DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-26-12 Baltimore, Maryland 21244-1850

Center for Medicaid, CHIP, and Survey & Certification

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MEDICAID DRUG REBATE PROGRAM

Release No. 83

For Participating Drug Manufacturers

AMP Smoothing Process

Section 2503(a) of the Affordable Care Act amended the Federal Upper Limits provision at section 1927(e) of the Social Security Act (the Act) to specify that the Secretary shall implement a smoothing process for AMP which shall be similar to the smoothing process used in determining the average sales price (ASP) of a drug or biological under Medicare Part B. In order to ensure that the smoothing process being utilized by manufacturers is uniform and consistent with statutory requirements, CMS is issuing the following guidance which is similar to the process used for calculating ASP as set forth in 42 CFR 414.804.

The monthly AMP should be calculated based on the weighted average of prices included in the AMP calculation for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units sold, excluding any price concessions set forth in section 1927(k)(1)(B) of the Act. In calculating monthly AMP, a manufacturer should estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts.

Following is an example of how manufacturers would calculate the monthly AMP by using a 12month rolling percentage to estimate the lagged price concessions:

- Total lagged price concessions over the most recent 12-month period = \$150,000
- Total sales subject to AMP reporting for the most recent 12-month period = \$600,000
- Total lagged price concessions divided by total sales = 150,000/600,000 = 0.25 (or 25%)
- The result (25%) is the percentage manufacturers subtract from their total sales for that month to estimate lagged price concessions for that month.
- Current month sales = \$50,000
- \$50,000 x 25% (estimated percentage of lagged price concessions) = \$12,500 estimated lagged price concessions for the current month

- \$50,000 \$12,500 = \$37,500 (net total sales after subtracting estimated lagged price concessions for the current month)
- Units sold during current month = 10,000 units
- \$37,500/10,000 units = \$3.75 AMP

Questions regarding Medicaid drug provisions can be submitted to the drug policy resource mailbox at RxDrugPolicy@cms.hhs.gov.

/s/

Barbara Edwards Director Disabled and Elderly Health Programs Group

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