

## V. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under paragraph (h) of § 447.534, there are two recordkeeping requirements:

(1) A manufacturer must retain records (written or electronic) for 3 years from the date the manufacturer reports that rebate period's data to CMS.

The records must include these data and any other materials from which the calculations of the average manufacturer price and best price are derived, including a record of any assumptions made in the calculations.

(2) A manufacturer must retain records beyond the 3-year period if one or more of the following circumstances exist: (A) 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, and (B) The audit findings or investigation related to the average manufacturer price and best price have not been resolved.

Under paragraph (i), there is a reporting requirement: A manufacturer must report to CMS changes to average manufacturer price or best price for a period not to exceed 12 quarters from the quarter in which the data were due.

These information collection requirements already exist. The recordkeeping requirements are in the contract between the drug manufacturer and CMS and are in any event usual and customary business practices. The regulation specifies timeframes; however, under the contract, we did not establish a timeframe.

The reporting requirement is currently approved under OMB number 0938-0578. The regulation merely adds a time limit in which the manufacturer must report changes; currently, there is none.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Groups, Attn.: Julie Brown,

CMS-2175-FC, Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Brenda Aguilar, CMS Desk Officer.

## VII. Regulatory Impact Analysis

### A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely assigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We believe this rule will have an economically significant effect. We believe the rule will save \$90 million annually over the next 5 years (\$50 million Federal savings and \$40 million State savings as shown in the table below). This figure represents 0.4 percent of total Medicaid drug expenditures in Federal fiscal year 2002. We consider this rule to be a major rule.

STATE AND FEDERAL SAVINGS OVER 5 YEARS

FY	2004	2005	2006	2007	2008
State .....	*\$40,000	\$40,000	\$40,000	\$40,000	\$40,000
Federal .....	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000

\*Note: Figures are in thousands.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million or less in any 1 year. For purposes of the RFA,

pharmaceutical manufacturers with 750 or fewer employees are considered small businesses according to the Small Business Administration's size standards matched to North American Industry Classification System, effective October 1, 2002, <http://www.sba.gov/size/sizetable2002.html>). Use of the Small Business Administration's size standards matched to North American Industry Classification System is in

compliance with the Small Business Administration's regulation that set forth size standards for health care industries at 65 FR 69432. Individuals and States are not included in the definition of a small entity. This rule will not have a significant impact on small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a