outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public file and available for public inspection without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

D. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate regional file/rulemaking identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

VIII. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: December 23, 2003.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

[FR Doc. 04–211 Filed 1–5–04; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2188–P]

RIN 0938–AN01

Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: On August 29, 2003, we published a final rule with comment period in the **Federal Register** that finalized two specific provisions: it established new 3-year recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program and set a 3-year time limitation during which manufacturers must report changes to average manufacturer price and best price for purposes of reporting data to us. In addition, it announced the pressing need for codification of fundamental recordkeeping requirements. On September 26, 2003, we issued a correction notice to change the effective date of the August 29, 2003 rule from October 1, 2003 to January 1, 2004. In this proposed rule, we propose removing the 3-year recordkeeping requirements and replacing them with 10-year recordkeeping requirements. We also propose that manufacturers must retain records beyond the 10-year period if the records are the subject of an audit or a government investigation.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 8, 2004.

ADDRESSES: In commenting, please refer to file code CMS–2188–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

Mail written comments (one original and two copies) to the following address

ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2188–P, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:
Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Marge Watchorn, (410) 786–4361.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7197.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

In order for a pharmaceutical manufacturer's products to be eligible for Medicaid reimbursement under section 1903(a) of the Social Security Act (the Act), the manufacturer must sign an agreement with us on behalf of the Secretary of Health and Human Services to participate in the Medicaid drug rebate program. Among the terms to which the manufacturer must agree is the requirement to retain pricing data to support the calculation of average manufacturer price and best price as defined in section 1927 of the Act. Absent a regulatory or statutory requirement, it has been our position that manufacturers must retain these records indefinitely.

On September 19, 1995, we published a proposed rule in the **Federal Register** that proposed numerous provisions related to the Medicaid drug rebate program. As relevant to this proposed rule, we proposed new 3-year recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program and proposed a 3-year time limitation during which manufacturers must report changes to average manufacturer price and best price for purposes of reporting data to us. On August 29, 2003, we published a final rule with comment period in the **Federal Register** that finalized both provisions. In addition, we announced the pressing need for codification of fundamental recordkeeping requirements. On September 26, 2003, we issued a correction notice in the **Federal Register** to change the effective date of the August 29, 2003 rule from October 1, 2003 to January 1, 2004. In a separate document published today in the **Federal Register** (CMS–2175–IFC), we are removing the 3-year recordkeeping requirements and replacing them with temporary 10-year recordkeeping requirements for the period January 1, 2004 through December 31, 2004.

In this proposed rule, we propose removing the 3-year recordkeeping requirements and replacing them with 10-year recordkeeping requirements. We also propose that manufacturers must retain records beyond the 10-year period if the records are the subject of an audit or a government investigation of which the manufacturer is aware. We propose that the 10-year recordkeeping requirement be effective without a sunset date provision.

II. Provisions of the Proposed Regulations

This proposed rule would establish a 10-year recordkeeping requirement for prescription drug manufacturers that participate in the Medicaid drug rebate program. This provision would be set forth in 42 CFR part 447 subpart I. Under the 10-year recordkeeping requirement, a drug manufacturer would be required to retain records for 10 years from the date the manufacturer reports that rebate period's data to us. In addition, a manufacturer would be required to retain data beyond the 10-year period if the records are the subject of an audit or a government investigation of which the manufacturer is aware and if the audit findings or investigation related to the manufacturer's average manufacturer price and best price have not been resolved.

III. 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.

Therefore, we are soliciting public comment on each of these issues for the following section of this document that contains information collection requirements:

Section 447.534(h) of this document contains the information collection requirements. We are seeking comment on these requirements in CMS–2175–IFC, in conjunction with a request for emergency approval for revisions to OMB 0938–0578. We are also seeking

comment through this proposed rule; we are requesting reapproval of these requirements.

There are two recordkeeping requirements in § 447.534(h):

(1)(i) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports that rebate period's data. 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. The 10-year timeframe applies to a manufacturer's quarterly submission of pricing data as well as any revised pricing data subsequently submitted to us.

(ii) A manufacturer must retain records beyond the 10-year period if both of the following circumstances exist: (A) The records are the subject of an audit or of a government investigation related to pricing data that are used in average manufacturer price or best price of which the manufacturer is aware, and (B) The audit findings or investigation related to the average manufacturer price and best price have not been resolved.

The burden associated with the recordkeeping is minimal, a maximum of $1.00 per year for a compact disc per manufacturer. Staffing costs are unknown and being researched; we welcome comments.

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this document to the Office of Management and Budget (OMB) for its review of these information collection requirements.

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 Group, Attn: Julie Brown, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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.

Comments submitted to OMB may also be e-mailed to the following address: e-mail: baguilar@omb.eop.gov; or faxed to OMB at (202) 395–6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, 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, if we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact

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 would not have an economically significant effect. We believe the rule would result in neither costs nor savings to the Medicaid program and that additional costs to drug manufacturers would be minimal. We do not consider this rule to be a major rule.

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 the 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. Because pharmaceutical manufacturers are not required to report their number of employees to the Small Business Administration, we are unable to determine how many of them are considered small entities. This rule would not have a significant impact on small businesses because although some pharmaceutical manufacturers may be small businesses, we estimated that the cost to manufacturers would be minimal, as described in section V.B below.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 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 would not have a significant impact on small rural hospitals because the provisions contained in this proposed rule would 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 would not impact State governments or the private sector.

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 would impose direct requirement costs on State governments.

B. Anticipated Effects

1. Effects on Drug Manufacturers

We do not collect information on the costs associated with manufacturer recordkeeping under the Medicaid drug rebate program. Therefore, in the absence of such information, we derived an estimate based on our annual costs of storing electronic pricing data that we receive from approximately 500 drug manufacturers. We store drug product data, including pricing information, for

approximately 55,000 drug products. Over the course of the 12 years the Medicaid drug rebate program has been in existence, we have gathered nearly 250 megabytes of information. This information fits on one compact disc. The cost of one blank compact disc is less than $1. We did not have a reasonable proxy available to estimate the staffing costs associated with maintaining the data, so our estimate does not include these costs.

On the whole, we believe this approach is reasonable because it is our understanding that these records are maintained by most manufacturers in an electronic format, while smaller companies may maintain their pricing records in written format. In order to more accurately evaluate the fiscal impact of this provision, we are requesting that manufacturers provide us with information on the costs they would expect to incur pursuant to retaining records for a 10-year period. To the extent possible, we ask that manufacturers make an effort to distinguish between the cost of meeting the 10-year recordkeeping requirement versus other recordkeeping requirements that may apply to the same records.

We do not anticipate that this rule would adversely affect a drug manufacturer's participation in the Medicaid Drug Rebate program or impact the current level of access and availability of prescription drugs for Medicaid beneficiaries. There would be no impact on contractors or providers.

2. Effects on the Medicaid Program

We are unable to quantitatively address the burden to States with respect to recordkeeping. This rule would not adversely affect a State's ability to obtain manufacturers' rebates or impact the current level of access and availability of prescription drugs for Medicaid beneficiaries. There would be no impact on Medicaid providers or contractors.

C. Alternatives Considered

Retain the 3-Year Recordkeeping Provision in the August 29, 2003 Final Rule With Comment Period

We considered retaining the 3-year recordkeeping provision in the August 29, 2003 final rule with comment period. However, we believe it is necessary to propose replacing the 3-year provision with a 10-year provision to address concerns raised by commenters regarding Federal and State investigations under the False Claims Act and related anti-fraud provisions.

Propose a Different Time Limitation

Another alternative would be to propose a longer or a shorter recordkeeping requirement. We did not choose a longer recordkeeping timeframe because we believe a 10-year period would offer immediate protection to address situations where investigations are under seal in False Claims Act *qui tam* actions. Further, the exception to the 10-year requirement would adequately address situations where investigations known to manufacturers are not yet resolved. We did not suggest a shorter recordkeeping timeframe in this rule because we are concerned that such a timeframe, should it eventually become effective, could be misconstrued to lead a manufacturer to believe it could prematurely discard vital evidence in a case of fraud against the government.

Finalize the 10-Year Requirement Without Issuing Another Proposed Rule

We considered finalizing the 10-year recordkeeping requirement without issuing another proposed rule. However, we believe that it is important to offer interested parties an opportunity to provide comments about whether a 10-year recordkeeping requirement is the proper timeframe to address the concerns raised on this provision.

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 that this rule would 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

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV part 447 as set forth below:

PART 447–PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart I–Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements

2. In § 447.534, paragraph (h)(2) is removed and paragraph (h)(1) is revised to read as follows:

§ 447.534 Manufacturer reporting requirements.

* * * * *

(h) *Recordkeeping requirements.* (1)(i) A manufacturer must retain records (written or electronic) for 10 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. The 10-year time frame applies to a manufacturer's quarterly submission of pricing data as well as any revised pricing data subsequently submitted to CMS.

(ii) A manufacturer must retain records beyond the 10-year period if both of the following circumstances exist:

(A) The records are the subject of an audit or of a government investigation related to pricing data that are used in average manufacturer price or best price of which the manufacturer is aware.

(B) The audit findings or investigation related to the average manufacturer price and best price have not been resolved.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 29, 2003.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 30, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–32330 Filed 12–31–03; 12:47 pm]

BILLING CODE 4120–01–P