

In this rule, we intend the terms “manufacturer,” “average manufacturer price (AMP),” and “best price (BP)” to have the same meaning as described and set forth in the national drug rebate agreements signed by manufacturers and the Secretary (on behalf of States). We also have used these terms in guidance documents that we have issued over the years pertaining to the Medicaid drug rebate program. We do not intend to alter these definitions in this rule. Rather, the primary purpose of this rule is to establish procedural requirements pertaining to manufacturer recordkeeping and pricing changes. We will set forth regulatory definitions of these terms in a subsequent document we will publish in the **Federal Register**.

B. 1995 Proposed Rule

On September 19, 1995, we published a proposed rule (60 FR 48442) in the **Federal Register** that specified requirements for State Medicaid agencies and conditions under which Federal payments would be made under the Medicaid program for covered outpatient drugs. The rule also specified the conditions for approval and renewal of rebate agreements with drug manufacturers participating in the Medicaid program.

In the September 1995 proposed rule, we also discussed prior period adjustments and pricing changes. A prior period adjustment is a change in the unit rebate amount based on a manufacturer's revised AMP or BP data for a prior rebate period after that rebate period's pricing data have been submitted to us. The prior period adjustments generally consist of a manufacturer's changes to pricing data resulting from sales data not being available before pricing submissions to us or changes in the methodology used to establish AMP or BP. We use the manufacturer's pricing data to generate the unit rebate amount for each 9-digit national drug code, which States use to calculate rebate amounts due from manufacturers. Any changes to a manufacturer's AMP or BP result in changes to the unit rebate amount and rebates due from the manufacturer. Thus, the prior period adjustments are necessary to correct rebate amounts that are owed by manufacturers or credits due to manufacturers.

Since the publication of the September 1995 proposed rule, States have expressed concerns regarding pricing changes and recalculations under the Medicaid drug rebate program. We have received requests for pricing recalculations for drug prices submitted as far back as 1991. The statute does not specifically provide for

such recalculations; however, we have permitted the recalculations where revisions were made to conform to the statute or rebate agreement. Unfortunately, there is a significant burden on States and manufacturers to maintain pricing data and supporting documentation for timeframes dating back to 1991. We have seen a recent increase in the number of these requests and the dollar value of the recalculations. In addition, manufacturers have expressed concerns regarding recordkeeping burdens. In response to these concerns, we are finalizing the recordkeeping requirements and the time limit on pricing recalculations proposed in the September 1995 rule. We will address the remaining provisions of the September 1995 rule in a subsequent rule we will publish in the **Federal Register**.

C. Legislative History

Section 1927 of the Social Security Act (the Act) authorizes the Medicaid drug rebate program. Section 1927 of the Act was amended by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and section 13602 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). Under section 1927 of the Act, manufacturers that have entered into a national rebate agreement must provide each State Medicaid program with rebate period payments (or other periodic rebate payments, as determined by the Secretary).

D. Requirements for Manufacturer's Data

Section 1927(b) of the Act gives the Secretary the authority to publish regulations that establish manufacturer recordkeeping requirements and the time limit for manufacturer pricing changes. To implement these provisions, we will require that a manufacturer must retain pricing data for 3 years from the date the manufacturer reports that period's data to us. Although the statute sets forth requirements on data reported to us by manufacturers, it does not provide recordkeeping requirements for manufacturer data. In the national drug rebate agreement, we did not establish a timeframe during which records must be maintained. The 3-year time period comports with the requirements for the maintenance of records on State Medicaid expenditures imposed on States. Section 433.32 requires that States retain records for 3 years from the date of submission of a final expenditure report for Federal financial participation.

E. Manufacturer's Pricing Data

Section 1927(b)(3)(A)(i) requires that manufacturers submit pricing information no later than 30 days after the end of each quarter. However, it does not establish a time limitation regarding pricing changes. While we recognize the need to permit manufacturers to submit revised prices within a timeframe, States and manufacturers should be protected from potential liabilities resulting from no time limit. We will require that manufacturers submit changes to AMP or BP within 3 years from the date that period's data are due. The timeframe for pricing changes set forth in this final rule is more fully described in section IV of the preamble, “Provisions of the Final Rule.”

II. Provisions of the Proposed Rule

In the September 19, 1995 proposed rule, we solicited comments on proposed requirements for State Medicaid agencies, the conditions under which Federal payments would be made under the Medicaid program for covered outpatient drugs, and the conditions for approval and renewal of rebate agreements with drug manufacturers. In this final rule with comment period, we are finalizing two of the provisions of the September 1995 proposed rule. We will address the remaining provisions of the September 1995 proposed rule and will publish a subsequent rule in the **Federal Register**.

In the September 1995 proposed rule, we proposed to add to part 447 a new subpart I entitled “Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements.” Within that subpart, we proposed a new § 447.534(g) to establish a 3-year recordkeeping requirement for manufacturer data pertaining to AMP and BP calculations. We also proposed a new § 447.534(h) to establish a 3-year time limit for manufacturers to report revised AMP or BP to us.

III. Analysis of and Response to Public Comments on the September 19, 1995 Proposed Rule

We received 19 timely comments in response to the September 19, 1995 proposed rule. We received comments from State government officials and representatives of the pharmaceutical industry including manufacturers, pharmacists, attorneys, and consultants. Although we received comments on a variety of topics pertaining to the proposed rule, we are addressing only the comments that pertain to the manufacturer recordkeeping requirements and the 3-year limitation