

Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications"

as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 22, 2003.

**James Jones,**

*Director, Office of Pesticide Programs.*

■ Therefore, 40 CFR chapter I is amended as follows:

#### PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

■ 2. A new section heading and text are added to § 180.513 to read as follows:

#### § 180.513 Chlorfenapyr; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide chlorfenapyr [4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] in or on the following raw agricultural commodities:

| Commodity                          | Parts per million |
|------------------------------------|-------------------|
| Vegetables, fruiting, group 8 .... | 1.0               |

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 447

[CMS-2175-CN]

RIN 0938-AM20

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

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

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects the effective date of a final rule with comment period published in the **Federal Register** on August 29, 2003 (68 FR 51912). That rule finalizes separately, in an accelerated timeframe, two specific provisions of the September 19, 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. It also announces our intention to continue to work on finalizing the complete drug

rebate regulation for the Medicaid drug rebate program. This document corrects the effective date.

**EFFECTIVE DATE:** The effective date of the August 29, 2003 final rule (68 FR 51912) amending 42 CFR part 447 is corrected from October 1, 2003 to January 1, 2004.

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

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On August 29, 2003, we published in the **Federal Register** a final rule with comment period entitled, "Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program." The rule establishes requirements for recordkeeping and time limits on price recalculations. The effective date of these requirements as stated in the August 2003 rule is October 1, 2003.

The Office of Management and Budget (OMB) declared that the August 2003 final rule is a major rule. Thus, we should have given January 1, 2004 as the effective date in accordance with 5 U.S.C. 801(a)(4). However, we erroneously incorporated an incorrect effective date of October 1, 2003. We have identified and corrected that error in the "Correction of Errors" section below.

**II. Correction of Errors**

In FR Doc. 03-21548 of August 29, 2003 (68 FR 51917), make the following correction:

- On page 51912, in column one, in the "Dates" section, remove "October 1, 2003" and replace it with "January 1, 2004."

**III. Waiver of Notice of Proposed Rulemaking and Delay of the Effective Date**

We ordinarily publish a general notice of proposed rulemaking in the **Federal Register** and invite prior public comment on a proposed rule. Final rules generally have a 30-day or longer prospective effective date. However, this document merely provides a correction to the effective date of the final rule with comment published on August 29, 2003. This correction is being made based on OMB's decision that the August 2003 final rule is a major rule. Thus, we should have given January 1, 2004 as the effective date in accordance with 5 U.S.C. 801(a)(4). However, we erroneously incorporated an incorrect effective date of October 1, 2003. It would be impracticable, unnecessary and contrary to the public interest to publish a proposed rule and solicit

comments since this document is technical in nature and does not impose new limits on the substantive rights of the industry or the public. Similarly, given the imminence of the effective date, it would serve no useful purpose to further delay the effective date of this technical correction. Therefore, to the extent that 5 U.S.C. 553 applies to this action, we find good cause to waive notice and comment procedures and our usual delay in the effective date.

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

Dated: September 24, 2003.

**Ann C. Agnew,**

*Executive Secretary to the Department.*

[FR Doc. 03-24550 Filed 9-25-03; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 483 and 488**

**[CMS-2131-F]**

**RIN 0938-AL04**

**Medicare and Medicaid Programs; Requirements for Paid Feeding Assistants in Long Term Care Facilities**

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

**ACTION:** Final rule.

**SUMMARY:** This final rule permits a long term care facility to use paid feeding assistants to supplement the services of certified nurse aides under certain conditions. States must approve training programs for feeding assistants using Federal requirements as minimum standards. Feeding assistants must successfully complete a State-approved training program and work under the supervision of a registered nurse or licensed practical nurse. The intent is to provide more residents with help in eating and drinking and reduce the incidence of unplanned weight loss and dehydration.

**EFFECTIVE DATE:** These regulations are effective on October 27, 2003.

**FOR FURTHER INFORMATION CONTACT:** Nola Petrovich, (410) 786-4671.

**SUPPLEMENTARY INFORMATION:** *Copies:* 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**

*Legislation*

Sections 1819(a) through (e) and 1919(a) through (e) of the Social Security Act (the Act) set forth the requirements that long term care facilities must meet to participate in the Medicare and Medicaid programs, respectively. Sections 1819(f)(2) and 1919(f)(2) of the Act contain requirements for nurse aide training and competency evaluation programs (NATCEP). Sections 1819(g) and 1919(g) of the Act contain the criteria that we use to assess a facility's compliance with the requirements. These statutory provisions were mandated by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100-203, enacted December 22, 1987). The requirements for long term care facilities are codified at 42 CFR part 483, subpart B; the nurse aide training and competency evaluation program requirements are codified at 42 CFR part 483, subpart D; and the survey, certification and enforcement procedures are codified at 42 CFR part 488, subparts E and F.

Sections 1819(b)(5)(F) and 1919(b)(5)(F) of the Act and regulations at § 483.75(e) define a nurse aide as any individual furnishing nursing or nursing-related services to residents in a facility, who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide services without pay. Sections 1819(f)(2) and 1919(f)(2) of the Act set forth the requirements for approval of a nurse aide training and competency evaluation program, but do not define "nursing" or "nursing related" skills. Section 483.152 of the regulations specifies nurse aide training requirements. These include, for example, basic nursing skills, personal care skills, communication and interpersonal skills, infection control, safety and emergency procedures, mental health and social service needs, residents' rights, care of cognitively impaired residents, and basic restorative services.

On March 29, 2002, we published in the **Federal Register** a proposed rule, "Requirements for Paid Feeding Assistants in Long Term Care Facilities" (67 FR 15149), that offered long-term care facilities the option to use paid feeding assistants, if consistent with State law.

**Current Program Experience**

Currently, there is no provision in the regulations for the use of single-task workers, such as paid feeding assistants, in nursing homes. To ensure the safety