GENERAL SERVICES ADMINISTRATION

REPORTING TO CONGRESS—THE COSTS OF OPERATING PRIVATELY OWNED AUTOMOBILES

Paragraph (b) of Section 5707 of Title 5, United States Code, requires the Administrator of General Services to periodically investigate the cost to Government employees of operating privately owned vehicles (airplanes, automobiles, and motorcycles) while on official travel, to report the results of the investigations to Congress, and to publish the report in the **Federal Register**. This report on the privately owned automobile mileage reimbursement rate is being published in the **Federal Register**. The investigations pertaining to the reimbursement rates for airplanes and motorcycles are still pending. Therefore, there are no changes to these rates at this time.

Dated: February 20, 2008.

Lurita Doan,

Administrator of General Services.

Reporting To Congress—The Costs of Operating Privately Owned Automobiles

5 U.S.C. 5707(b)(1)(A) requires that the Administrator of General Services, in consultation with the Secretary of Defense, the Secretary of Transportation, and representatives of Government employee organizations, conduct periodic investigations of the cost of travel and operation of privately owned vehicles (airplanes, automobiles, and motorcycles) to Government employees while on official travel, and report the results to the Congress at least once a year. 5 U.S.C. 5707(a)(1) requires that the Administrator of General Services issue regulations prescribing mileage reimbursement rates and determine the average, actual cost per mile for the use of each type of privately owned vehicle based on the results of these cost investigations. Such figures must be reported to the Congress within 5 working days after the cost determination has been made in accordance with 5 U.S.C. 5707(b)(2)(C).

Pursuant to the above, the General Services Administration (GSA), in consultation with the above-specified parties conducted an investigation of the cost of operating a privately owned automobile (POA). As provided in 5 U.S.C. 5704(a)(1), the automobile reimbursement rate cannot exceed the single standard mileage rate established by the Internal Revenue Service (IRS). The IRS has announced a new single standard mileage rate for POAs of $0.505, which was effective January 1, 2008. As required, GSA is reporting the results of the investigation and the cost per mile determination. Based on cost studies conducted by GSA, I have determined the per-mile operating costs of a POA to be $0.505. Reimbursement rates for the use of a privately owned airplane and a privately owned motorcycle remain unchanged at this time as these investigations are still pending.

This report to Congress on the cost of operating POAs will be published in the **Federal Register**.

[FR Doc. E8–5091 Filed 3–13–08; 8:45 am]

BILLING CODE 6820–14–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2238–IFC]

RIN 0938–AP26

Medicaid Program; Multiple Source Drug Definition

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

ACTION: Interim final rule with comment period.

SUMMARY: On July 17, 2007, we published a final rule with comment period in the **Federal Register** that implemented provisions of the Deficit Reduction Act of 2005 pertaining to prescription drugs under the Medicaid program. In that rule, we finalized certain provisions of the Medicaid drug rebate program, including definitions concerning average manufacturer price, best price, single source drug, and multiple source drug. In this interim final rule with comment period, we are revising the definition of ''multiple source drug'' to better conform with the statutory provisions. This interim final rule with comment period solicits additional public comment on the revised definition of ''multiple source drug.''

DATES: *Effective date:* These regulations are effective on April 14, 2008.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 14, 2008.

ADDRESSES: In commenting, please refer to file code CMS–2238–IFC. 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 instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2238–IFC, 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 (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2238–IFC, 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 (one original and two copies) before the close of the comment period to either of the following addresses: a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the HHH 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. 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: Gail Sexton, (410) 786–4583.

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 be also 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 with comment period (72 FR 39142) in the **Federal Register** implementing the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid Program. In that rule, we defined terms used in the Medicaid drug rebate program. We codified requirements pertaining to the calculation and reporting of the average manufacturer price (AMP) and best price by pharmaceutical manufacturers and amended existing regulations concerning Federal upper payment limits for certain covered outpatient drugs. The final rule was effective October 1, 2007. This interim final rule is not being issued in response to public comments received on the July 2007 AMP final rule with comment period. We are still considering those comments.

On November 15, 2007, the National Association of Chain Drug Stores and the National Community Pharmacists Association filed a motion for a preliminary injunction in the United States District Court for the District of Columbia. They contended, in part, that the definition of ''multiple source drug'' adopted in the July 17, 2007, final rule (''drug rebate rule'') is contrary to the statutory language in that it defined a multiple source drug, in part, as a drug which is sold or marketed in the United States, as opposed to the State. Plaintiffs are concerned that all drug products are not generally available in every State. *National Association of Chain Drug Stores, et al.* v. *Health and Human Services*, Civil Action No. 1:07–cv–02017 (RCL). In light of these concerns, we are issuing this interim final rule with comment period and revising the definition of ''multiple source drug.'' We believe, however, that when an FDA-approved equivalent generic drug is sold or marketed in the United States, at least one generic drug product is sold or marketed in every State. Accordingly, we expect the effect of this revision, if any, to be small.

This interim final rule to the extent that it may affect Medicaid reimbursement rates for retail pharmacies is subject to the injunction issued by the United States District Court for the District of Columbia in *National Association of Chain Drug Stores, et al.* v. *Health and Human Services,* Civil Action No. 1:07–cv–02017 (RCL).

II. Provisions of the Interim Final Rule

In 42 CFR 447.502, we defined key terms used to calculate payment and rebates concerning Medicaid prescription drugs. We defined multiple source drug as a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent, is pharmaceutically equivalent and bioequivalent, as determined by the FDA, and is sold or marketed in the United States during the rebate period. We are revising this definition of multiple source drug to state that the drug product is sold or marketed in the ''State'' during the rebate period, as opposed to sold or marketed in the ''United States'' during the rebate period. By changing ''United States'' to ''State'' we define the term, ''multiple source drug'' in accordance with the language in the Social Security Act (the Act). Further, in accordance with section 1927(k)(7)(C)(iii) of the Act, we consider the drug to be sold or marketed in a State if it appears in a published national listing of average wholesale prices that we have selected—currently, Red Book, Bluebook, or Medi-Span—provided the listed product is generally available to the public through retail pharmacies in that State.

In light of our experience with the Federal upper limit (FUL) program, we believe that there is a national market for prescription drug products, and that if a drug is available in a State, it will be available in every State. From our experience, once an FDA-approved equivalent generic drug enters the market, there are nearly always at least two equivalent products available everywhere (the brand drug and at least one equivalent generic drug) such that a FUL will be properly applied. Furthermore, we do not have any record of receiving requests to delete or modify a FUL price based on a drug not being available in a particular State or a geographic location. Plaintiffs in the National Association of Chain Drug Stores litigation contend, however, that there may be situations where certain drug products are not available to the public through retail pharmacies in every State. We do not interpret the law to require us to continually survey drug availability in the retail pharmacies of every State, and note that pharmacies and States are in a substantially better position to assess the availability of drugs in their areas. Therefore, we will consider all covered outpatient drugs to be generally available in a State except in those situations where there is evidence to the contrary. Such evidence could include notification from pharmacies to the State that a drug cannot be purchased in that State, provided the State can confirm that to be the case. CMS will issue regulatory guidance on this issue in the future should the need arise.

When the State confirms that a covered outpatient drug is not a multiple source drug in the State, that drug is not subject to the FUL in that State for the applicable rebate period. Where the drug does not qualify as a multiple source drug in the State, the State should apply its alternative pricing methodologies as set forth in the approved State plan.

While this change in the definition of multiple source drug may impact the FUL program, it should have no impact on the manufacturer's calculation of rebates. The definition as revised is consistent with the statutory provision, which has been in effect since the inception of the drug rebate program. Manufacturers calculate rebates based, in part, on whether the drug product is produced, distributed, or marketed under a new drug application approved by the FDA. In such situations, the rebate calculation is based on a percentage of the AMP or the difference between AMP and best price, whichever is greater. Where a drug is not marketed pursuant to such a new drug application, the manufacturer calculates rebate payments based on a fixed percentage (11 percent) of the average manufacturer price. Accordingly, rebate calculations should not be affected by the revisions in this regulation. Thus, we are not changing our policy regarding rebates or manufacturer reporting requirements for these drugs.

III. 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.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued, or if the agency is promulgating interpretive rules, general statements of policy, or rules of agency procedure or practice.

We do not believe that we need to delay publication of this rule pending completion of a notice and comment period. We are conforming the regulation to the statutory definition of multiple source drug and informing the public of the procedures and practices the agency will follow to ensure compliance with those statutory provisions. However, to the extent that notice and comment rulemaking would otherwise apply, we find good cause to waive such requirements.

Specifically, we find it unnecessary to undertake notice and comment rulemaking in this instance in light of the statutory language. We are applying the definition specified in statute and we believe it is redundant to, in effect, propose a rule to incorporate the words of a provision already contained in the statute. We would not be able to change the definition in this regulation in response to public comment. We are also describing a procedure to ensure compliance with the relevant provisions of the statute. This description is exempt from notice and comment rulemaking as an interpretive rule, general statement of policy, and/or rule of agency procedure or practice. As we have previously stated, we believe that there is a national market for prescription drugs and that a drug product available as a multiple source drug in one State will be available as a multiple source drug in every State. However, in light of the concerns raised in litigation, we believe it is necessary to establish a process to ensure State availability and consistency with the statute. Therefore, under 5 U.S.C. 553(b), we find good cause to waive notice and comment rulemaking procedures for this revision, if such procedures are required at all.

V. Collection of Information Requirements

This document does not impose any information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

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 interim final rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this interim final rule with comment period will not have a significant economic impact on a substantial number of small entities.

The only small entities that will potentially be affected by this interim final rule are small pharmacies. We believe that the effect will be small because we have not identified any situation in which there is at least one FDA-approved equivalent generic drug available as a multiple source drug in one State but in which no FDA-approved equivalent generic is available in another State. To the extent a State would find, however, that a drug is not a multiple source drug in that State because no FDA-approved equivalent product is available in that State, the only effect will be to permit that State to disregard the FUL price for the one drug that is available in that State when determining the aggregate limit that the State can reimburse for that drug and claim Federal financial participation. States may choose not to change their reimbursement to pharmacies for those drugs. Should States decide to change reimbursement, the change would usually be to increase the price paid to pharmacies.

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 604 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 and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this interim final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals. Small rural hospitals would be affected only to the extent that no FDA-approved equivalent product is available in that State for a particular outpatient drug provided through their outpatient pharmacies. As discussed above for pharmacies, States may choose to change reimbursement for drugs in such groups, but this change is expected to be to increase reimbursement. 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. That threshold level is currently approximately $120 million. This interim final rule will 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. This regulation will impose only a very small burden, if any, on States. When a pharmacy has notified a State that a drug on the CMS FUL list may not be available as a multiple source drug in that State, the State must confirm that the drug is generally not available in the

State. The State, however, has no obligation to make an independent assessment of drug availability in the absence of such notification by a pharmacy. We believe that the vast majority of drugs of manufacturers that participate in the Medicaid program are generally available on a national basis. We believe that all or nearly all of the drugs are distributed by national wholesalers and are generally available in every State. This interim final rule will only apply in those rare cases in which a particular FDA-approved drug product is not available to the retail pharmacies in a particular State and, as a result, only one FDA-approved drug product is available to those pharmacies. In this circumstance, a State would need to verify the information received from its pharmacies that no equivalent drug is available. This would impose only a small burden on States. State systems are designed to allow for payment changes as a routine matter and to change the composition of the FUL groups or delete FUL groups. Since this regulation does not impose any significant costs on State or local governments, the requirements of E.O. 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 Sections 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 amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS 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).

■ 2. Section 447.502 is amended by:

■ A. Republishing the introductory text of the definition for ''Multiple source drug''; and

■ B. Revising paragraph (3) of the definition for ''Multiple Source Drug'' to read as follows:

§ 447.502 Definitions.

* * * * *

Multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

* * * * *

(3) Is sold or marketed in the State during the rebate period as follows:

(i) A covered outpatient drug is considered sold or marketed in a State if it appears in a published national listing of average wholesale prices, selected by the Secretary, provided the covered outpatient drug is generally available to the public through retail pharmacies in that State.

(ii) A covered outpatient drug is not subject to the FUL for a rebate period if it is not a multiple source drug in the State for that rebate period.

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

Dated: February 21, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 21, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. 08–1022 Filed 3–10–08; 2:42 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 92

[FWS–R7–MB–2007–0009; 91200–1231–9BPP L2]

RIN 1018–AV53

Migratory Bird Subsistence Harvest in Alaska; Harvest Regulations for Migratory Birds in Alaska During the 2008 Season

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service or we) is publishing migratory bird subsistence harvest regulations in Alaska for the 2008 season. This proposed rule establishes regulations that prescribe dates when harvesting of birds may occur, species that can be taken, and methods and means excluded from use. These regulations were developed under a Co-management process involving the Service, the Alaska Department of Fish and Game, and Alaska Native representatives. These regulations enable the continuation of customary and traditional subsistence uses of migratory birds in Alaska. The rulemaking is necessary because the regulations governing the subsistence harvest of migratory birds in Alaska are subject to annual review. This rulemaking enacts region-specific regulations that go into effect on April 2, 2008, and expire on August 31, 2008.

DATES: The amendments to subpart C of 50 CFR part 92 become effective April 14, 2008. The amendments to subpart D of 50 CFR part 92 are effective April 2, 2008, through August 31, 2008.

FOR FURTHER INFORMATION CONTACT: Fred Armstrong, (907) 786–3887, or Donna Dewhurst, (907) 786–3499, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Mail Stop 201, Anchorage, AK 99503.

SUPPLEMENTARY INFORMATION:

How Do I Find the History of These Regulations?

Background information, including past events leading to this action, accomplishments since the Migratory Bird Treaties with Canada and Mexico were amended, and a history addressing conservation issues can be found in the following **Federal Register** documents:

Date	**Federal Register** citation
August 16, 2002	67 FR 53511.
July 21, 2003	68 FR 43010.
April 2, 2004	69 FR 17318.
April 8, 2005	70 FR 18244.
February 28, 2006	71 FR 10404.
April 11, 2007	72 FR 18318.

These documents, which are all final rules setting forth the annual harvest regulations, are readily available at *http://alaska.fws.gov/ambcc/regulations.htm.*

Why Is This Current Rulemaking Necessary?

This current rulemaking is necessary because, by law, the migratory bird harvest season is closed unless opened by the Secretary of the Interior, and the regulations governing subsistence harvest of migratory birds in Alaska are subject to public review and annual approval. The Alaska Migratory Bird Co-management Council (Co-management Council) held a meeting in April 2007 to develop recommendations for changes effective for the 2008 harvest season. These recommendations were presented to the Service Regulations Committee (SRC) on August 1 and 2, 2007, and were approved.

This rule finalizes regulations for the taking of migratory birds for subsistence uses in Alaska during 2008. This rule lists migratory bird species that are open