

Subpart I—Payment for Drugs

§ 447.502 [Amended]

2. Section 447.502 is amended by removing the definition of “multiple source drug.”

§ 447.504 [Removed and reserved]

3. Section 447.504 is removed and reserved.

4. Section 447.510 is amended by—
A. Republishing paragraph (a) introductory text.

B. Revising paragraphs (a)(1), (c)(2)(i), and (d)(2).

The revisions read as follows:

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with section 1927 (k)(1) of the Social Security Act.

* * * * *

(c) * * *

(2) * * *

(i) A manufacturer’s recalculation of the base date AMP must only reflect the revisions to AMP as provided for in section 1927(k)(1) of the Social Security Act.

* * * * *

(d) * * *

(2) *Calculation of monthly AMP.* Monthly AMP should be calculated based on section 1927(k)(1) of the Social Security Act, except the period covered should be based on monthly, as opposed to quarterly AMP sales.

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5. Section 447.512 is amended by—
A. Removing and reserving paragraph (a).

B. Revising the introductory text of paragraph (b).

C. Revising paragraph (c).

The revisions read as follows:

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) [Reserved]

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established must not exceed, in the aggregate, payments levels that the agency has determined by applying the lower of the—

* * * * *

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which specific

limit has been established does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A check-off box on a form is not acceptable but a notation like “brand necessary” is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 [Removed and reserved]

5. Section 447.514 is removed and reserved.

6. Section 447.518 is amended by:

A. Revising paragraph (b)(1)(i).

B. In paragraph (b)(2), removing the citations “§§ 447.512 and § 447.514” and adding citation “§ 447.512” in its place.

The revision reads as follows:

§ 447.518 State plan requirements, findings and assurances.

* * * * *

(b) * * *

(1) * * *

(i) In the aggregate, its Medicaid expenditures for multiple source drugs are in accordance with the established upper limits.

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Authority: Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program.

Dated: August 18, 2010.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

Approved: August 31, 2010.

Kathleen Sebelius,
Secretary.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 61

[Docket ID: FEMA–2010–0021]

RIN 1660–AA70

National Flood Insurance Program, Policy Wording Correction

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule; request for comments.

SUMMARY: By this Notice of Proposed Rulemaking, the Federal Emergency Management Agency (FEMA) is proposing a technical correction to the FEMA, Federal Insurance and Mitigation Administration, Standard Flood Insurance Policy regulations. In this proposed rule, FEMA intends to increase the clarity of one of the provisions of the Standard Flood Insurance Policy by adding in two unintentionally omitted words.

DATES: Comments must be submitted on or before November 2, 2010.

ADDRESSES: You may submit comments, identified by Docket ID: FEMA–2010–0021, by one of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

E-mail: FEMA-RULES@dhs.gov.

Include Docket ID: FEMA–2010–0021 in the subject line of the message.

Fax: (703) 483–2999.

Mail/Hand Delivery/Courier: Office of Chief Counsel, Federal Emergency Management Agency, Room 835, 500 C Street, SW., Washington, DC 20472–3100.

To avoid duplication, please use only one of these methods. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For instructions on submitting comments, See the Public Participation portion of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Edward L. Connor, Acting Federal Insurance and Mitigation Administrator, DHS/FEMA, 1800 South Bell Street, Arlington, VA 20598–3010. Phone: (202) 646–3429. Facsimile: (202) 646–7970. E-mail: Edward.Connor@dhs.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this Notice of Proposed Rulemaking (NPRM). Comments that will provide the most assistance to the Federal Emergency Management Agency (FEMA) in developing this rule will refer to a specific provision of the NPRM, explain the reason for any comments, and include other information or authority that supports such comments. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided. If you submit a comment,

please include the Docket ID for this rulemaking, FEMA–2010–0021, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

A. Privacy Act

Please be aware that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual who submitted the comment (or signed the comment, if submitted on behalf of an association, business, labor union, etc.) You may want to review the Federal Docket Management System system of records notice published in the **Federal Register** on March 24, 2005 (70 FR 15086).

B. Submission of Sensitive Information

Do not submit comments that include trade secrets, confidential commercial or financial information to the public regulatory docket. Please submit such comments separately from other comments on the rule. Comments containing this type of information should be appropriately marked as containing such information and submitted by mail to the address specified in the **ADDRESSES** section of this NPRM. If FEMA receives a request to examine or copy this information, FEMA will treat it as any other request under the Freedom of Information Act (FOIA), 5 U.S.C. 552, and the Department of Homeland Security's FOIA regulation found in 6 CFR part 5 and FEMA's regulations found in 44 CFR part 5.

C. Public Meeting

FEMA does not plan to hold a public meeting on this NPRM, but you may submit a request for one at the address specified in the **ADDRESSES** section of this NPRM explaining why one would be beneficial. If FEMA determines that a public meeting would aid this rulemaking, FEMA will hold one at a time and place announced by a notice in the **Federal Register**.

II. Background

Under the authority of sections 1304 and 1345 of the National Flood Insurance Act of 1968, Public Law 90–448, 82 Stat. 574, as amended (42 U.S.C. 4011, 4081), FEMA provides insurance protection against flood damage to homeowners, businesses, and others by means of the National Flood Insurance Program (NFIP). The sale of flood insurance is largely implemented by private insurance companies that participate in the NFIP Write-Your-Own (WYO) Program. Through the WYO

Program, insurance companies enter into agreements with FEMA to sell and service flood insurance policies and adjust claims after flood losses.

The policy sold is the FEMA Standard Flood Insurance Policy (SFIP), which is published in 44 CFR part 61, Appendix A. The SFIP has six parts, the Dwelling Form (App A(1)), General Property Form (App A(2)), Residential Condominium Building Association Policy (App A(3)), Endorsement to Dwelling Form (App A(4)), Endorsement to General Property Form (App A(5)), and the Endorsement to Residential Condominium Building Association Policy (App A(6)). The language in the Dwelling Form and the General Property Form are similar with respect to their discussion of the property covered. For example, the paragraph at 44 CFR part 61 Appendix A(1) III.B.3 contains the same substance as the paragraph at 44 CFR part 61 Appendix A(2) III.B.4.

However, 44 CFR part 61 Appendix A(2) III.B.4 reads:

Items of property in a building enclosure below the lowest elevated floor of an elevated post-FIRM building located in zones A1–A30, AE, AH, AR, AR/A, AR/AE, AR/AH, AR/A1–A30, V1–V30, or VE, or in a basement, regardless of the zone, is limited to the following items, if installed in their functioning locations and, if necessary for operation, connected to a power source:
* * *

While 44 CFR part 61 Appendix A(1) III.B.3 reads:

Coverage for items of property in a building enclosure below the lowest elevated floor of an elevated post-FIRM building located in zones A1–A30, AE, AH, AR, AR/A, AR/AE, AR/AH, AR/A1–A30, V1–V30, or VE, or in a basement, regardless of the zone, is limited to the following items, if installed in their functioning locations and, if necessary for operation, connected to a power source: * * *

III. Discussion of Rule

On May 31, 2000, FEMA published an NPRM at 65 FR 34823 that proposed to revise the SFIP so that it would conform to “plain language” standards. The rule also proposed changes that would bring the three forms of the SFIP more in line with the format of the insurance industry's homeowners policy. FEMA also proposed changes in the coverage.

On October 12, 2000, FEMA published a final rule at 65 FR 60757. The final rule changed the SFIP so that it was in “plain language” and restructured the format to resemble the homeowners policy. FEMA also made changes in the policy's coverage and addressed the comments received after the publication of the NPRM.

The SFIP General Property Form is missing “Coverage for” at the beginning of 44 CFR part 61 Appendix A(2) III.B.4. This omission started in the NPRM. However, the omission did not affect 44 CFR until the final rule's effective date of December 31, 2000. The words “Coverage for” do not substantively change the effect of the paragraph in question, as FEMA has always interpreted the substance of the paragraph as discussing those items which are or are not covered by the policy. However, to clarify and ensure consistency with the other paragraphs in Appendix A, FEMA is proposing to correct the paragraph by adding the words “Coverage for” at the beginning of 44 CFR part 61 Appendix A(2) III.B.4. With this proposed change, it would be clear on its face that the paragraph discusses the limitations of coverage for these certain types of items.

IV. Regulatory Analyses

A. Executive Order 12866, Regulatory Planning and Review

This proposed rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866, “Regulatory Planning and Review” (58 FR 51735, Oct. 4, 1993), accordingly FEMA has not submitted it to the Office of Management and Budget (OMB) for review. This rule is solely adding two unintentionally omitted words to the SFIP and will not affect the way that FEMA interprets or applies the policy. FEMA expects that this change would have no economic impact.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires that special consideration be given to the effects of proposed regulations on small entities. This rule will not have an economic impact on the regulated public. Therefore, FEMA certifies that this will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act of 1995

As required by the Paperwork Reduction Act of 1995 (PRA) Public Law 104–13 (44 U.S.C. 3501 *et seq.*), as amended, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Although this proposed regulatory change will not result in a new collection of information affected by the PRA, the collection of information for the National Flood Insurance Program Policy Forms is approved under OMB

Number, 1660–0006. The expiration date for 1660–0006 is August 31, 2012.

D. Executive Order 13132, Federalism

A rule has implications for federalism under Executive Order 13132, “Federalism” (64 FR 43255, Aug. 10, 1999), if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. FEMA has analyzed this proposed rule under Executive Order and determined that it does not have implications for federalism.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat. 48 (Mar. 22, 1995) (2 U.S.C. 1501 *et seq.*), requires Federal agencies to assess the effects of their discretionary regulatory actions that may result in the expenditure by a State, local, or Tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. As this proposed rule will not have a substantive effect on the public, this rule is not an unfunded Federal mandate.

F. Executive Order 12630, Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights” (53 FR 8859, Mar. 18, 1988).

G. Executive Order 12898, Environmental Justice

Under Executive Order 12898, as amended “Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, Feb. 16, 1994), FEMA incorporates environmental justice into its policies and programs. Executive Order 12898 requires each Federal agency to conduct its programs, policies, and activities that substantially affect human health or the environment, in a manner that ensures that those programs, policies, and activities do not have the effect of excluding persons from participation in, denying persons the benefit of, or subjecting persons to discrimination because of their race, color, or national origin or income level.

No action that FEMA can anticipate under this proposed rule will have a disproportionately high and adverse human health or environmental effect on any segment of the population.

Accordingly, the requirements of Executive Order 12898 do not apply to this proposed rule.

H. Executive Order 12988, Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, “Civil Justice Reform” (61 FR 4729, Feb. 7, 1996), to minimize litigation, eliminate ambiguity, and reduce burden.

I. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, “Consultation and Coordination With Indian Tribal Governments” (65 FR 67249, Nov. 9, 2000), because it does not have a substantial direct effect on one or more Indian Tribes, 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.

J. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule will not create environmental health risks or safety risks for children under Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks (62 FR 19885, Apr. 23, 1997).

K. National Environmental Policy Act

Rulemaking is a major Federal action subject to the National Environmental Policy Act of 1969, Public Law 91–190, 83 Stat. 852 (Jan. 1, 1970) (42 U.S.C. 4321 *et seq.*), as amended. The *List of exclusion categories* at 44 CFR 10.8(d)(2)(ii) excludes the preparation, revision, and adoption of regulations from the preparation of an environmental assessment or environmental impact statement, where the rule relates to actions that qualify for categorical exclusions. Technical corrections to a rulemaking are categorically excluded under 44 CFR 10.8(d)(2)(i) and no extraordinary circumstances exist requiring the need to develop an environmental assessment or environmental impact statement. Thus, the preparation, revision, and adoption of regulations related to this action is categorically excluded.

List of Subjects in 44 CFR Part 61

Flood insurance, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, FEMA proposes to amend 44 CFR chapter I as follows:

PART 61—INSURANCE COVERAGE AND RATES

1. The authority citation for part 61 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

Appendix A(2) to Part 61—[AMENDED]

2. Amend Appendix A(2) to part 61, by removing “Items” and adding “Coverage for items” in its place in paragraph III.B.4.

Dated: August 27, 2010.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010–22045 Filed 9–2–10; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 100311144–0159–01]

RIN 0648–AY75

International Fisheries; Pacific Tuna Fisheries; Vessel Capacity Limit in the Purse Seine Fishery in the Eastern Pacific Ocean

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS is proposing regulations under the Tuna Conventions Act of 1950 (Act), as amended, to increase the vessel capacity limit for the U.S. purse seine fishery operating in the eastern Pacific Ocean (EPO) and make U.S. regulations more consistent with the Inter-American Tropical Tuna Commission (IATTC) Resolution on the Capacity of the Tuna Fleet Operating in the Eastern Pacific Ocean. These revisions would ensure that the United States is satisfying its obligations under the Tuna Conventions Act while dismantling regulatory constraints preventing economic development of the U.S. industry.

DATES: Comments must be submitted in writing by October 4, 2010. A public hearing will be held at 9 a.m. to 12 p.m. PDT, September 9, 2010, Long Beach, CA.