

**Appendices A and B—[Amended]**

■ 2. Appendices A and B to part 355 are amended by removing the entry for CAS No. 732-11-6 for the Chemical Name Phosmet.

[FR Doc. 04-26162 Filed 11-24-04; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Part 447**

[CMS-2175-F]

RIN 0938-AM20

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

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

**ACTION:** Final rule.

**SUMMARY:** This final rule finalizes 10-year recordkeeping requirements for drug manufacturers under the Medicaid drug rebate program. Manufacturers must retain records for 10 years from the date the manufacturer reports data to us for a rebate period.

This final rule also finalizes the requirement that manufacturers must retain records beyond the 10-year period if the records are known by the manufacturer to be the subject of an audit or a government investigation.

Furthermore, this final rule responds to public comments on the January 6, 2004 interim final rule with comment period and the proposed rule pertaining to the 10-year recordkeeping requirements, respectively.

**DATES:** This rule is effective January 1, 2005.

**FOR FURTHER INFORMATION CONTACT:** Kim Howell, (410) 786-6762.

**SUPPLEMENTARY INFORMATION:****I. Background**

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

Absent a regulatory or statutory requirement, it has been our position that manufacturers must retain these records indefinitely.

On September 19, 1995, we published a proposed rule (60 FR 48442) in the **Federal Register** that proposed numerous provisions related to the Medicaid drug rebate program. As relevant to this rule, we proposed a new 3-year recordkeeping requirement for drug manufacturers under the Medicaid drug rebate program and proposed a 3-year time limitation during which manufacturers must recalculate and report data to us on the average manufacturer price and best price. On August 29, 2003, we published a final rule with comment period (68 FR 51912) in the **Federal Register** that finalized both provisions. On September 26, 2003, we issued a correction notice (68 FR 55527) in the **Federal Register** to change the effective date of the August 29, 2003 rule from October 1, 2003 to January 1, 2004.

**II. Provisions of the Proposed Regulations and Interim Final Rule**

On January 6, 2004, we published an interim final rule with comment period that removed the 3-year recordkeeping requirement issued in the August 29, 2003 final rule with comment period, and replaced it with 10-year recordkeeping requirements on a temporary basis for manufacturers participating in the Medicaid drug rebate program, and solicited comments on the 10-year requirement.

Under the 10-year recordkeeping requirement, we required that manufacturers retain records for 10 years from the date the manufacturer reports data to us for a rebate period. We also required that manufacturers 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 and if the audit findings or investigation related to the average manufacturer price and best price have not been resolved. The provisions of the January 6, 2004 interim final rule related to record retention are scheduled to sunset on December 31, 2004.

In addition, the January 6, 2004 interim final rule with comment period responded 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). 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 False Claims Act

(FCA) and other possible fraud and abuse violations.

Also, on January 6, 2004, we published a proposed rule (69 FR 565) that would remove the 3-year recordkeeping requirement and replace it with 10-year recordkeeping requirement on a permanent basis. We also proposed that manufacturers must retain records beyond the 10-year period if the manufacturers are aware that the records are the subject of an audit or a government investigation and if the audit findings or investigation related to the manufacturer's average manufacturer price and best price have not been resolved. This final rule finalizes both the interim final rule and the proposed rule that we published on January 6, 2004.

**III. Analysis of and Response to Public Comments on the January 6, 2004 Interim Final With Comment Period and Proposed Rule**

We received 3 timely comments in response to the January 6, 2004 interim final rule with comment period and proposed rule. We received comments from an attorney who represents the pharmaceutical industry, a coalition comprised of national advocacy groups, and a non-profit organization. These comments and our responses are summarized below.

**Comment:** One commenter urged us to promulgate the 10-year requirement as a final rule, effective before the expiration of the current 10-year requirement on December 31, 2004.

**Response:** We agree; therefore, we are issuing this final rule to permanently establish the 10-year recordkeeping requirements for manufacturers.

**Comment:** One commenter expressed the opinion that the January 6, 2004 interim final rule and proposed rule should be modified to change the record retention requirements back to 3 years. A manufacturer would still have the discretion to retain records for as long as it wanted, but would not be subject to a mandatory requirement in excess of the 3-year period. The government would not be restricted by these rules from pursuing claims under the False Claims Act (FCA) or applicable health care laws against a manufacturer for fraud, abuse, or knowingly submitting false data to the government. Changing the record retention requirement back to 3 years would reconcile the current conflict between the 10-year record retention requirement and the 3-year price recalculation reporting requirement. The commenter further stated that the interim final rule and the proposed rule should be finalized to clearly state that the 3-year time

limitation is a statute of limitations and that a manufacturer will not be liable or obligated to pay the government or be entitled to be the beneficiary of any errors in calculations for periods outside of the 3-year time limitation.

*Response:* We believe that it is necessary to replace the 3-year provision with a 10-year provision to address concerns regarding Federal and State investigations for fraud under the FCA and related anti-fraud provisions concerning the Medicaid drug rebate program. Since the manufacturer is often unaware of the qui tam investigations, we must ensure that manufacturers participating in the Medicaid drug rebate program do not 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. The qui tam whistleblower provisions 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.

As noted in the January 6, 2004 interim final rule, we received comments suggesting that the 3-year recordkeeping requirements were too short, but none to convince us to expand the time limit on pricing recalculations. Therefore, since 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. Furthermore, the 3-year limitation rule was designed to establish time limits for reporting recalculations and to decrease associated administrative burdens on manufacturers and States. After further consideration, we firmly believe that the 10-year provision 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 activities regarding the issues of potential fraud and abuse violations and litigation.

*Comment:* One commenter expressed the opinion that the 10-year recordkeeping requirement is a significant improvement over the original rule, and will provide a more effective safeguard against improper or fraudulent drug price inflation and abuse of both the Medicaid rebate program and the program under section 340B of the Public Health Service Act. However, the commenter believes that an even longer period of record

retention should be required of drug manufacturers.

*Response:* We recognize that there is some cross-over between the data required for the Medicaid drug rebate program and the 340B program. However, our regulation is solely designed to address the Medicaid drug rebate program. We believe that a 10-year recordkeeping requirement is consistent with the FCA and offers immediate protection to address potential fraud and abuse violations and litigation.

#### IV. Provisions of the Final Rule

We are adopting the provisions of the regulation text in the January 6, 2004 proposed rule. We are making editorial changes to § 447.534(h)(1)(i) and we are removing paragraph (h)(2), which was included in the interim final rule with comment. This final rule establishes a permanent 10-year recordkeeping requirement for prescription drug manufacturers that participate in the Medicaid drug rebate program. This provision would be set forth in 42 CFR part 447 subpart I. Under the 10-year recordkeeping requirement, we require that a drug manufacturer retain records for 10 years from the date the manufacturer reports that rebate period's data to us. In addition, we require a manufacturer retain data beyond the 10-year period if the manufacturer is aware that the records are the subject of an audit or a government investigation and if the audit findings or investigation related to the manufacturer's average manufacturer price and best price have not been resolved.

In addition, in § 447.534, we are removing the paragraph (ii) [Reserved] at the end of the section, which is a misprint. The paragraph that precedes it is the lower case letter "i." It was misconstrued for the roman numeral one (i). Thus, paragraph (ii) is erroneous and should be removed.

#### V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment when 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 PRA 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.

However, the collection requirements referenced below are currently approved by OMB, under OMB control number 0938-0578, entitled "Medicaid Drug Rebate Program, Manufacturers".

#### Section 447.534 Manufacturer Reporting Requirements

Paragraph (h) of this section states a manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for a rebate period. 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 and any revised pricing data subsequently submitted to CMS.

#### VI. 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 do not believe this rule will have an economically significant effect. We believe the rule will not result in costs 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 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 numbers of employees to the Small Business Administration, we find there is no practical way to determine how many are considered small entities out of a total of 3,295 firms and establishment as reported by the United States Census Bureau (see <http://www.census.gov/csd/susb/usaalliol.xls>). Therefore, we believe this rule will not have a significant impact on small businesses because, although some pharmaceutical manufacturers may be small businesses, we estimate 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 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 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 any 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 in the final rule, we requested 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 asked that manufacturers make an effort to distinguish between the costs of meeting the 10-year recordkeeping requirement versus other recordkeeping requirements that may apply to the same records. However, we did not receive any information or data in response to our request regarding the expected cost that would be incurred pursuant to retaining records for a 10-year period necessary to determine whether our original assumptions were unsubstantiated. Accordingly, we continue to believe that our estimates are reasonable.

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 regarding Federal and State investigations for fraud under the FCA concerning the Medicaid drug rebate program.

##### *Establish a different time limitation.*

Another alternative would be to establish a longer or 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 that it could prematurely destroy vital evidence in a potential fraud and abuse litigation.

##### *Finalize the 10-year recordkeeping requirement with a sunset date provision.*

We considered finalizing the 10-year recordkeeping requirement with a sunset date provision. However, we did not choose to finalize the provision with a sunset date because as discussed previously, we have concerns about the potential premature destruction of evidence in false claims act litigation.

**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 as set forth below:

**PART 447—PAYMENTS FOR SERVICES**

■ 1. The authority for 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, the following changes are made:

- A. Paragraph (h)(1)(i) is revised.
- B. Paragraph (h)(1)(ii) is republished.
- C. Paragraph (h)(2) is removed and reserved.
- D. Paragraph (i) is republished.
- E. The paragraph designated (ii) [Reserved] at the end of the section is removed.

**§ 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 data to CMS for that rebate period. 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) [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.

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

Dated: August 18, 2004.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: September 8, 2004.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 04-25969 Filed 11-24-04; 8:45 am]

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**FEDERAL COMMUNICATIONS COMMISSION****47 CFR Part 73**

[DA 04-3522, MB Docket No. 04-253, RM-11007]

**Digital Television Broadcast Service; Greeley, CO**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission, at the request of Thomas Desmond, allots DTV channel 45 to Greeley, Colorado, as the community's first local commercial television service. See 69 FR 45301, July 29, 2004. DTV channel 45 can be allotted to Greeley, Colorado, in compliance with the Sections 73.623(d) and 73.625(a) at reference coordinates 40-25-15 N. and 104-31-30 W. With this action, this proceeding is terminated.

**DATES:** Effective January 3, 2005.

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418-1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 04-253, adopted November 4, 2004, and released November 18, 2004. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC, 20554, telephone 301-816-2820, facsimile 301-816-0169, or via e-mail [joshir@erols.com](mailto:joshir@erols.com).

This document does not contain [new or modified] information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. In addition, therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4).

The Commission will send a copy of this Report & Order in a report to be sent to Congress and the General Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

**List of Subjects in 47 CFR Part 73**

Digital television broadcasting, Television.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

**PART 73—[AMENDED]**

■ 1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.622 [Amended]**

■ 2. Section 73.622(b), the Table of Digital Television Allotments under Colorado, is amended by adding Greeley, DTV channel 45.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 04-26158 Filed 11-24-04; 8:45 am]

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