

on price recalculations set forth in this final rule with comment period. These comments and our responses are summarized below:

A. Manufacturer Recordkeeping Requirements

Comment: One commenter noted that the 3-year records retention standard will provide a useful records management timeframe.

Response: We agree; therefore, we are issuing this final rule with comment period to establish the 3-year recordkeeping requirements for manufacturers.

B. Time Limitation on Manufacturer Price Recalculations

Comment: One commenter expressed the opinion that the burden for calculating the amount of rebate adjustments should rest with the manufacturer when the adjustment results from changes to AMP or BP, rather than the State.

Response: The State has never been responsible for calculating the amount of rebate adjustments. The manufacturer is responsible for recalculating the amount of rebate adjustments.

Comment: One commenter noted the need to clarify the 3-year timeframe as it applies to prior period adjustments.

Response: We concur with the need to provide clarification. We define the 3-year limitation as equivalent to 12 quarters because the Medicaid drug rebate program operates on a quarterly basis. Pricing information is exchanged and processed on a quarterly basis and rebates are due and paid on a quarterly basis. Therefore, wherever we refer in this document to a 3-year timeframe for recalculations and pricing changes, we interpret it as 12 quarters from the quarter in which the data were due.

Comment: One commenter noted that 3 years is too long a timeframe for applying retroactive prior period adjustments and recommended that the allowed retroactive period not exceed 24 months.

Response: We recognize the potential burden for States and manufacturers to apply prior period adjustments during a 3-year retroactive timeframe, as opposed to a 24-month timeframe. Nevertheless, as we discussed earlier in the "Background" section of this preamble, we continue to believe that a 3-year timeframe is reasonable because it comports with requirements for maintenance of records on State Medicaid expenditures. Furthermore, it is consistent with the manufacturer's recordkeeping requirements set forth in this document.

Comment: One commenter noted that the 3-year prior period adjustment standard will provide a useful records management timeframe. Other commenters expressed appreciation for the 3-year time limitation, saying that it is essential to enable a manufacturer to close its books for a fiscal year.

Response: As discussed earlier in the "Background" section of this preamble, we agree.

IV. Provisions of the Final Rule

This final rule with comment period incorporates two of the provisions in the proposed rule issued on September 19, 1995. We will address the remaining provisions of the September 1995 proposed rule in a subsequent document we will publish in the **Federal Register**. This rule adopts the following provisions in the September 1995 proposed rule:

Under part 447, "Payments for Services," we are adding a new subpart I, entitled "Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements." We are reserving § 447.500 through § 447.532 and § 447.536 through § 447.550.

Under § 447.534, "Manufacturer reporting requirements," we are reserving paragraphs (a) through (f). We are redesignating paragraph (g) in the September 1995 proposed rule as paragraph (h) and are reserving the newly redesignated paragraph (g). We are also redesignating paragraph (h) as paragraph (i). We are revising newly redesignated paragraphs (h) and (i).

Under § 447.534(h), we are establishing a requirement that manufacturers must retain for 3 years from the date the manufacturer reports that rebate period's data to us, all records (written or electronic) of these data, and any other materials from which the calculations of the AMP and BP were derived. A manufacturer must retain records beyond the 3-year period if one or more of the following circumstances exist:

- The records are the subject of an audit or of a government investigation of which the manufacturer is aware related to average manufacturer price or best price.
- The audit findings or investigation related to the AMP and BP have not been resolved.

If the audit findings or investigation have been resolved, manufacturers are not required to retain historical pricing data that fall outside the 3-year recordkeeping requirement. We want to clarify that § 447.534(h) was not designed to address recordkeeping requirements when a manufacturer is the subject of an audit or government

investigation by the Office of Inspector General (OIG) or any other government entity. In the September 1995 proposed rule, we proposed requiring manufacturers to retain data beyond the 3-year timeframe if the records are the subject of an audit. Because we did not specifically address OIG investigations in the September 1995 proposed rule, we want to clarify this point in this final rule. Therefore, we are revising § 447.534(h) from the language in the September 1995 proposed rule to specify that manufacturers must retain data beyond 3 years if the records are the subject of an audit or a government investigation.

Under § 447.534(i), we are establishing a 3-year time limitation for a manufacturer to submit drug pricing changes. We define the 3-year period as 12 quarters. Therefore, we require that the manufacturer report to us changes to AMP or BP for a period not to exceed 12 quarters from the quarter in which the data were due.

The terms of the Medicaid Drug Rebate Agreement require manufacturers to submit pricing data for each calendar quarter no later than 30 days after the end of that quarter. For example, for data pertaining to the second quarter of 2003 (April 1, 2003 through June 30, 2003), the due date for submitting pricing data is July 30, 2003, which falls during the third quarter of 2003.

For purposes of implementing the 3-year timeframe for reporting pricing changes to us, we define 3 years as 12 quarters from the quarter in which the data were due. For example, data from the second quarter of the year 2000 (April 1, 2000 through June 30, 2000) were due July 30, 2000 (the third quarter of 2000). Twelve quarters from the third quarter of 2000 (the quarter in which the data were due) is the third quarter of 2003. Based on the due date for submitting pricing data, data submitted during the third quarter of 2003 were due on July 30, 2003. Therefore, pricing changes pertaining to data from the second quarter of 2000 were due to us no later than July 30, 2003.

As with all pricing data submitted under the Medicaid drug rebate program, if CMS, the Office of Inspector General, or another authorized government agency reviews a manufacturer's pricing data and determines that adjustments or revisions are necessary, irrespective of the quarter, the manufacturer is bound under the Medicaid Drug Rebate Agreement to comply with that determination.