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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."