AMP causes it to result in a value of zero or a negative amount. Values of zero or negative amounts are generally due to extraordinarily high chargebacks, adjustments, discounts, rebates (other than for this program). Fluctuations to AMP, due to these circumstances, are expected on occasion. In order to minimize occurrences of zero and/or a negative AMP, all factors affecting AMP from previous quarters should be allocated to the proper quarter. Alternatively, if a zero and/or a negative amount occurs in a given quarter, the value to be reported to HCFA is the last calculated AMP that was valid. In other words, the AMP that is reported is the last calculated AMP that was a valid value greater than zero. However, zero and negative AMP amounts should never be reported. Questions regarding this issue should be directed to Vince Powell on (410) 786-3314.

BUYING INNOVATOR PRODUCTS FOR RESALE

We have had several questions regarding the purchase and repackaging of innovator products and how they must be reported to HCFA. As previously stated in Manufacturer Release Number 26, Baseline information, such as Market Date and Baseline AMP MUST follow the NDA of the product. It DOES NOT follow the NDC of the product. If one manufacturer purchases an innovator product from another separate manufacturer (i.e., a manufacturer outside the selling manufacturer's corporate structure) and repackages it under the buyer's NDC, the buyer needs to establish this new NDC with the Market Date and Baseline AMP equal to that of the innovator. The Drug Category, likewise, needs to be set to "I"; NOT "N." When the buyer purchases this product, it should be with the understanding that the selling manufacturer will provide the buyer with the Market Date and Baseline AMP equal to the seller's.

Also, Therapeutic Equivalency, Product Name, Drug Type and Unit Type should be the same for multiple package sizes of the same product. Similarly, the unit type for multiple package sizes of the same product should be the same, e.g., "ML" or "GM." Also, one package size cannot be designated as Rx and another as OTC.

Please remember that the buyer is responsible for obtaining these data from the selling manufacturer before establishing the product under the buyer's NDC.

RECALCULATING UNIT REBATE AMOUNTS (URA)

This is to remind labelers about their responsibility for recalculating incorrect URAs on State invoices. Incorrect URAs include those containing actual values (but not current), as well as those with zero dollar values. It is your responsibility to calculate the correct URA and report that URA to the State along with your quarterly rebate payment.

Zero URA values should not be ignored by labelers. Zero dollar values on an invoice do not mean that you do not owe a rebate on that NDC. Failure to properly pay under this circumstance will cause you to owe interest when payment is finally made, or, if payment remains unpaid the result could be termination from the program.

When you receive an invoice with incorrect or zero values in the URA fields it is an indication that one of the following conditions has occurred.

1. You did not submit pricing data/timely data to HCFA for the quarterly URA calculation and inclusion on the State file.
2. Your pricing data was supplied to HCFA but rejected, and you did not get your corrected pricing data to HCFA before the deadline.
3. Your pricing data was submitted/accepted by HCFA but caused an exception on the 50/50 report.

Please remember that regardless of the cause for an incorrect or zero URA on an invoice, it is YOUR RESPONSIBILITY to recalculate the URA and report that URA to the State along with the rebate payment using the ROSI form. In addition, the recalculation of the URA as a result of any corrections for prior quarters to your AMP/BP, Baseline AMP, and/or Market Date is YOUR RESPONSIBILITY and must be reported to the State immediately using the Prior Quarter Adjustment Statement.

Please note that States should not use the prior period adjustments (PPAs) sent by HCFA to adjust their invoices to you, but only to verify that a URA change from the labeler matches the URA change sent from HCFA. Any PPAs on a State invoice may be disregarded by the labeler. However, as noted above, you are responsible for recalculating URAs as a result of PPAs and for making the appropriate rebate payment(s).

The material discussed above is covered in the Drug Rebate Operational Training Guide in sections F, G, and J. Questions or comments should be directed to Vince Powell on (410) 786-3314.

MDRI DISKETTE USERS

Each quarter we receive diskettes that have no data files on them. We contact these companies and ask for a new diskette and assurance that the data files have been properly generated BEFORE sending them to us. This causes many hours of lost time for both you and us. Therefore, we are asking that after you generate the quarterly product/pricing files, you assure that the files are ACTUALLY on the diskettes BEFORE sending them to us. The easiest way to do this is to do a DIRECTORY (DIR A:) of the diskette AFTER it is downloaded and before sending to us. Questions regarding this should be directed to Judy Allison on (410) 786-3330 or Vince Powell on (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. The State invoices you receive should 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.

OTHER ATTACHMENTS

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

Sally K. Richardson
Director

cc:
All Regional Administrators
All Associate Regional Administrators, Division of Medicaid