information may be received which may relate to a case under the investigative jurisdiction of another agency. The maintenance of this information may be necessary to provide leads for appropriate law enforcement purposes and to establish patterns of activity which may relate to the jurisdiction of other cooperating agencies.

(D) From subsection (e)(2) because collecting information to the fullest extent possible directly from the subject individual may or may not be practical in a criminal and/or civil investigation.

(E) From subsection (e)(3) because supplying an individual with a form containing a Privacy Act Statement would tend to inhibit cooperation by many individuals involved in a criminal and/or civil investigation. The effect would be somewhat adverse to established investigative methods and techniques.

(F) From subsections (e)(4)(G), (H), and (I) because this system of records is exempt from the access provisions of subsection (d).

(G) From subsection (e)(5) because the requirement that records be maintained with attention to accuracy, relevance, timeliness, and completeness would unfairly hamper the investigative process. It is the nature of law enforcement for investigations to uncover the commission of illegal acts at diverse stages. It is frequently impossible to determine initially what information is accurate, relevant, timely, and least of all complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light.

(H) From subsection (e)(8) because the notice requirements of this provision could present a serious impediment to law enforcement by revealing investigative techniques, procedures, and existence of confidential investigations.

(I) From subsection (f) because the agency's rules are inapplicable to those portions of the system that are exempt and would place the burden on the agency of either confirming or denying the existence of a record pertaining to a requesting individual might in itself provide an answer to that individual relating to an on-going investigation. The conduct of a successful investigation leading to the indictment of a criminal offender precludes the applicability of established agency rules relating to verification of record, disclosure of the record to that individual, and record amendment procedures for this record system.

(J) From subsection (g) because this system of records should be exempt to the extent that the civil remedies relate to provisions of 5 U.S.C. 552a from which this rule exempts the system.

(iv) *Authority:* (A) Investigative material compiled for law enforcement purposes, other than material within the scope of subsection 5 U.S.C. 552a(j)(2), may be exempt pursuant to 5 U.S.C. 552a(k)(2). However, if an individual is denied any right, privilege, or benefit for which he would otherwise be entitled by Federal law or for which he would otherwise be eligible, as a result of the maintenance of the information, the individual will be provided access to the information exempt to the extent that disclosure would reveal the identity of a confidential source. NOTE: When claimed, this exemption allows limited protection of investigative reports maintained in a system of records used in personnel or administrative actions.

(B) Therefore, portions of this system of records may be exempt pursuant to 5 U.S.C. 552a(k)(2) from the following subsections of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f).

(v) *Reasons:* (A) From subsection (c)(3) because to grant access to the accounting for each disclosure as required by the Privacy Act, including the date, nature, and purpose of each disclosure and the identity of the recipient, could alert the subject to the existence of the investigation. This could seriously compromise case preparation by prematurely revealing its existence and nature; compromise or interfere with witnesses or make witnesses reluctant to cooperate; and lead to suppression, alteration, or destruction of evidence.

(B) From subsections (d) and (f) because providing access to investigative records and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; enable individuals to conceal their wrongdoing or mislead the course of the investigation; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(C) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of each piece of information in the early stages of an investigation. In some cases, it is only after the information is evaluated in light of other evidence that its relevance and necessity will be clear.

(D) From subsections (e)(4)(G) and (H) because this system of records is compiled for investigative purposes and is exempt from the access provisions of subsections (d) and (f).

(E) From subsection (e)(4)(I) because to the extent that this provision is construed to require more detailed disclosure than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants.

(F) Consistent with the legislative purpose of the Privacy Act of 1974, the AF will grant access to nonexempt material in the records being maintained. Disclosure will be governed by AF's Privacy Regulation, but will be limited to the extent that the identity of confidential sources will not be compromised; subjects of an investigation of an actual or potential criminal or civil violation will not be alerted to the investigation; the physical safety of witnesses, informants and law enforcement personnel will not be endangered, the privacy of third parties will not be violated; and that the disclosure would not otherwise impede effective law enforcement. Whenever possible, information of the above nature will be deleted from the requested documents and the balance made available. The controlling principle behind this limited access is to allow disclosures except those indicated above. The decisions to release information from these systems will be made on a case-by-case basis.

* * * * *

Dated: December 24, 2003.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 04–24 Filed 1–5–04; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2175–IFC]

RIN 0938–AM20

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

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

ACTION: Interim final rule with comment period.

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 interim final rule with comment period, we are removing the 3-year recordkeeping requirements, replacing them with 10-year recordkeeping requirements on a temporary basis, and soliciting comments on the 10-year requirements.

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. These provisions contain a sunset date with respect to the record retention requirements to ensure that we reexamine whether the retention rule remain necessary and effective.

This interim final rule with comment period also responds to public comments on the August 29, 2003 final rule with comment period that pertain to the 3-year recordkeeping requirement at § 447.534(h).

EFFECTIVE DATE: This rule is effective January 1, 2004.

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–2175–IFC. 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–2175–IFC, P.O. Box 8018, Baltimore, MD 21244–8018.

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: *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. 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 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 this interim final rule with comment period, we are removing the 3-year recordkeeping requirements, replacing them with 10-year recordkeeping requirements on a temporary basis, and soliciting comments on the 10-year requirements. 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. These requirements regarding record retention will be in effect until December 31, 2004 or when we publish final recordkeeping requirements in the **Federal Register**, whichever occurs first.

We are also publishing this interim final rule with comment period to address some of the comments received on the final rule with comment period we published on August 29, 2003 (68 FR 51912). Specifically, we are addressing comments pertaining to the 3-year recordkeeping requirements at § 447.534(h). The 3-year recordkeeping requirement for drug manufacturers participating in the Medicaid drug rebate program has caused a significant amount of concern from commenters with regard to the rule's potential effect on the False Claims Act (FCA) and other possible fraud and abuse violations.

II. Provisions of the Final Rule With Comment Period

On August 29, 2003, we published a final rule with comment period (68 FR 51912) in the **Federal Register** that finalized two specific provisions: It established new 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 recordkeeping requirements. On September 26, 2003, we issued a correction notice (68 FR 51912) to delay the effective date of the August 29, 2003 rule from October 1, 2003 to January 1, 2004.

III. Analysis of and Responses to Public Comments

We received 12 public comments in response to the August 29, 2003 rule. We received comments from State government officials, representatives of the pharmaceutical industry including manufacturers, attorneys, consultants, provider representatives, and a non-profit organization. We received comments on a variety of topics pertaining to the final rule with comment period, as well as comments pertaining to the general Medicaid drug rebate program. For example, several commenters raised issues regarding disputes under the Medicaid drug rebate program, which were not addressed in the August 29, 2003 rule. We are not responding to comments that pertain to the 3-year time limitation for price recalculations at this time; we intend to respond to those comments in a subsequent document that we will publish in the **Federal Register**. In this document, we are summarizing and responding to those comments that pertain to the 3-year recordkeeping requirements at *§ 447.534(h).* These comments and our responses are summarized below:

Recordkeeping Requirements at § 447.534(h)

Comment: One commenter noted that there is significant crossover between data required under the Medicaid drug rebate program, section 340B of the Public Health Service Act, and section 603 of the Veterans Health Care Act (VHCA). The commenter indicated that this rule is inconsistent with the 5-year record retention requirement in the VHCA. The commenter also requested that we define the term, ''authorized government agency,'' as it appeared in section IV of the August 29, 2003 rule. As written, this term implies that if, for example, the Department of Veterans Affairs (DVA) determines that a manufacturer's underlying pricing data contain errors, then the manufacturer must retroactively revise average manufacturer price or best price.

Response: We recognize that there is some cross-over between the data required for the Medicaid drug rebate program, the 340B program, and section 603 of VHCA. However, our regulation is designed to address Medicaid drug rebate best price and average manufacturer price calculations. Due to concerns raised regarding record destruction and the fraud and abuse violations, we also acknowledge the need to increase the record retention period and have chosen a longer 10-year recordkeeping requirement. We expect this longer retention period will alleviate concerns regarding inadvertent record destruction that might impact the 340B program or section 603 of VHCA. We also note that the FCA exists outside the scope of these regulations and applies equally to all of the data provided to the Federal agencies listed and that manufacturers may keep records to support their calculations for all three programs accordingly. With regard to the term, ''authorized government agency,'' our intent was to include any agency with oversight authority and jurisdiction over the Medicaid drug rebate program (for example, the Office of the Inspector General or the Department of Justice).

Comment: One commenter asked for clarification regarding how a manufacturer can provide data supporting its position for periods more than 12 quarters if those data are not to be retained.

Response: In this rule, we are extending the minimum record retention requirement from 3 to 10 years. Therefore, we are requiring that a manufacturer retain data in excess of 12 quarters. Thus, a manufacturer can provide data as may be necessary to substantiate its calculations. Nevertheless, the time limitation for pricing recalculations issued in the August 29, 2003 rule will go into effect on January 1, 2004.

Comment: One commenter expressed concern for manufacturers who find the inconsistent recordkeeping requirements among the Federal drug programs to be confusing. Specifically, if manufacturers are bound by timeframes longer than 3 years, the 3-year recordkeeping requirement in the August 29, 2003 rule is moot. Since we used the 3-year recordkeeping requirement as a reason to justify the 3-year time limitation for price recalculations, we need to reconcile these differences before moving ahead with time limits for pricing changes.

Response: As noted earlier, we acknowledge that different Federal programs may have varying standards in place with regard to recordkeeping; however, we are only regulating the recordkeeping requirements for Medicaid drug rebate pricing data in this rule. We received numerous comments suggesting the 3-year recordkeeping requirements were too short, but none to convince us to expand the time limit on pricing recalculations. We believe that the concerns raised regarding the impact of the recordkeeping requirements on the FCA and State fraud and abuse provisions are compelling. Moreover, because manufacturers are in full possession of the documents that they need to make pricing recalculations, we continue to believe that 3 years is an adequate timeframe to permit manufacturers to recalculate their pricing data. Nevertheless, we want 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. For these reasons, we are establishing a temporary recordkeeping standard that is longer than the time limitation for price recalculations promulgated in the August 29, 2003 rule and soliciting public comments on the longer standard.

Comment: Two commenters urged us to address comments received on the August 29, 2003 rule and issue a final rule in the near future. One commenter asked when we will publish a final rule.

Response: We are addressing comments that pertain to the provisions in the August 29, 2003 rule in this interim final rule with comment period, which includes a sunset date provision. We anticipate that we will issue a final rule once we have addressed all the comments which we receive on this interim rule.

Comment: Several commenters noted strong opposition to the 3-year recordkeeping requirement, expressing concern with any provision that could permit the destruction of potential evidence of fraud and thereby interfere with efforts to eliminate fraud related to the Medicaid program. One commenter emphasized the importance of the FCA in allowing persons with evidence of fraud against Federal programs or contracts to bring suit on behalf of the government. Another commenter noted that requiring drug manufacturers to maintain their pricing data for only 3 years is a regrettable policy choice that will impose negative financial burdens on providers who participate in the drug pricing program under Section 340B (42 U.S.C. section 256b) of the Public Health Service Act. The commenters noted that there are dozens of pending cases and investigations involving allegations of fraudulent pricing practices by prescription drug manufacturers, many of which look back well beyond the last 3 years. In addition, commenters noted that there are ongoing confidential investigations of similar allegations of fraud that are, by necessity, conducted without notification to the manufacturers. Further, qui tam actions have been filed under seal throughout the country and the preliminary investigation of those matters typically takes place without notice to the manufacturers. The commenters noted that premature destruction of documents concerning average manufacturer prices and best prices could severely hamper these investigations.

Some commenters indicated that a record retention requirement of 6 years, with carve-outs relating to records and data concerning matters under investigation, would strike a more effective balance between efficiency and law enforcement concerns. One commenter recommended a 7-year record retention requirement. Another commenter recommended that we promulgate a recordkeeping requirement with the same substantive standard as that in the FCA: 10 years. That commenter further noted that anything less than a 10-year recordkeeping requirement will seriously undermine the FCA's ability to combat fraud against the Medicaid drug rebate program. Several commenters recommended that we simply remove the recordkeeping requirement.

Response: We concur with commenters who indicated that the 3-year recordkeeping requirement should be increased to address law enforcement concerns. After further consideration, we believe that, due to potential fraud and abuse violations and litigation, a 10-year recordkeeping requirement will be more appropriate and sufficient to ensure a Federal standard with regard to the Medicaid drug rebate program that will not hinder the activities of Federal and State law enforcement officials. Nonetheless, we are soliciting public comment on whether a 10-year recordkeeping requirement is the proper timeframe to address the concerns raised on this provision.

Comment: One commenter questioned the true benefit to manufacturers from the record retention provision in the rule if adjustments can be made to periods older than 3 years under a government investigation.

Response: We recognize the commenter's concerns and note that this provision will have no effect on a manufacturer that correctly calculates its average manufacturer price and best

price. However, we held open the exception to the 3-year period to give all government agencies with oversight authority the opportunity to review manufacturer records and to prevent a manufacturer from claiming that the original 3-year recordkeeping timeframe in any way protected that manufacturer from needing to report correct data. With the new 10-year recordkeeping requirement and its consistency with the FCA, we believe we have made the relationship even clearer.

Comment: In light of ongoing government investigations, one commenter asked whether we still advise manufacturers to discard records that are older than 3 years.

Response: At no time have we advised manufacturers to discard Medicaid drug rebate records. This rule addresses the retention of manufacturer pricing records under the Medicaid drug rebate program and is not designed to provide advice regarding document destruction. We now recognize that the 3-year record retention requirement set forth in the August 29, 2003 rule should be extended in order to address concerns and potential conflicts with Federal and State law enforcement efforts.

We believe that the 10-year recordkeeping requirement is necessary in light of the unique nature of the Medicaid drug rebate program. In particular, we are concerned that because of the way the drug rebate program operates, and the complexity of drug pricing, the program is potentially more susceptible to continuing errors, fraud or abuse. For example, while other programs or activities may be subject to individual, one-time errors, fraud or abuse, the drug rebate program could be more susceptible to such activities via ongoing utilization of a practice, procedure or formula instituted in the past, that is perpetuated and remains undetected. In accordance with section 1927 of the Act and the drug rebate agreement, manufacturers that participate in the drug rebate program submit best price and average manufacturer price with respect to their drugs on a quarterly basis. Manufacturers, not the Secretary, are in possession of the documentation used to substantiate those prices. We believe that the 10-year recordkeeping requirement is necessary in order to preserve critical pricing records and that a timeframe less than 10 years could interfere with efforts to eliminate the documented fraud and abuse related to the drug rebate program.

IV. Provisions of the Interim Final Regulations With Comment Period

This interim final rule with comment period removes the 3-year recordkeeping requirement issued in the August 29, 2003 rule and replaces it with a 10-year recordkeeping requirement from January 1, 2004 through December 31, 2004. This provision will be set forth in 42 CFR part 447 in a new subpart I entitled ''Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements'' at § 447.534(h). Under the 10-year recordkeeping requirement, a drug manufacturer must retain records for 10 years from the date the manufacturer reports that rebate period's data to us. In addition, a manufacturer must retain data beyond the 10-year period if the records are the subject of an audit or a government investigation and if the audit findings or investigation related to the average manufacturer price and best price have not been resolved.

V. 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.

We have, however, submitted a request for emergency approval of the information collection requirements in this final rule. We are requesting an emergency approval because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320, to ensure compliance with the False Claims Act (FCA). We could not reasonably comply with normal clearance procedures because public harm is likely to result if the agency cannot enforce the requirements of the FCA because records may be destroyed.

As stated earlier in this preamble, we are concerned that, without this final rule and implementation of the longer record retention requirement, manufacturers participating in the Medicaid drug rebate program will destroy records concerning drug price calculations, as well as data supporting those calculations after 3 years. If the requirements cannot be implemented immediately, there is a chance that manufacturers could minimize their potential civil liability under the FCA by destroying their Medicaid rebate records through December 31, 2000. As a result, the effective use of the FCA to investigate fraud regarding the Medicaid drug rebate program could be severely limited at a considerable cost to the Federal and State treasuries.

We are requesting OMB review and approval of this collection, with a 180-day approval period. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

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 of this document contains the following information collection requirements.

Under paragraph (h) of § 447.534, there are two 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. 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 related to the average manufacturer price and best price have not been resolved.

These information collection requirements, except for the timeframe, already exist. The recordkeeping requirements are in the contract

between the drug manufacturer and CMS, with the retention period not specified. The regulation merely revises timeframes specified for maintaining records in the current regulation.

The burden associated with the recordkeeping is minimal. While we have no data on the staffing costs associated with retaining the data, we estimate that it will cost each manufacturer no more than $1.00, the maximum cost of a compact disc for electronic storage per manufacturer, or a total cost maximum cost of $500 per year. (We base the estimate on the assumption that the manufacturers will store 1 year's data per disc, although it is not necessary to have one disc per year.) The cost to manufacturers that maintain paper copies will be even less as they will just have to keep their paper copy of what they submit to us. Again, the staffing costs cannot be estimated at this time.

We will be collecting data on the cost of staffing.

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, CMS–2175–IFC, 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 emailed to the following address: email: *baguilar@omb.eop.gov*; or faxed to OMB at (202) 395–6974.

VI. Good Cause To Waive the 30-Day Delay in Effective Date

In accordance with section 553(d) of the Administrative Procedure Act (5 U.S.C. 553(d)), final rules ordinarily are not effective until at least 30 days after their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and its reasons in the rule issued.

In this rule, we are removing the 3-year recordkeeping requirement from the August 29, 2003 rule and replacing it with a 10-year recordkeeping requirement for manufacturers that participate in the Medicaid drug rebate program. Due to concerns regarding the FCA and the potential destruction of drug pricing records, we find good cause to waive the 30-day delay in the effective date of the provision in this rule revising the record retention requirement. As discussed below, failure to waive the delay in effective date would be contrary to the public interest. The FCA establishes civil liability for persons or entities who knowingly submit false or fraudulent claims for Federal funds. Essential to the strength of the FCA are its qui tam whistleblower provisions, which allow persons with evidence of fraud against Federal programs or contracts to bring suit on behalf of the government. Qui tam actions are filed under seal and preliminary investigations often take place without notice to manufacturers. While the August 29, 2003 rule would only require manufacturers to keep drug pricing records 3 years following the date the manufacturer first reported the data to us for purposes of average manufacturer price and best price, it could be misinterpreted to permit these records to be discarded for other purposes. As noted, the August 29, 2003 rule would require manufacturers to retain earlier records if they were aware of an unresolved audit or government investigation concerning the manufacturers' average manufacturer price or best price. However, since the manufacturer is often unaware of qui tam investigations, we are concerned that, without this final rule, manufacturers participating in the Medicaid drug rebate program would erroneously conclude that they could discard records concerning drug price calculations, as well as data supporting those calculations that are subject to the FCA and other fraud laws. If the rule is not revised, there is a chance that manufacturers would seek to minimize their potential civil liability under the FCA by discarding their Medicaid rebate records through December 31, 2000. As a result, the effective use of the FCA to investigate fraud regarding the Medicaid drug rebate program could be severely limited at a considerable cost to the Federal and State treasuries. Accordingly, we believe there is a compelling public interest to waive the 30-day delay in effective date for this revision.

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 not have an economically significant effect. We believe the rule will result in neither costs nor savings to the Medicaid program and that additional costs to drug manufacturers will 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 will not have a significant impact on small businesses because although some pharmaceutical manufacturers may be small businesses, we estimated that the cost to manufacturers will be minimal, as described in section VII.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 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 in this final rule 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 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 will 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 will 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 is 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 will 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 is 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 replace the 3-year provision with a 10-year provision to address concerns raised by commenters regarding Federal and State investigations under the FCA and related anti-fraud provisions.

Establish a different time limitation.

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

Finalize the 10-year requirement without a sunset date provision.

We considered finalizing the 10-year recordkeeping requirement without a sunset date provision. However, we believe that it is important to offer the regulated community an opportunity to provide comments on the impact that such a provision will have before we finalize the 10-year recordkeeping requirement beyond the December 31, 2004 date. In addition, we want 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, 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 recordkeeping requirements, Rural areas.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 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)(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 timeframe 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.

(2) The provisions in paragraph (h)(1) of this section concerning record retention terminate on December 31, 2004.

* * * * *

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

Dated: December 29, 2003.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 29, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–32329 Filed 12–31–03; 12:47 pm]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket No. FEMA–D–7549]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the Base (1% annual chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

DATES: These modified BFEs are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Director reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities.

The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This interim rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, floodplains, reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows: