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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2175-FC]

RIN 0938-AM20

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

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

ACTION: Final rule with comment period.

SUMMARY: On September 19, 1995, we published a proposed rule in the **Federal Register** that introduced requirements for States and manufacturers pertaining to the Medicaid drug rebate program. We received several comments from States and manufacturers regarding recordkeeping requirements and drug price recalculations. This final rule with comment period finalizes separately, in an accelerated timeframe, two specific provisions of the September 1995 proposed rule. It establishes new recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program. It also sets forth 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 announces the pressing need for codification of fundamental recordkeeping requirements. Furthermore, it announces our intention to continue to work on finalizing the complete drug rebate regulation for the Medicaid drug rebate program.

DATES: *Effective Date:* October 1, 2003.

Comment Date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 28, 2003.

ADDRESSES: In commenting, please refer to file code CMS-2175-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and

Human Services, Attention: CMS-2175-FC, PO Box 8016, Baltimore, MD 21244-8016.

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 three 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 commenters 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, call telephone number: (410) 786-7195.

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I. Background

A. Overview

We are publishing this final rule with comment period to address the issues of manufacturer recordkeeping requirements and price recalculations under the Medicaid drug rebate program. We decided to issue a final rule with comment period rather than a final rule to give interested parties an additional opportunity to provide comments on these provisions. We believe the additional comment period is appropriate given the time that has elapsed between the publication of the September 19, 1995 proposed rule (60 FR 48442) and the publication of this rule.

We are publishing this rule to address concerns regarding the administration of the Medicaid drug rebate program for manufacturers and States. In the absence of a regulatory recordkeeping requirement, manufacturers are in effect required to retain pricing data for an indefinite period. The 3-year recordkeeping requirement will enable manufacturers to close their books within a reasonable timeframe. This recordkeeping requirement will mirror the 3-year timeframe established for States to retain records at 42 CFR 433.32.

We believe establishing a timeframe for manufacturers to submit revised pricing data to us also streamlines the administration of the Medicaid drug rebate program. Due to recalculations involving hundreds of millions of State and Federal Medicaid dollars and over 10 years of paperwork, we believe it is essential that a standard timeframe be established within which manufacturers and CMS, or States, are permitted to submit revised drug prices. This timeframe will also assist States that would otherwise be required to retain their drug utilization data indefinitely to verify changes in rebate amounts resulting from retroactive manufacturer recalculations. Therefore, as of the effective date of this rule, manufacturers will have 12 quarters from the quarter in which the data were originally due to submit revised pricing data to us. This timeframe is described in further detail in section IV of the preamble, "Provisions of the Final Rule."

In this rule, we intend the terms “manufacturer,” “average manufacturer price (AMP),” and “best price (BP)” to have the same meaning as described and set forth in the national drug rebate agreements signed by manufacturers and the Secretary (on behalf of States). We also have used these terms in guidance documents that we have issued over the years pertaining to the Medicaid drug rebate program. We do not intend to alter these definitions in this rule. Rather, the primary purpose of this rule is to establish procedural requirements pertaining to manufacturer recordkeeping and pricing changes. We will set forth regulatory definitions of these terms in a subsequent document we will publish in the **Federal Register**.

B. 1995 Proposed Rule

On September 19, 1995, we published a proposed rule (60 FR 48442) in the **Federal Register** that specified requirements for State Medicaid agencies and conditions under which Federal payments would be made under the Medicaid program for covered outpatient drugs. The rule also specified the conditions for approval and renewal of rebate agreements with drug manufacturers participating in the Medicaid program.

In the September 1995 proposed rule, we also discussed prior period adjustments and pricing changes. A prior period adjustment is a change in the unit rebate amount based on a manufacturer's revised AMP or BP data for a prior rebate period after that rebate period's pricing data have been submitted to us. The prior period adjustments generally consist of a manufacturer's changes to pricing data resulting from sales data not being available before pricing submissions to us or changes in the methodology used to establish AMP or BP. We use the manufacturer's pricing data to generate the unit rebate amount for each 9-digit national drug code, which States use to calculate rebate amounts due from manufacturers. Any changes to a manufacturer's AMP or BP result in changes to the unit rebate amount and rebates due from the manufacturer. Thus, the prior period adjustments are necessary to correct rebate amounts that are owed by manufacturers or credits due to manufacturers.

Since the publication of the September 1995 proposed rule, States have expressed concerns regarding pricing changes and recalculations under the Medicaid drug rebate program. We have received requests for pricing recalculations for drug prices submitted as far back as 1991. The statute does not specifically provide for

such recalculations; however, we have permitted the recalculations where revisions were made to conform to the statute or rebate agreement. Unfortunately, there is a significant burden on States and manufacturers to maintain pricing data and supporting documentation for timeframes dating back to 1991. We have seen a recent increase in the number of these requests and the dollar value of the recalculations. In addition, manufacturers have expressed concerns regarding recordkeeping burdens. In response to these concerns, we are finalizing the recordkeeping requirements and the time limit on pricing recalculations proposed in the September 1995 rule. We will address the remaining provisions of the September 1995 rule in a subsequent rule we will publish in the **Federal Register**.

C. Legislative History

Section 1927 of the Social Security Act (the Act) authorizes the Medicaid drug rebate program. Section 1927 of the Act was amended by section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and section 13602 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). Under section 1927 of the Act, manufacturers that have entered into a national rebate agreement must provide each State Medicaid program with rebate period payments (or other periodic rebate payments, as determined by the Secretary).

D. Requirements for Manufacturer's Data

Section 1927(b) of the Act gives the Secretary the authority to publish regulations that establish manufacturer recordkeeping requirements and the time limit for manufacturer pricing changes. To implement these provisions, we will require that a manufacturer must retain pricing data for 3 years from the date the manufacturer reports that period's data to us. Although the statute sets forth requirements on data reported to us by manufacturers, it does not provide recordkeeping requirements for manufacturer data. In the national drug rebate agreement, we did not establish a timeframe during which records must be maintained. The 3-year time period comports with the requirements for the maintenance of records on State Medicaid expenditures imposed on States. Section 433.32 requires that States retain records for 3 years from the date of submission of a final expenditure report for Federal financial participation.

E. Manufacturer's Pricing Data

Section 1927(b)(3)(A)(i) requires that manufacturers submit pricing information no later than 30 days after the end of each quarter. However, it does not establish a time limitation regarding pricing changes. While we recognize the need to permit manufacturers to submit revised prices within a timeframe, States and manufacturers should be protected from potential liabilities resulting from no time limit. We will require that manufacturers submit changes to AMP or BP within 3 years from the date that period's data are due. The timeframe for pricing changes set forth in this final rule is more fully described in section IV of the preamble, “Provisions of the Final Rule.”

II. Provisions of the Proposed Rule

In the September 19, 1995 proposed rule, we solicited comments on proposed requirements for State Medicaid agencies, the conditions under which Federal payments would be made under the Medicaid program for covered outpatient drugs, and the conditions for approval and renewal of rebate agreements with drug manufacturers. In this final rule with comment period, we are finalizing two of the provisions of the September 1995 proposed rule. We will address the remaining provisions of the September 1995 proposed rule and will publish a subsequent rule in the **Federal Register**.

In the September 1995 proposed rule, we proposed to add to part 447 a new subpart I entitled “Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements.” Within that subpart, we proposed a new § 447.534(g) to establish a 3-year recordkeeping requirement for manufacturer data pertaining to AMP and BP calculations. We also proposed a new § 447.534(h) to establish a 3-year time limit for manufacturers to report revised AMP or BP to us.

III. Analysis of and Response to Public Comments on the September 19, 1995 Proposed Rule

We received 19 timely comments in response to the September 19, 1995 proposed rule. We received comments from State government officials and representatives of the pharmaceutical industry including manufacturers, pharmacists, attorneys, and consultants. Although we received comments on a variety of topics pertaining to the proposed rule, we are addressing only the comments that pertain to the manufacturer recordkeeping requirements and the 3-year limitation

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.

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

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

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).

■ 2. A new subpart I, consisting of § 447.500 through § 447.550, is added to read as follows:

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

Sec.
447.500–447.532 [Reserved]
447.534 Manufacturer reporting requirements.
447.536–447.550 [Reserved]

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

§§ 447.500–447.532 [Reserved]

§ 447.534 Manufacturer reporting requirements.

(a)–(g) [Reserved]

(h) *Recordkeeping requirements.* (1)(i)

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.

(ii) 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.

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

(2) [Reserved]

(i) *Timeframe for reporting revised average manufacturer price or best price.* A manufacturer must report to CMS revisions to average manufacturer price or best price for a period not to exceed 12 quarters from the quarter in which the data were due.

(ii) [Reserved]

§§ 447.536–447.550 [Reserved]

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

Dated: January 16, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 29, 2003.

Tommy G. Thompson,

Secretary.

Editorial Note: This document was received in the Office of the Federal Register on August 19, 2003.

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BILLING CODE 4120–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket No. FEMA–7815]

Suspension of Community Eligibility

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

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

EFFECTIVE DATES: The effective date of each community's suspension is the third date ("Susp.") listed in the third column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Mike Grimm, Mitigation Division, 500 C Street, SW.; Room 412, Washington, DC 20472, (202) 646–2878.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase

flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives a 6-month, 90-day, and 30-day notification