



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 4<sup>th</sup> decimal place and padding the 5<sup>th</sup> and 6<sup>th</sup> 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](mailto: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

<b>Date of Auction</b>	<b>Invest. Rate</b>	<b>Date of Auction</b>	<b>Invest. Rate</b>	<b>Date of Auction</b>	<b>Invest. Rate</b>
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	08-21-06	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

## TOPICAL INDEX – DRUG LABELER RELEASES 1 - 78

TOPIC	RELEASE #
340B Program	46, 51
50% Rebate Cap - Technical Amendment Passed	07
400/400 Edit Reports	75
Adding New Package Sizes to Existing Products	09
Additional Rebate Calculation Revision	10
Address Change (Express Mail)	70
Adjustment Code for CMS-304 & CMS-304a	21, 77
Adjustments that Cause Rebate Corrections	26
Administrative Fees' Effect on AMP & BP	14
Anthrax/Delay of 3/2001 Data	53
Average Manufacturer Price (AMP)	
BP/Upps Clarification	03
Additional Guidance - AMP calculation	29, 31
Calculation Methodology Revision	14, 61, 78
For Terminated Drugs	07
Hemophilic Drugs Clarification	11
Monthly AMP Methodology (Assumptions)	78
Multiple Package Size	43
AMP/BP, Calculating for Different Quarters	07
AMP/BP Calculations-Pharmacy Benefit Managers (PBMs)	28-29
AMP Recalculations	78
Backup Drug Rebate Library	73
Baseline Change Resulting from OBRA of 1993	13, 15
Batch Edit Report Summary Sheet E-mailed	65
Best Price (BP)	
340B Covered Entities	51
Calculation Methodology Revision	78
Calculation (VHCA)	06
DSH Covered Entities	11
Effect of Sales to HMOs, etc.	47, 68
Exclusions	07
MPDIMA of 2003	63
TennCare	11, 38
Versus Average Manufacturers Price	15
Buying Innovator Products for Resale	26
Buying/Selling Products	70
Closure During Federal Furloughs	21
CMS R-144 (State Invoice) – Changes	75
Common Data Errors	02
Contact Information/Ownership Changes	04, 06, 17, 21, 33, 63
CPI-U Rounding	78
CPI-U Values	22, 48
Data Definition Update	04, 10
Data Edit Reports	
Batch Edit Reports/Maintaining Backup Files	73
Revised Cover Letters	73
Data File Update	02
Data Requests	59

## TOPICAL INDEX – DRUG LABELER RELEASES 1 - 78

TOPIC	RELEASE #
Deficit Reduction Act of 2005 (DRA)	76
Depot Prices	03
Depot Prices-TRRx	69
DESI -	
Codes	09
Field Changes	15
Indicator Change	03-04
Program Overview	04
Discounts/Price Arrangements	02
Diskette Program/Data File (New)	5, 53
Diskette Users	07, 33, 38, 53
WINDOWS Version Only	25, 27
Dispute Resolution Issues	24, 26, 31, 39
E-Mail Address	62
Meetings	63, 65, 67, 70, 72, 77
Transfer of Function	58
Web Site	59
Workgroup Survey Results	13
Drug Category Change	23
Drug Data Reporting for Medicaid (DDR)	76
Package Size Intro Date	78
Purchase Product Date	78
Drug Product Deletions/Reporting Requirements	04, 30, 45
Drug Product Information Changes	03, 30, 45
Duplicate Payment Prevention (VHCA)	06
E-Mail Address for Operational Questions	72
E-Mail Address for Technical Questions	60
Failure of Manufacturers to Notify States of	
Disputes or Pay Rebates	24
FDA Approval Date	09, 73
FDA Date Submission for OTC Drugs	10
FDA/MDRI Data Match	51, 52, 54, 55
Hands-On Training	22, 23
Heparin/Saline Flush Syringes & Other Non-Drug Products	66
HIPPA – Prescription Numbers	59
Hotline	11, 18
Improper Rebate Withholding/Interest Implications	54
Individual Co-Payments or Insurance Payments	06
Information Sharing	21
Inner/Outer NDC Numbers (reporting)	71
Innovator Products, Buying for Resale	38
Interest Calculation under Section V(b)	07, 40, 46
Interest:	
Failure to Pay	26, 40
When PPAs are Submitted	58

## TOPICAL INDEX – DRUG LABELER RELEASES 1 - 78

TOPIC	RELEASE #
Internet:	
Home Page	38, 50, 56, 72
Prescription Reimbursement Information	59
Pharmacy Plus Demonstrations	59
Invoice/Remittance Advice Report Survey	10
Invoicing for State Pharmacy Assistance Programs	57
Labeler Codes - Addition Procedures	13
Late Data Submissions	04, 09, 53
Mailing Pricing Data\Other Correspondence to CMS	06, 17, 21, 36
Market Date	09, 73
MDR Technical E-mail Address	60, 69
Medicaid Drug Rebate Data Guide for Labelers	78
Minimum Rebate Percentage & Rebate Cap (VHCA)	06, 07
Multiple Package Sizes	57
New Diskette Program/Data File	05
New Package Size Reporting	51
OIG Review	57
Omnibus Budget Reconciliation Act of 1993	09
Parenteral/Enteral Products	02
Partial Rebate Payments	19
Personnel Changes	60, 65, 71
Pharmacy Benefit Managers (PBMs)	28, 30
Pharmacy Plus Demonstrations Webpage	59
Policy E-Mail Address	53, 56
Powder-Filled Vials, Ampules, & Syringes	11
Prescription Reimbursement Information Website	59
Prior Authorization	19
Prior Period Adjustment Processing	19
Prior Quarter Adjustment Statement (PQAS) Approval	22
Prior Quarter Adjustment Statement Form Use	27, 32, 62
Proposed Discount Equal Access Legislation	16
Public Health Service Drug Pricing Program	13
Publication of Drug Rebate Regulations CMS-2175-FC	61
Quarterly Pricing Data	
Notification of Receipt	63
Requirements	02-03, 07, 08, 12, 38
Revisions/Updates (diskette and telecommunication)	69
Questions and Answers	26
Rebate Agreement: Optional Effective Dates	46
Rebate Percentages for 1994	12
Rebates for Drugs Purchased Through the FSS	53
Rebates on OTC Drug Product	06
Rebate/Reimbursement Issues	25, 31, 54
Recalculation Requests	76,78
Reconciliation of State Invoice (ROSI) Approval	22, 26
Reconciliation of State Invoice Form Use	27, 32, 62
Recordkeeping Regulations	63
Regulation (CMS-2175-F)	67



## TOPICAL INDEX – DRUG LABELER RELEASES 1 - 78

TOPIC	RELEASE #
Regulation (CMS-2238-P)	76
Regulations, Publication of Proposed	19
Re-Introducing a Product to the Market	73
Remittance Advice Report (RAR)	07, 15-16, 20
Remittance Advice Report Implementation Workgroup	17-18
Reporting NDCs for Generic Products	04
Re-Use of NDCs	51, 73
Selling Products to Another Labeler	43, 48
Separate Rebate Agreements with States	11, 48, 53
Shelf Life	03, 31
Staff Relocation	16, 35, 36, 37
State Issues	
Hearing Process	13
Rebate Payments	03
Remittance Advice Contacts	09
State Pharmacy Assistance Programs-Revised Criteria	59, 68, 73
State/R.O. Drug Rebate Contact Persons	06, 08, 17, 46
T-bill Rates	37, 39, 65
Technical Contacts	62
Tennessee Behavioral Health Pharmacy Benefit	38
Termination Appeal Process	11
Termination Dates	31, 48
Termination From Program	19
Therapeutic Equivalency Code	25-26
Tolerance Threshold for Interest	15
Training Guide Obsolete	77
Unique Medicaid Factors & Rebate Disputes	14
Unit-Dose Packaging	04
Unit Rebate Amount Discrepancy Report	37
Unit Rebate Calculation (URA)	02, 78
New CMS Edits	13
Recalculations	24, 38
Recalculations for Incorrect URAs for 1Q98	35, 36
Rounding Method Change	46, 47, 48, 51, 78
Discrepancy Report	34
Unit Type	
Convert to NCPDP 7 plus add AEACH@(EA)	13
Conversion Date Change	09
EACH	73
Specification Changes	06, 08
Updated Version of Diskette Program/Sterling Reporting	67
Utilization Adjustments	22
VA Appropriations Act	03
Vermont Rebate Invoices	23
Veterans Health Care Act of 1992 (VHCA)	06
Virus Transmission Via Diskette	16, 18
Vitamins	30
Y2K	32, 33, 34

**TOPICAL INDEX – DRUG LABELER RELEASES 1 - 78**

**TOPIC**

**RELEASE #**

---