

significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not have a significant impact on small rural hospitals because the provisions contained herein do not pertain to hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. We anticipate this rule will impact State governments through increased Medicaid savings, in the aggregate, of \$40 million per year. We anticipate this rule will impact the private sector, in the aggregate, by less than \$110 million. We anticipate this rule will cost drug manufacturers, in the aggregate, \$90 million per year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not anticipate this rule will impose direct requirement costs on State governments.

B. Anticipated Effects

1. Effects on Drug Manufacturers

We anticipate the rule will cost drug manufacturers \$90 million in the aggregate. To derive this estimate, we examined the rebate adjustment data from several States for the four quarters from the third quarter of 2001 through the second quarter of 2002. We separated the data from adjustments for each quarter into two parts:

- Adjustments over the previous 12 quarters; and
- Adjustments beyond the previous 12 quarters. From those data, we estimated the percentage of total rebate adjustments within 12 quarters nationally. We then projected what percentage of total adjustments would not occur given the 12-quarter limit. Then we estimated the national rebate adjustments by quarter by calculating the adjustments as a percentage of total rebates by State and multiplying that by the total national rebates. We then multiplied the projected total national

rebate adjustments by the projected percentage of rebates that would not occur within 12 quarters to estimate the total impact of the proposal. Over the four quarters of data (third quarter of 2001 through the second quarter of 2002), we found that that resulted in approximately \$90 million.

The estimated number of drug manufacturers currently participating in the Medicaid Drug Rebate Program is approximately 550. As previously indicated, businesses with 750 employees or fewer are considered small businesses. At this time, we are unable to determine how many of the 550 drug manufacturers have 750 or fewer employees. No single manufacturer will be affected significantly by this rule. As a group, the participating drug manufacturers will probably have a mixed reaction to this rule. We anticipate that some drug manufacturers will likely object to a narrowing of their window of opportunity to submit pricing changes to us. We are unable to quantitatively address the burden to manufacturers with respect to recordkeeping. Absent this rule, manufacturers are in effect required to retain their pricing and sales records indefinitely. Therefore, some of the manufacturers may be relieved that we are setting forth clear guidelines for records retention that closely mirror the industry standard for records retention.

We do not anticipate that this rule will adversely affect a drug manufacturer's participation in the Medicaid Drug Rebate program nor impact the current level of access and availability of prescription drugs for Medicaid beneficiaries. There is no impact to contractors or providers.

2. Effects on the Medicaid Program

We anticipate the rule will result in \$50 million in Federal Medicaid savings and save State Medicaid programs \$40 million in the aggregate. This rule will have a positive effect on the State Medicaid agencies. State Medicaid agencies are having difficulty fully funding their Medicaid programs. They will likely be relieved that we are setting forth a rule that will limit their fiscal vulnerability for manufacturers implementing retroactive pricing changes that result in greatly increased costs to their programs.

We are unable to quantitatively address the burden to States with respect to recordkeeping. Absent this rule, States are in effect required to retain drug utilization data indefinitely in order to verify the revised or reduced rebates from manufacturers attributable to retroactive pricing changes. Therefore, we expect that a majority of

the States will be relieved that we are setting forth clear guidelines for manufacturer records retention.

This rule will not adversely affect a State's ability to obtain manufacturers rebates nor impact the current level of access and availability of prescription drugs for Medicaid beneficiaries. There is no impact to Medicaid providers or contractors.

C. Alternatives Considered

Delay Publication of This Final Rule

We considered not publishing this final rule. However, we believe this rule is necessary to address the burden to States and manufacturers with respect to recordkeeping in the Medicaid drug rebate program. We chose to issue this rule given the concerns repeatedly expressed by manufacturers and States regarding the recordkeeping requirements and the time limit on pricing changes.

Establish a Different Time Limitation

Another alternative would be to establish a longer or a shorter time limitation for recordkeeping and pricing changes. We did not choose a longer recordkeeping timeframe because it would not relieve a reasonable amount of the burden to manufacturers. In addition, a longer time limit on pricing changes would not sufficiently alleviate States' fiscal vulnerability with regard to retroactive pricing changes. We did not choose a shorter recordkeeping timeframe because it would create a disparity among Federal recordkeeping requirements. The 3-year timeframe set forth for both requirements mirrors existing records retention requirements for States. Furthermore, because the recordkeeping and pricing change provisions are interrelated, we believe the timeframes should be the same for these provisions.

D. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and