2007 edition, available at *http://www.paralympic.org/export/sites/default/IPC/IPC_Handbook/Section_2/2008_2_Classification_Code6.pdf,* and qualifies the veteran for participation in a sport sanctioned by the United States Paralympics.

(Authority: 38 U.S.C. 322(d))

Paralympic Training Center refers to the following locations: the United States Olympic Training Center at Chula Vista, California; the United States Olympic Training Center at Colorado Springs, Colorado; the United States Olympic Training Center at Lake Placid, New York; the Lakeshore Foundation in Birmingham, Alabama; and the University of Central Oklahoma in Edmond, Oklahoma.

(Authority: 38 U.S.C. 322(d))

§ 76.2 Assistance allowance.

(a) VA will pay an allowance to a veteran with a disability who is:

(1) Invited by the United States Paralympics (USP) to compete for a slot on, or selected for, the USP Team for any month or part of any month in which the veteran is training or competing in any event sponsored by the USP or the IPC; or

(2) Residing at a USP training center in connection with any paralympic training or competition for the period certified under § 76.3.

(b) In providing this allowance, VA will periodically assess funding for the allowance. If a periodic assessment reveals that funding is insufficient to pay all applicants, VA will first pay in full veterans with service-connected disabilities, and then pay others in full in the order in which their completed applications are received.

(Authority: 38 U.S.C. 322(d))

§ 76.3 Application and certification.

To receive an allowance—

(a) A veteran must submit a complete application identifying any dependents upon which a higher payable rate of allowance may be based; and

(b) USP must provide certification of the veteran's participation in training or competition sponsored by the USP or the IPC, or residence at a USP training center, for the period for which payment is requested. The certification must specify whether the payment is due for training, competition, or residence, and the dates of the training, competition, or residence for which payment is due.

(Authority: 38 U.S.C. 322(d))

§ 76. Amount of allowance.

The following rules govern the amount of allowance payable to veterans under this section.

(a) Payment will be made at the rate paid for a full-time institutional program under chapter 31 of title 38, United States Code (Chapter 31) that is in effect for a period of certified participation, as prescribed by paragraph (b) of this section. (*See* 38 CFR 21.260.)

(b) Payment may be made for each day at 1/30 of the monthly rate to veterans who train or compete in USP or IPC sponsored events for each day of training or competition, or to veterans who reside at a USP training center, for each day of residence, or on a monthly basis at the monthly rate to veterans who train or compete continuously for a full month, or to veterans who reside at a USP training center for a full month.

(c) VA will pay the allowance at a rate paid to a veteran with dependents for a full-time Chapter 31 institutional program upon receipt of appropriate documentation that a veteran who qualifies for the allowance has dependents. (*See* 38 CFR 21.260.)

(Authority: 38 U.S.C. 322(d), 3108)

[FR Doc. 2010–21921 Filed 9–2–10; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2238–P2]

RIN 0938–AP67

Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs

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

ACTION: Proposed rule.

SUMMARY: In this rule, we are proposing to withdraw two provisions from the "Medicaid Program; Prescription Drugs" final rule (referred to hereafter as "AMP final rule") published in the July 17, 2007 **Federal Register.** The provisions we are proposing to withdraw are as follows: The determination of average manufacturer price (AMP), and the Federal upper limits (FULs) for multiple source drugs. We are also proposing to withdraw the definition of "multiple source drug" as it was revised in the "Medicaid Program; Multiple Source Drug Definition" final rule published in the October 7, 2008 **Federal Register.**

The provisions of the AMP final rule and the definition of multiple source drug that we are proposing to withdraw were challenged in a lawsuit that was filed in November 2007. The challenged regulations have been superseded in significant part by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, and the FAA Air Transportation Modernization and Safety Improvement Act. This document would withdraw the regulatory provisions challenged in the aforementioned litigation.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 4, 2010.

ADDRESSES: In commenting, please refer to file code CMS–2238–P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2238–P2, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2238–P2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey 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 persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—

Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Wendy Tuttle, (410) 786–8690.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also 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, phone 1–800–743–3951.

I. Background

On July 17, 2007, we published a final rule, titled "Medicaid Program; Prescription Drugs" in the **Federal Register** (72 FR 39142) (referred to hereafter as "AMP final rule"), which implemented sections 6001(a) through (d), 6002, and 6003 of the Deficit Reduction Act of 2005 (Pub. L. 109–171, enacted on February 8, 2006) (DRA) as well as codified parts of section 1927 of the Social Security Act (the Act) that pertain to requirements for drug manufacturers' calculation and reporting of average manufacturer price (AMP) and best price, and revised existing regulations that set Federal upper limits (FULs) for certain covered outpatient drugs. The AMP final rule also implemented section 1903(i)(10) of the Act, as revised by the DRA with regard to the denial of FFP in expenditures for certain physician administered drugs. Finally, the AMP final rule addressed other provisions of the Medicaid Drug Rebate Program.

On November 7, 2007, a complaint was filed with the United States District Court for the District of Columbia by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) (collectively, the Plaintiffs), which alleged that the AMP final rule unlawfully changes the methodology by which pharmacies are reimbursed for dispensing prescription drugs to Medicaid patients. The Complaint sought to enjoin the Department of Health and Human Services and CMS (the Defendants) from implementing the AMP final rule for purposes of reimbursing pharmacies and posting on a public Web site the data calculated pursuant to the AMP final rule. In addition, it sought declaratory relief that the AMP final rule fails to comply with the Act.

On December 19, 2007, the Court issued a preliminary injunction after finding that the "Plaintiffs are likely to succeed on the merits of their claims that Defendants violated the Administrative Procedure Act and acted contrary to law and/or arbitrarily and capriciously in creating" the AMP final rule because "the AMP Rule does not comply with either the statutory definition of 'average manufacturer price' or the statutory definition of 'multiple source drug' as stated by the Court." Accordingly, the preliminary injunction prohibits CMS from "[u]ndertaking any and all action to implement the AMP Rule to the extent such action affects Medicaid reimbursement rates for retail pharmacies under the Medicaid program," and, subject to certain exceptions, prohibits CMS from "[p]osting any AMP data on a public Web site or otherwise disclosing any AMP data to any individual or entities." The preliminary injunction, however, does not enjoin implementation of the AMP final rule as it relates to the calculation of rebates for the Medicaid rebate program, or the disclosure of AMP data to States as necessary for the administration of that program.

On March 14, 2008, in response to this litigation, CMS published an interim final rule with comment period to revise the definition of multiple source drug to better conform to the statutory definition of "multiple source drug" found in section 1927(k)(7) of the Act, and to inform the public of the procedures and practices the Agency would follow to ensure compliance with those statutory provisions. The subsequent final rule was published on October 7, 2008. The Plaintiffs, however, amended their filing with the Court contending that the revised multiple source drug definition and implementation procedures remained inconsistent with the statute.

On July 15, 2008, the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) was enacted. Section 203 of MIPPA prohibited HHS from imposing FULs prior to October 1, 2009, for multiple source drugs under § 447.514(b) as published in the July 17, 2007, AMP final rule. In accordance with the law, CMS resumed publishing FULs for multiple source drugs, using the methodology in § 447.332 as in effect on December 31, 2006. The methodology in § 447.332 applied through September 30, 2009. Since the preliminary injunction was issued, CMS has been unable to implement certain provisions of the DRA (as implemented in the July 17, 2007 AMP final rule). As a result of the lawsuit, and subsequent preliminary injunction, CMS has been enjoined from implementing the AMP-based FULs that the DRA had required. However, manufacturers were not affected by the injunction and continue to calculate and report AMP for the purpose of Medicaid rebates, in accordance with the Determination of AMP as specified in the AMP final rule.

Section 2503(a) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted on March 23, 2010), amended section 1927(e) of the Act by revising the Federal upper reimbursement limit to be no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. It also amends section 1927(k) of the Act by revising the definitions of AMP, multiple source drug, and wholesaler. In addition, it adds to section 1927(k) of the Act the definition of the term "retail community pharmacy," and eliminates the term "retail pharmacy class of trade." The amendments made by section 2503(a) of the Patient Protection and Affordable Care Act, as amended by section 1101(c) of the Health Care and Education Reconciliation Act (Pub. L. 111–152, enacted on March 30, 2010)

and section 202 of the FAA Air Transportation Modernization and Safety Improvement Act (Pub. L. 111–226, enacted on August 10, 2010), are effective October 1, 2010.

II. Provisions of the Proposed Regulations

In light of the lawsuit and preliminary injunction imposed by the Court and, in light of the changes in the relevant statutory language, CMS proposes the following revisions to the AMP final rule published on July 17, 2007:

- Section 447.504, "Determination of AMP," should be withdrawn in its entirety;
- Section 447.514, "Upper limits for multiple source drugs," should be withdrawn in its entirety; and
- The definition of "multiple source drug" in § 447.502, "Definitions" (as it was amended by the Multiple Source Drug Rule published on October 7, 2008), should be withdrawn.

The terms "average manufacturer price" and "multiple source drug" would be defined by section 1927 of the Act, including changes made by section 2503 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, and the FAA Air Transportation Modernization and Safety Improvement Act. In particular, drug manufacturers would be advised to base their AMP calculations on the definitions set forth in section 1927 of the Act, instead of on the AMP and AMP-related definitions provided in existing regulations and guidance.

CMS expects to develop regulations that will implement the provisions of section 2503 of the Patient Protection and Affordable Care Act.

Additionally, there are three sections within the AMP final rule that make reference to the sections being proposed for withdrawal. Section 447.510 "Requirements for manufacturers", makes reference to § 447.504 "Determination of AMP", and § 447.512 "Drugs: Aggregate upper limits for payment", and § 447.518 "State plan requirements", make reference to § 447.514 "Upper limits for multiple source drugs. We are proposing conforming regulatory amendments to those sections.

III. Collection of Information Requirements

This document does not impose any new information collection and recordkeeping requirements. The burden associated with the reporting requirements contained in § 447.510(a) are currently approved under OMB #0938–0578 with an expiration date of October 31, 2010.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 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). This regulatory action withdraws those regulatory provisions that have been superseded by the Affordable Care Act. We do not expect that this proposed rule will have any economic effects. Therefore, this proposed rule is not considered an economically significant 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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

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 603 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million. This rule would have no consequential effect on State, local, or tribal governments or on 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. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

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 proposes to amend 42 CFR chapter IV as set forth below:

PART 447—PAYMENT FOR SERVICES

1. The authority 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 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.

* * * * *

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.

* * * * *

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.

[FR Doc. 2010–22115 Filed 9–2–10; 8:45 am]

BILLING CODE 4120–01–P

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,