(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.)

§ 76.3 Application and certification.

(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.

§ 76.4 Multiple source drugs.

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 multiple source drug 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.)

§ 76.5 Assistance allowance.

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

(1) Invited by the United States Paralympic (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.

§ 76.6 Amount of allowance.

The following rules govern the amount of allowance payable to veterans under this section.
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) 786–6690.

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
manufac
tration, 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
reimbursement 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
contary 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
intended rule to give 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
(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, 2008.

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 implementation 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.
(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.
(3) In the aggregate, its Medicaid expenditures for multiple source drugs are in accordance with the established upper limits.
(b) State plan requirements, findings and assurances.
(1) In its aggregate, payments levels that have been established must not exceed, in the aggregate, payments levels that have been established by applying the lower of the—.
(2) The agency has determined by applying findings and assurances.
(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.
§§ 447.512 and § 447.514
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.
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:
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,