DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, Maryland 21244 -1850

June 26, 2007

MEDICAID DRUG REBATE PROGRAM **Release No. 78**

Bulletin

For
Participating Drug Manufacturers

MANUFACTURER ASSUMPTIONS FOR MONTHLY AMP METHODOLOGY

We have received numerous questions regarding whether a manufacturer can make assumptions with respect to monthly AMP methodology in the absence of specific guidance in the Social Security Act or Federal regulations, and if so should those assumptions for the monthly AMP methodology be submitted to CMS?

In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculation of AMP (monthly & quarterly) and Best Price, consistent with the general requirements and intent of section 1927 of the Act, Federal regulations and the Medicaid Drug Rebate Agreement.

We request that manufacturers not submit their assumptions for the monthly nor quarterly AMP and Best Price methodology to CMS. However, a record (written or electronic) outlining these assumptions must be maintained by the manufacturer in accordance with the recordkeeping requirements in 42 CFR § 447.534. Should a manufacturer disregard these instructions and submit such assumptions, they will not be reviewed and their receipt should not be considered as acquiescence by CMS to the submitted assumptions.

GUIDANCE ON AVERAGE MANUFACTURER PRICE (AMP) AND BEST PRICE (BP) METHODOLOGY RECALCULATIONS

We have received requests from manufacturers with pending recalculation submissions that CMS authorize prospective changes in the methodology used, by the manufacturer to calculate Average Manufacturer Price (AMP) and/or best price. Effective immediately, a manufacturer with a pending recalculation request may implement the revised pricing methodology on a prospective basis beginning with the date it notified us of the recalculation.

Additionally, a manufacturer with a new recalculation request regarding AMP and/or best price (submitted to CMS after the date of this release) may proceed with implementing the revised pricing methodology on a prospective basis without further review by CMS. We continue to request that manufacturers notify CMS and receive authorization in advance of any retroactive change in the method used to calculate their AMP and/or best price, along with revised AMP and/or best price data for the drugs affected, the relevant 11-digit NDC numbers, the fiscal magnitude of the change, and a statement as to the reason for the change in methodology.

As in the case with all pricing data submitted under the Medicaid drug rebate program, if a subsequent review of a manufacturer's methodology for calculating AMP and/or best price or other pricing data by CMS, by the Office of Inspector General, or another authorized government agency determines or reveals that additional adjustments or revisions are necessary, the manufacturer should comply with that determination. Additionally, in accordance with Section 1927 and Federal regulations at 42 CFR § 447.534, manufacturers must maintain records (written or electronic) for 10 years from the date the manufacturer reports data (or reports revised pricing data) to CMS for that rebate period, including the reported data, and any other materials from which the calculations of AMP and BP are derived, as well as any assumptions made in the calculations. A manufacturer must retain records beyond the 10-year period if they are the subject of an unresolved audit or government investigation of which the manufacturer is aware relating to pricing data that are used in AMP or BP.

CMS is not expressing an opinion in advance of the prospective recalculation as to whether the revised pricing calculation is consistent with the methodology set forth in the statute and rebate agreement. CMS's receipt of revised pricing data or a recalculation request (or any acknowledgment of such receipt) is not, and may not be considered to be, an advisory opinion under Section 1128D (b) of the Social Security Act, since only the Inspector General of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under that section. Further, CMS's receipt of revised pricing data or a recalculation request is not a release of any liability.

NEW REBATE INDICATOR FOR SOME ZERO URAs

The 1Q2007 product and pricing data collection was the first quarterly collection using the new DDR system. There were some glitches in the transfer of data from DDR to MDR that incorrectly caused some URAs to calculate as zero.

Labelers are required to calculate their own URAs when one is not supplied by CMS to the states; however, in some limited circumstances, CMS may choose to provide missing URAs for

labeler convenience using a new rebate indicator 7. Labelers that received zero URAs for 1Q2007 may check in DDR to see if their zero URAs were supplied with the new indicator. In the event the URAs are still not reflected in DDR, labelers should calculate their own URA and use the ROSI to remit for 1Q2007 invoices. The 1Q2007 URAs will be loaded to DDR if the pricing data for that quarter is valid and submitted prior to the 2Q2007 rebate calculation.

NEW LABELER REBATE DATA GUIDE AVAILABLE SOON IN DDR

The new Medicaid Drug Rebate Data Guide for Labelers will be available as a download in DDR soon. This guide was developed for and is intended for use by labeler Technical Contacts and/or their designees that report data to CMS; therefore, Operations staff will respond to questions from those parties that have been granted access to DDR. CMS will post an alert on the Bulletin screen announcing the availability of the new guide.

EXCEPTION TO URA ROUNDING

CMS began rounding the URAs to the 4th decimal place and padding the 5th and 6th decimal places with zeros in 1Q2001. It has come to our attention that URAs occasionally calculate to zero due to very low AMPs. Some labelers would calculate their URA and submit a rebate payment to the states in these instances; however, we heard from states that some labelers do not pay anything in these cases even though the states have utilized their drugs.

Beginning with the 2Q2007 rebate calculations, CMS will not round the URA when the AMP submission is low enough to result in a URA of zero. In the event a state's invoicing system cannot accommodate this change, the state may continue to bill these URAs at zero and the labeler should manually calculate the URA and/or obtain the non-rounded URA from DDR and pay states using the ROSI form.

COMING SOON: NEW DATA FIELDS

DDR was designed, in part, to help labelers comply with their rebate agreement by letting the labeler know, by NDC, which required data is missing each quarter. Due to the short regulatory time frame in which to design, test and implement DDR, some features have not yet been implemented. One of these features is a new, optional product data field: Purchased Product Date. This field will allow labelers to input a date on which they purchased a product so that DDR will not require pricing from periods earlier than that date. Currently, pricing owed by a labeler is tracked from the Market Date of the NDC, which does not consider products purchased from another labeler.

A similar data field will be added to the product reporting area of DDR, Package Size Intro Date. This date will be required when a new package size is added so that the labeler will not be shown as out of compliance for monthly periods prior to a package size's introduction to the market. The DDR User's Guide will be updated with new product record layouts to reflect the addition of these data fields when this change is implemented. A CMS alert will also be posted on the Bulletin screen in DDR to remind labelers when the new data fields are available.

CPI TO THREE DECIMAL PLACES

Beginning with the Consumer Price Index (CPI) for January 2007, the Bureau of Labor Statistics, Department of Labor, is publishing the CPI to three decimal places. Prior to January, the CPI had been published to one decimal place. This change should have a negligible effect on the additional rebate calculation for S and I drugs. CMS systems changes have been made and the expanded CPI will be used in the 2Q2007 rebate calculations.

Please direct your drug rebate data questions to MDROperations@cms.hhs.gov.

/s/

Edward C. Gendron
Director
Finance, Systems and Budget Group

2 Attachments

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

WEEKLY U.S. T-BILL INVESTMENT RATE

Weekly 91-day Treasury Bill Auction Rates

Date of Auction	Invest. Rate		Date of Auction	Invest. Rate		Date of Auction	Invest. Rate
10-03-05	3.606		05-01-06	4.807		12-04-06	4.999
10-11-05	3.714		05-08-06	4.864		12-11-06	4.926
10-17-05	3.875		05-15-06	4.864		12-18-06	4.952
10-24-05	3.942		05-22-06	4.828		12-25-06	5.004
10-31-05	3.983		05-30-06	4.843		01-01-07	5.062
11-07-05	3.963		06-05-06	4.833		01-08-07	5.072
11-14-05	4.004		06-12-06	4.926		01-15-07	5.108
11-21-05	4.034		06-19-06	4.958		01-22-07	5.129
11-28-05	3.994		06-26-06	5.036		01-29-07	5.145
12-05-05	4.025		07-03-06	5.088		02-05-07	5.145
12-12-05	3.911		07-10-06	5.056		02-12-07	5.160
12-19-05	3.988		07-17-06	5.098		02-19-07	5.171
12-26-05	3.999		07-24-06	5.108		02-26-07	5.185
01-02-06	4.169		08-07-06	5.124		03-05-07	5.112
01-09-06	4.252		08-14-06	5.114		03-12-07	5.112
01-17-06	4.377		08-21-04	5.109		03-19-07	5.075
01-23-06	4.397		08-28-06	5.093		03-25-07	5.070
01-30-06	4.485		09-04-06	4.984		04-02-07	5.055
02-06-06	4.485		09-11-06	4.947		04-09-07	5.023
02-13-06	4.553		09-18-06	4.942		04-16-07	5.008
02-21-06	4.563		09-25-06	4.895		04-23-07	4.976
02-27-06	4.625		10-02-06	4.890		04-30-07	4.924
03-06-06	4.615		10-09-06	4.978		05-07-07	4.898
03-13-06	4.625		10-16-06	5.072		05-14-07	4.867
03-20-06	4.662		10-23-06	5.124		05-21-07	4.914
03-27-06	4.610		10-30-06	5.108		05-28-07	4.919
04-03-06	4.651		11-06-06	5.088		06-04-07	4.846
04-10-06	4.688		11-13-06	5.088		06-11-07	4.773
04-17-06	4.719		11-20-06	5.071		06-18-07	4.617
04-24-06	4.755		11-27-06	5.036		06-25-07	4.820

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