September 23, 2003

MEDICAID DRUG REBATE PROGRAM RELEASE #61

For
Participating Drug Manufacturers

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.

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

Attachment

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

WEEKLY U.S. T-BILL DISCOUNT RATE

weekly 90-day treasury bill auction rates

Date of Auction	Discount Rate
04-22-02	1.720
04-29-02	1.760
05-06-02	1.773
05-13-02	1.781
05-20-02	1.760
05-28-02	1.760
06-03-02	1.752
06-10-02	1.752
06-17-02	1.732
06-24-02	1.712
07-01-02	1.719
07-08-02	1.724
07-15-02	1.712
07-22-02	1.692
07-29-02	1.712
08-05-02	1.627
08-12-02	1.659
08-19-02	1.659
08-26-02	1.661
09-03-02	1.639
09-09-02	1.676
09-16-02	1.692
09-23-02	1.639
09-30-02	1.566
10-07-02	1.615
10-15-02	1.659
10-21-02	1.696
10-28-02	1.578
11-04-02	1.433
11-12-02	1.211

Date of Auction	Discount Rate
11-18-02	1.227
11-25-02	1.228
12-02-02	1.231
12-09-02	1.215
12-16-02	1.219
12-23-02	1.207
12-30-02	1.207
01-06-03	1.207
01-13-03	1.199
01-21-03	1.179
01-27-03	1.159
02-03-03	1.175
02-10-03	1.171
02-18-03	1.179
02-24-03	1.195
03-03-03	1.198
03-10-03	1.077
03-17-03	1.137
03-24-03	1.174
03-31-03	1.121
04-07-03	1.158
04-14-03	1.186
04-21-03	1.182
04-28-03	1.141
05-05-03	1.117
05-12-03	1.089
05-20-03	1.040
05-28-03	1.121
06-02-03	1.133
06-09-03	1.024

Date of Auction	Discount Rate
06-16-03	0.854
06-23-03	0.830
06-30-03	0.903
07-07-03	0.907
07-14-03	0.895
07-21-03	0.911
07-28-03	0.964
08-04-03	0.964
08-11-03	0.960
08-18-03	0.964
08-25-03	0.997
09-02-03	0.988
09-08-03	0.951
09-15-03	0.947
09-22-03	0.953