

September 23, 2003

MEDICAID DRUG REBATE PROGRAM

RELEASE #126

For State Medicaid Directors

CMS-2175-FC: REGULATION ISSUED AUGUST 29, 2003

On August 29, 2003, CMS issued a regulation entitled Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program. This rule establishes two provisions pertaining to the Medicaid drug rebate program. The first provision establishes manufacturer recordkeeping requirements. Manufacturers must retain pricing records for three years from the date the manufacturer reports that data to CMS. Manufacturers must retain records beyond three years if the records are the subject of audit findings or a government investigation or if the audit findings or investigation have not been resolved. The second provision establishes a timeframe for reporting revised average manufacturer price (AMP) or best price to CMS. Manufacturers must report revisions to AMP or best price for a period not to exceed 12 quarters from the quarter in which the data were due.

The statute and Medicaid Drug Rebate Agreement require manufacturers to report data on AMP and best price for all covered outpatient drugs within 30 days following the last day of each quarter. Adjustments to AMP or best price for prior quarters up to twelve quarters after the quarter in which the data were due shall also be reported on the same basis, within 30 days following the last day of each quarter. Requests for changes to AMP or best price for a period in excess of twelve quarters after the quarter in which the data was due will no longer be accepted by CMS as of the effective date of this rule. This limitation does not apply to completed requests for changes to AMP or best price for a period in excess of

twelve quarters that are received by CMS prior to the effective date of this rule. However, requests in excess of twelve quarters that are received after the effective date of this rule will not be considered for review and the manufacturer will not have the opportunity to submit additional documentation.

For a manufacturer's request for recalculation of AMP or best price to be considered by CMS, it must include supporting documentation for the recalculation. This documentation is specified by CMS in the Medicaid Drug Rebate Program Manufacturer Releases No. 14 (December 21, 1994), "Notice to HCFA of Revised Average Manufacturer Price (AMP) Calculation Methodology" and No. 29 (June 5, 1997), "Additional Guidance on Average Manufacturer Price (AMP) Calculations." In accordance with those releases, manufacturers must provide the following documentation to CMS:

- Justification for the change in methodology
- The methodologies used to originally calculate the reported AMPs or best prices
- The revised methodologies used for the proposed recalculations
- The fiscal magnitude of the changes
- Documentation to support the changes
- Whether these changes are retrospective and/or prospective
- The quarters affected by the recalculation

Manufacturers must maintain adequate documentation to support the recalculation request and make the documentation available to CMS or, if necessary, the Office of Inspector General (OIG) or another authorized government agency upon request. CMS will acknowledge receipt of the proposed recalculation and notify the manufacturer when the revised pricing data for the specified quarters may be submitted. Manufacturers are not to submit any recalculated AMP or best price data until notified in writing to do so by CMS.

As is the case with all pricing data submitted under the Medicaid drug rebate program, if a subsequent review of the manufacturers' pricing data by CMS, the OIG, or another authorized government agency determines or reveals that adjustments or revisions are necessary irrespective of the quarter, the manufacturer is bound under the statute and the Medicaid Drug Rebate Agreement to comply with that determination.

TERMINATED LABELER

The following labeler code is being voluntarily terminated effective January 1, 2004:

Pecos Pharmaceutical (Labeler Code 59879).

ATTACHMENT

A copy of the current listing of the 90-day treasury bill auction rates beginning with the period April 22, 2002, is 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/

Wayne Smith
Acting Director
Finance, Systems and Budget Group
Center for Medicaid and State Operations

Attachment

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

WEEKLY U.S. T-BILL DISCOUNT RATE
 weekly 90-day treasury bill auction rates

Date of Auction	Discount Rate	Date of Auction	Discount Rate	Date of Auction	Discount Rate
04-22-02	1.720	11-18-02	1.227	06-16-03	0.854
04-29-02	1.760	11-25-02	1.228	06-23-03	0.830
05-06-02	1.773	12-02-02	1.231	06-30-03	0.903
05-13-02	1.781	12-09-02	1.215	07-07-03	0.907
05-20-02	1.760	12-16-02	1.219	07-14-03	0.895
05-28-02	1.760	12-23-02	1.207	07-21-03	0.911
06-03-02	1.752	12-30-02	1.207	07-28-03	0.964
06-10-02	1.752	01-06-03	1.207	08-04-03	0.964
06-17-02	1.732	01-13-03	1.199	08-11-03	0.960
06-24-02	1.712	01-21-03	1.179	08-18-03	0.964
07-01-02	1.719	01-27-03	1.159	08-25-03	0.997
07-08-02	1.724	02-03-03	1.175	09-02-03	0.988
07-15-02	1.712	02-10-03	1.171	09-08-03	0.951
07-22-02	1.692	02-18-03	1.179	09-15-03	0.947
07-29-02	1.712	02-24-03	1.195	09-22-03	0.953
08-05-02	1.627	03-03-03	1.198		
08-12-02	1.659	03-10-03	1.077		
08-19-02	1.659	03-17-03	1.137		
08-26-02	1.661	03-24-03	1.174		
09-03-02	1.639	03-31-03	1.121		
09-09-02	1.676	04-07-03	1.158		
09-16-02	1.692	04-14-03	1.186		
09-23-02	1.639	04-21-03	1.182		
09-30-02	1.566	04-28-03	1.141		
10-07-02	1.615	05-05-03	1.117		
10-15-02	1.659	05-12-03	1.089		
10-21-02	1.696	05-20-03	1.040		
10-28-02	1.578	05-28-03	1.121		
11-04-02	1.433	06-02-03	1.133		
11-12-02	1.211	06-09-03	1.024		

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