

§ 423.100 Definitions.

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Part D drug means—

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act)—

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■ 3. Amend § 423.120 by—

■ A. Revising (b)(2) introductory text.

■ B. Revising (b)(2)(i).

■ C. Adding (b)(2)(v).

The revisions and additions to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(2) Provision of an Adequate Formulary. A Part D plan's formulary must—

(i) Except as provided in paragraphs (b)(2)(ii) and (v) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

* * * * *

(v) Effective contract year 2010, a Part D Sponsor's formulary will include all Part D drugs in a category or class that CMS has identified as meeting the two conditions set forth in section 1860D–4(b)(3)(G)(i) of the Act. CMS may establish certain exceptions, which may include the application of drug utilization management under certain circumstances, through a process that provides for public notice and comment, and ensures that any exception to such requirements is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1–Infected Adults and Adolescents).

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 12, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: January 9, 2009.

Michael O. Leavitt,

Secretary.

[FR Doc. E9–783 Filed 1–15–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 88 and 89

RIN 0991–AB46

Office of Global Health Affairs: Regulation on the Organizational Integrity of Entities That Are Implementing Programs and Activities Under the Leadership Act; Correction

OFFICE: Office of Global Health Affairs, HHS.

ACTION: Rule; Correction.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the **Federal Register** on December 24, 2008, entitled “Regulation on the Organizational Integrity of Entities That Are Implementing Programs and Activities Under the Leadership Act” (73 FR 78997).

DATES: Effective January 20, 2009.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. E8–30686, published on December 24, 2008 (73 FR 78997), there were technical errors that are identified and corrected in the Correction of Errors section below. The correction of errors identified in this correction notice do not change any policies contained in the final rule published December 24, 2008, and thus are effective as if they had been included in the final rule.

II. Summary of Errors

HHS published a final rule entitled “Regulation on the Organizational Integrity of Entities That Are Implementing Programs and Activities Under the Leadership Act.” This final rule provided for creation of a new Part 88 of 45 CFR. A final rule published on December 19, 2008 (73 FR 78071), entitled “Ensuring That Department of

Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law,” however, also purported to create a new Part 88. We are correcting this error by creating a new Part 89 and moving the regulatory text from the final rule published on December 24, 2008 (73 FR 78997) to Part 89. We are correcting text throughout the preamble and regulatory text to reflect this move.

III. Correction of Errors

In FR Doc. E8–30686, published on December 24, 2008 (73 FR 78997), make the following corrections:

[Corrections to the preamble]

1. On page 78997, in the heading, third line, “45 CFR Part 88” is corrected to read “45 CFR Part 89.”

2. On page 78998, in the first column, following the sixth full paragraph, the heading “Section 88.1 Definitions” is corrected to “Section 89.1 Definitions.”

3. On page 78998, in the second column, following the fifth paragraph, the heading “Section 88.2 Objective Integrity of Recipients” is corrected to “Section 89.2 Objective Integrity of Recipients.”

4. On page 78998, in the third column, in the first full paragraph, line 6, “section 88.3” is corrected to “section 89.3.”

5. On page 78998, in the third column, following the first full paragraph, the heading “Section 88.3 Certifications” is corrected to “Section 89.3 Certifications.”

6. On page 78998, in the third column, third full paragraph, line 3, “section 88.3(d)(1)” is corrected to “section 89.3(d)(1).”

7. On page 78998, in the third column, fourth full paragraph, lines 3–4, “section 88.3(d)(2) and (3)” is corrected to “section 89.3(d)(2) and (3).”

8. On page 79001, in the first column, following the second full paragraph, the heading “List of Subjects in the 45 CFR Part 88” is corrected to “List of Subjects in the 45 CFR Part 89.”

[Corrections to the regulatory text]

9. On page 79001, in the first column, in the words of issuance, immediately following paragraph captioned “Editorial Note,” revise the paragraph to read “For the reasons stated in the preamble, the Office of Global Health Affairs amends 45 CFR subtitle A to add Part 89 as follows:”

10. On page 79001, in the first column, in the part heading, “Part 88” is corrected to “Part 89.”

11. On page 79001, in the first column, in the table of contents, “88.1 Definitions” is corrected to “89.1 Definitions.”

12. On page 79001, in the first column, in the table of contents, “88.2 Organizational integrity of recipients” is corrected to “89.2 Organizational integrity of recipients.”

13. On page 79001, in the first column, in the table of contents, “88.3 Certifications” is corrected to “89.3 Certifications.”

14. On page 79001, in the first column, the heading “88.1 Definitions” is corrected to “89.1 Definitions.”

15. On page 79001, in the second column, the heading “88.2 Organizational integrity of recipients” is corrected to “89.2 Organizational integrity of recipients.”

16. On page 79001, in the third column, in newly redesignated § 89.2, in paragraph (b), “required by § 88.3” is corrected to “required by § 89.3.”

17. On page 79001, in the third column, the heading “88.3 Certifications” is corrected to “89.3 Certifications.”

Dated: January 12, 2009.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. E9–843 Filed 1–15–09; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 190, 191, 192, 193, 194, 195, and 199

RIN 2137–AE29

[Docket No. PHMSA–2007–0033]

Pipeline Safety: Administrative Procedures, Address Updates, and Technical Amendments

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule adopts, with minor modifications, an interim final rule issued by PHMSA on March 28, 2008, conforming PHMSA’s administrative procedures with the Pipeline Inspection, Protection, Enforcement, and Safety Act of 2006 by establishing the procedures PHMSA will follow for issuing safety orders and handling requests for special permits, including emergency special permits. The rule also notifies operators about electronic docket information availability; updates addresses for filing reports, telephone numbers, and routing

symbols; and clarifies the time period for processing requests for written interpretations of the regulations. This final rule makes minor amendments and technical corrections to the regulatory text in response to written public comments received after issuance of the interim final rule.

DATES: *Effective Date:* This final rule is effective February 17, 2009.

FOR FURTHER INFORMATION CONTACT: Larry White, PHMSA, Office of Chief Counsel, 202–366–4400, or by e-mail at lawrence.white@dot.gov.

SUPPLEMENTARY INFORMATION:

Background

On March 28, 2008, PHMSA issued an interim final rule (73 FR 16562) conforming PHMSA’s administrative procedures with the Pipeline Inspection, Protection, Enforcement, and Safety Act of 2006 (PIPES Act) (Pub. L. 109–468) by establishing the procedures PHMSA will follow for issuing safety orders and handling requests for special permits, including emergency special permits. The interim final rule also notified operators about electronic docket information availability; updated addresses, telephone numbers, and routing symbols; and clarified the time period for processing requests for written interpretations of the regulations. Because we considered these amendments to be procedural and ministerial in nature, PHMSA made them effective immediately, while inviting public comment on any and all terms. Having since received and considered written comments in response to our March 28, 2008, notice, PHMSA now is issuing this final rule, incorporating minor amendments and technical corrections to the regulatory text.

Safety Orders. Pursuant to section 13 of the PIPES Act, the interim final rule established the process by which PHMSA will initiate safety order proceedings to address identified pipeline integrity risks that may not rise to the level of a hazardous condition requiring immediate corrective action under 49 U.S.C. 60112, but should be addressed over time to prevent failures. The rule requires PHMSA to provide operators with notice and an opportunity for a hearing before issuing a safety order and expressly authorizes informal consultation in advance of an administrative hearing. In the absence of consent, a safety order must be based on a finding by the Associate Administrator for Pipeline Safety that a pipeline facility has a condition that poses a risk to public safety, property, or the

environment. In making the required finding, the Associate Administrator considers all relevant information, including the nine considerations expressly enumerated in 49 U.S.C. 60117(l)(2). PHMSA expects the majority of safety order proceedings to be resolved by consent agreement between the operator and PHMSA. The safety order process established in the interim final rule is largely unchanged in this final rule.

Special Permits. To clarify the procedures governing special permits, and to establish new procedures for exercise of the agency’s emergency authority, the interim final rule added a new section, entitled “Special permits,” to our administrative procedures in 49 CFR Part 190. The rule outlines the procedures under which pipeline operators (and prospective operators) may request special permits. It specifies the information that must be provided in each application and, in accordance with 49 U.S.C. 60118(c)(1)(B), provides for public notice and hearing on applications for (non-emergency) special permits. Section 10 of the PIPES Act provided PHMSA with the authority to issue an emergency waiver of a pipeline safety regulation without prior notice and hearing if necessary to address an emergency involving pipeline transportation, and the rule outlines the procedures for operators to request such emergency special permits. The special permit process established in the interim final rule is largely unchanged in this final rule.

Other Amendments. The interim final rule also amended part 190 by adding a new paragraph notifying operators that all materials they submit in response to administrative enforcement actions may be placed on publicly accessible websites. The rule sets forth the procedure for seeking confidential treatment, along with other information concerning the agency’s new enforcement transparency website. The rule also reflects the recent relocation of DOT Headquarters and the transition from the Department’s electronic docket management system to the government-wide electronic docket system (found at regulations.gov), enabling electronic service of enforcement documents. This final rule also amends 49 CFR Parts 191–199 to correct the address for filing annual, accident, and safety-related condition reports for hazardous liquid pipelines (which was inadvertently omitted from the interim final rule) and corrects addresses, telephone numbers, and routing symbols in the regulations for filing various other forms and reports.