States prior to publication of the notice in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective October 7, 2008.

List of Subjects in 40 CFR Part 59

Air pollution control, Consumer and commercial products, Confidential business information, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 30, 2008.

Stephen L. Johnson,

Administrator.

■ For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 59—[AMENDED]

■ 1. The authority citation for part 59 continues to read as follows:

Authority: 42 U.S.C. 7414 and 7511b(e).

Subpart A—General

■ 2. Section 59.1 is revised to read as follows:

§ 59.1 Final determinations under Section 183(e)(3)(C) of the CAA.

This section identifies the consumer and commercial product categories for which EPA has determined that CTGs will be substantially as effective as regulations in reducing VOC emissions in ozone nonattainment areas:

(a) Wood furniture coatings;

(b) Aerospace coatings;

(c) Shipbuilding and repair coatings;

(d) Lithographic printing materials;

(e) Letterpress printing materials;

(f) Flexible packaging printing materials;

(g) Flat wood paneling coatings;

(h) Industrial cleaning solvents;

(i) Paper, film, and foil coatings;

(j) Metal furniture coatings;

(k) Large appliance coatings;

(l) Miscellaneous metal products coatings;

(m) Plastic parts coatings;

(n) Auto and light-duty truck assembly coatings;

(o) Fiberglass boat manufacturing materials; and

(p) Miscellaneous industrial adhesives.

[FR Doc. E8–23750 Filed 10–6–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS–2238–F]

RIN 0938–AP26

Medicaid Program; Multiple Source Drug Definition

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

ACTION: Final rule.

SUMMARY: This final rule revises the definition of ''multiple source drug'' to better conform the regulatory definition to the provisions of section 1927(k)(7) of the Social Security Act. It also responds to public comments received on the March 14, 2008 interim final rule with comment period.

DATES: *Effective Date:* This final rule is effective November 6, 2008.

FOR FURTHER INFORMATION CONTACT: Gail Sexton, (410) 786–4583.

SUPPLEMENTARY INFORMATION:

I. Background

In the July 17, 2007 **Federal Register** we published a final rule with comment period (72 FR 39142) implementing the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid Program. In that rule, we codified terms pertaining to the calculation and reporting of average manufacturer price (AMP) and best price and amended existing regulations regarding the calculation of the Federal upper limits (FULs) for certain covered outpatient drugs. The rule was effective October 1, 2007. On March 14, 2008, we issued an interim final rule with comment period (73 FR 13785) that revised the definition of multiple source drug to conform to the statutory provisions. As stated in that rule, the interim final rule with comment period was not issued in response to public comments received on the Medicaid prescription drug rule. 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 Medicaid prescription drug 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 argued that all drugs 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). Although we continue to believe that, when an FDA-approved, therapeutically, pharmaceutically, and bioequivalent drug is sold or marketed in the United States, at least one therapeutically, pharmaceutically, and bioequivalent drug is sold or marketed in every State, we issued an interim final rule with comment period to revise the definition of ''multiple source drug.'' We stated that we expected the effect of the revision, if any, to be minimal.

We are publishing this final rule to address comments received on the interim final rule with comment period published on March 14, 2008 (73 FR 13785). Specifically, we are addressing comments pertaining to the definition of ''multiple source drug'' in the March 14, 2008 interim final rule with comment period. For a full discussion of the multiple source drug definition provisions see the March 14, 2008 interim final rule with comment period (73 FR 13785).

As noted in the interim final rule with comment period, this 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 § 447.502, we defined key terms used for payment and rebates for Medicaid covered outpatient drugs. We defined multiple source drug, with respect to a rebate period, as a covered outpatient drug for which there is at least one other drug product which is: (1) Rated as therapeutically equivalent (for the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov/cder/orange/default.htm* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857); (2) pharmaceutically equivalent and bioequivalent, as determined by the FDA; and (3) sold or marketed in the United States during the rebate period.

In the March 14, 2008 interim final rule with comment period, we revised the definition of ''multiple source drug'' at § 447.502 to state, in part, that a covered outpatient drug is a multiple source drug when it is sold or marketed in the ''State'' during the rebate period. In accordance with section 1927(k)(7)(C)(iii) of the Social Security Act (''the Act'') and as discussed in the interim final rule with comment period, we consider a 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. We also addressed our belief, based on our experience with the FUL and the drug rebate program that a national market exists for covered outpatient drugs. We also provided in the interim final rule with comment period, that when 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. We further provided that where the drug does not qualify as a multiple source drug in the State, the State should apply the appropriate pricing methodologies as set forth in the approved State plan.

III. Analysis of and Responses to Public Comments

We received nine items of correspondence that addressed the March 14, 2008 interim final rule with comment period. We received comments from drug manufacturers and wholesalers, retail pharmacies, and membership organizations. To the extent that comments were outside the scope of the March 14, 2008 interim final rule with comment period they are not addressed in this final rule. A summary of the major issues and our responses are discussed below.

A. General Comments

Comment: We received several comments expressing general support and appreciation for CMS revising the definition of ''multiple source drug.'' One commenter specifically stated that the statutory definition of ''multiple source drug'' has existed since 1990, and it is important for CMS to include that definition in the regulations. One commenter noted that States appreciate the increased flexibility to determine a product's availability and to be able to adjust FUL prices accordingly.

Response: We appreciate these and all comments received relating to our interim final rule with comment period revising the definition of ''multiple source drug.''

B. Adherence to the Administrative Procedures Act

Comment: Several commenters stated that the interim final rule with comment period was not promulgated in accordance with the Administrative Procedure Act (APA) which provides that a Federal agency provide the public with notice of, and an opportunity to comment on, proposed agency rulemaking before issuing a final rule, which includes a statement of basis and purpose that responds to public comments. Several commenters were in disagreement with CMS that a formal notice and comment rulemaking process was not necessary because they said the new rule was not an ''interpretive'' rule, a general statement of policy, and/or a rule of agency procedure or practice.

Response: We disagree. We are applying the definition of ''multiple source drug'' as specified in the statute and informing the public of the procedures and practices the agency will follow to ensure compliance with the statutory provisions. We do not believe that we need to propose a rule to incorporate the words of a provision already contained in the statute, and we therefore found good cause for waiving the notice and comment procedures. We believe that such a proposed rule would not be necessary because we would not be able to change the definition in the rule in response to public comments. In addition, as discussed in the interim final rule with comment period, we believe that the interim final rule with comment period is exempt from notice and comment rulemaking as an interpretative rule, general statement of policy and/or rule of agency procedure or practice.

Furthermore, we have provided an opportunity for comment and have now considered all comments in issuing this final rule.

Comment: One commenter stated that the fact that the Court issued a preliminary injunction against the old rule does not, as a matter of law, constitute good cause to eliminate notice and comment rulemaking. Another commenter stated that CMS had time to go through the notice and comment rulemaking, because the rule cannot be enforced due to Federal court injunction.

Response: We issued the interim final rule with comment period revising the definition of ''multiple source drug'' to better conform the definition to the statutory language and to address the concerns raised by plaintiffs in the Medicaid prescription drug rule litigation. In that litigation, the plaintiffs contended, in part, that the definition of ''multiple source drug'' adopted in the Medicaid prescription drug 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.'' We issued this rule to apply the definition specified in the statute. We believe it is unnecessary to propose a rule to, in effect, incorporate the words of the statute and to establish a procedure to ensure compliance with that statutory provision.

Furthermore, we have provided an opportunity for comment and have now considered all comments in issuing this final rule.

C. Interpretive Versus Substantive Rule

Comment: Several commenters submitted reasons why they believe that this rule should not be considered an interpretive rule, as explained above, but rather, a substantive rule, and thus subject to notice and comment rulemaking. One commenter stated that this rule should be considered a substantive rule because it will be published in the **Federal Register**. Several commenters stated that this rule amends another substantive rule subject to notice and comment rulemaking, and thus should also be considered substantive. Other commenters stated that rules which affect methodologies for calculating Federal funding levels are substantive rules that are subject to notice and comment under the APA. Several commenters stated that, because the new rule establishes significant new burdens on pharmacies and States regarding the State availability standard that has never been imposed by either the statute or CMS, it must be considered a substantive rule.

Response: We disagree. We issued the March 14, 2008 interim final rule with comment period to revise the Medicaid prescription drug rule to better conform to the statute. The statute includes a provision that a multiple source drug is sold or marketed in the State during the rebate period and a separate provision that describes when a drug is considered to be sold or marketed in a State. We revised the Medicaid prescription drug rule to include these provisions and put forth procedures to ensure compliance with the statute. We consider these provisions to be exempt from notice and comment rulemaking as an interpretive rule, general statement of policy, and/or rule of agency procedure or practice. Moreover, to the extent that notice and comment rulemaking might apply, we found good cause to waive

such requirements given that the revisions were made to revise the rule to better comply with the statute.

Furthermore, we have provided an opportunity for comment and have now considered all comments in issuing this final rule.

D. Definition—Regulation Text Changes

Comment: Several commenters suggested that the term ''multiple source drug'' as it is currently defined should be revised. One commenter stated that CMS should (1) change the introductory portion to read, ''multiple source drug'' means, with respect to a rebate period, a covered outpatient drug for which there ''are at least two drug products which'', and (2) change the initial word of paragraphs (1)–(3) of the definition from ''is'' to ''are.'' Several commenters stated that for CMS to comply with the statute, the term ''covered outpatient drug'' in the rule must be replaced with ''drug product'' in paragraphs 3(i) and 3(ii) of the definition of ''multiple source drug'' to assure that FULs are applied properly.

Response: We have revised the definition of multiple source drug in this final rule in accordance with the language in the Act. We have retained the term ''covered outpatient drug'' in paragraph (3)(ii) of that definition because FULs are set for ''multiple source drugs,'' which under section 1927(k)(7)(A)(i) of the Act are a subset of ''covered outpatient drugs.''

E. Drug Versus Drug Product—Compliance With the Social Security Act

Comment: Several commenters stated that the language of the rule does not follow the language of the statute because the rule does not properly distinguish between a ''drug'' and a ''drug product.'' Several commenters stated that the distinction between drug and drug product is important. Several commenters noted that a ''drug'' is a chemical ingredient contained in one or more drug products but that a ''drug product'' is a ''finished dosage form'' such as a tablet or capsule. The commenters stated that a drug may be generally available to the public through retail pharmacies in a State even though an individual drug product is not generally available to the public through retail pharmacies in a State.

Response: We appreciate the comment and have revised the regulation to conform to the statute. We note, however, that the Act does not distinguish between the terms ''drug'' and ''drug product'' in the manner suggested in these comments.

F. National Availability

Comment: One commenter stated that drug products cannot be assumed to have national availability because regional manufacturers, marketers, distributors and wholesalers may sell exclusively to entities in a specific class of trade and may not make their drug products generally available to any or all pharmacies in a given State or to the general public, even though they are listed in the national compendia. Another commenter stated that there are many instances of limited and sporadic supply of a drug product, particularly in the first year after a new multiple source drug product is introduced to the market, so that not all pharmacies have access to sufficient supply.

Response: We believe, based on our experience with the FUL program that when an FDA-approved, therapeutically, pharmaceutically, and bioequivalent drug product is sold or marketed on a nationwide basis, at least one therapeutically, pharmaceutically, and bioequivalent drug product is generally sold or marketed in every State. However, we have established a process in this rule to determine whether a listed product is generally available through retail pharmacies in a State. If a State concludes that a particular covered outpatient drug has no therapeutically, pharmaceutically, and bioequivalent drug product that is generally available in that State and, as a result, does not meet the definition of a multiple source drug in the State, that drug would not be subject to the FUL in that State. When at least two therapeutically, pharmaceutically, and bioequivalent drug products are generally available to the public through retail pharmacies within the State, the drug will be considered a multiple source drug. In the case where the covered outpatient drug is not a multiple source drug, that drug would not be subject to the FUL in that State for the applicable rebate period.

G. National Availability—Compliance With the Social Security Act

Comment: Several commenters stated that CMS' assumption that drug products are nationally available does not ''interpret'' the statute, but rather contradicts the statute. Other commenters stated that CMS assumes nationwide availability of all drug products without a legal or factual basis for that assumption. Several commenters stated that CMS has not compiled evidence to justify its assumption of national availability. One commenter stated that an assumption that all drug products are available nationwide would render the statute's State availability standard completely superfluous. Another commenter said that the same assumption of national availability was contained in CMS' original definition of ''multiple source drug'' which looked to whether drug products were available ''in the United States'' rather than in each ''State.''

Response: The State availability requirement has been in the Social Security Act since the Omnibus Budget Reconciliation Act of 1990. Nonetheless, we have received few complaints that drug products listed in the national compendia are not widely available, and the few complaints that we have received generally suggested availability problems occurring nationwide, rather than availability problems unique to a particular State. Therefore, in light of our experience with the implementation of section 1927 of the Act, we believe that when an FDA-approved, therapeutically, pharmaceutically, and bioequivalent drug product is sold or marketed on a nationwide basis, that at least one therapeutically, pharmaceutically, and bioequivalent drug product is sold or marketed in every State. However, to the extent that a particular covered outpatient drug has no therapeutically, pharmaceutically, and bioequivalent drug product generally available to the public through retail pharmacies within a State, this rule gives States the flexibility to disregard the FUL for that drug and apply alternate pricing methodologies as set forth in the State's approved plan.

Comment: One commenter stated that a Federal court enjoined implementation of the July 17, 2007 rule's definition of ''multiple source drug'' because it violated the provisions of the statute's State availability standard. Several commenters stated that despite the court's ruling, CMS has made it clear that the agency will continue to ignore the statute's State availability standard and continue to assume that all drugs are available nationally, and that pharmacies and States may enforce the statute's State availability standard, but CMS will not.

Response: We disagree. We have revised the definition of ''multiple source drug'' as it appeared in the Medicaid prescription drug rule to be consistent with statutory language and fully compliant with the court's preliminary ruling. We have not ignored the State availability requirement; we have set forth a mechanism for determining whether a drug is a ''multiple source drug.'' As we stated in the March 14, 2008 interim final rule, when a State confirms that a covered outpatient drug is not a multiple source

drug in that State, that drug is not subject to a FUL in that State. We have further clarified in our final rule that when at least two therapeutically, pharmaceutically, and bioequivalent drug products, covered under the Medicaid drug rebate program, are generally available within the State, the drug will be considered a multiple source drug. In the case where the covered outpatient drug is not a multiple source drug, that drug would not be subject to the FUL in that State for the rebate period. Thus, we have given States increased flexibility to determine a product's availability. We believe that this is the most effective means to ensure that drug products not available in a State are identified and not treated as multiple source drugs.

Comment: A few commenters stated that if Congress had intended that CMS simply assume that equivalent drug products are available nationwide, it would not have adopted a specific process for CMS to confirm availability in each State.

Response: Congress did not adopt a specific process for CMS to confirm State availability but left it to the agency to set forth such a process. We adopted the process set forth in the interim final rule with comment period because we believe that pharmacies and States are in a substantially better position to assess the availability of drugs available for purchase in their areas. For example, the States have daily updated claims files and could validate drug availability in a more timely and efficient manner than could be done at the Federal level. In addition, pharmacies are in the best position to know the drug products to which they have access.

H. State Availability—Compliance With the Social Security Act

Comment: A few commenters stated that this rule does not comply with the Act's ''State availability'' standard, which they state requires CMS to confirm whether particular drug products are generally available to the public through retail pharmacies in each State. A few commenters stated that CMS must actually implement the statutory language by not applying FULs unless it has first confirmed State availability as mandated by the statute. The commenters further stated that the statute does not authorize CMS to calculate and apply FULs and then impose on pharmacies and States the burden of investigating whether particular drug products satisfy the State availability standard. The commenters state that the Federal statute clearly discusses the duty of ''the Secretary'' to apply FULs to multiple source drug products that satisfy the State availability standard.

Response: We disagree. The statute does not prohibit States from assisting in the availability determination or, as noted previously, otherwise set forth any mechanism for determining whether a drug is ''generally available.'' We believe the most efficient means to do so is to have the State make the initial determination that drugs are not generally available in that State. The Act, as amended by the DRA, clearly contemplates the creation of a single nationwide FUL list. To first confirm availability of each and every drug on a State-by-State basis before setting a FUL would render the FUL provisions established by the DRA administratively impossible to implement, and would create an undue burden that would make the publication of a timely list unlikely. This practice would be inconsistent with the statute which provides that the Secretary establish a FUL for each multiple source drug that enters the market on a timely basis.

Comment: Several commenters asserted that CMS incorrectly instructs States that the State availability standard focuses on whether drugs are unavailable to pharmacies, not whether drug products are generally available to the public through retail pharmacies.

Response: We disagree. Since the statute uses the phrase ''generally available to the public through retail pharmacies,'' we have decided that availability to retail pharmacies is a necessary component of the State availability determination. We believe that if a drug is available to a retail pharmacy, then it will be available to the public.

Comment: A commenter stated that CMS has traditionally surveyed manufacturers to determine if products are available before setting a FUL. The commenter stated that he believes that CMS should undertake a similar task to determine whether each dosage form and strength of a multiple source drug is generally available to the public through retail pharmacies in each State.

Response: As noted previously, we do not interpret the law to require us to continually survey drug availability in the retail pharmacies of every State. Such continuous surveys would be burdensome and very time consuming and could likely result in an untimely and outdated FUL list. In addition, such surveys would be inconsistent with our understanding of other statutory amendments in the DRA where Congress contemplated that we establish FULs on a timely basis. For example, section 1927(f)(1) of the Act requires the Secretary's response within 7 days after notification of availability of multiple source products. We also note that pharmacies and States are in a substantially better position to assess the general availability of drugs in their areas.

I. State Availability and FUL Reimbursement

Comment: Several commenters expressed concern about the FUL reimbursement in regard to drug availability in the State. One commenter asked if States will receive an exemption from the FUL retroactively because a State determination concerning the availability of a drug will presumably be after a FUL effective date, and after CMS confirms availability issues. Another commenter stated that FULs should only be based on the AMPs of products that satisfy the State availability standard.

Response: If a State can confirm that a covered outpatient drug is not a multiple source drug in the State, for a particular rebate period, the FUL will not apply to that drug in that State for that rebate period. Where the drug does not qualify as a multiple source drug in the State, the State should apply the appropriate pricing methodologies as set forth in the approved State plan. We have further clarified in our final rule that when at least two therapeutically, pharmaceutically, and bioequivalent drug products, covered under the Medicaid drug rebate program, are generally available within the State, the drug will be considered a multiple source drug. In the case where a covered outpatient drug is not a multiple source drug within the State, that drug would not be subject to the FUL in that State for the rebate period. The final comment regarding the calculation of the FUL based on certain products is outside of the scope of this rule.

Comment: One commenter stated that the rule notes that if a particular State could confirm that a drug is unavailable from two sources, the FUL will be lifted for the rebate period.

Response: In the case where a State can confirm that a covered outpatient drug is not a multiple source drug in the State, for a particular rebate period, the FUL will not apply to that drug in that State for that rebate period. Where the drug does not qualify as a multiple source drug in the State, the State should apply the appropriate pricing methodologies as set forth in the approved State plan.

Comment: One commenter requested further information on how the multiple source definition is to be applied in a rebate period, that is, quarterly, when

the FUL process will be on a monthly schedule.

Response: We appreciate the comment, but the definition of multiple source drug contemplates availability determinations on a rebate, as opposed to a monthly, period.

Comment: CMS has not always assigned FULs to every group of drug products, so one commenter assumed that CMS took this approach in recognition of the lack of product availability in one or more States. One commenter stated that it is apparent that CMS limited its conclusion about at least two equivalent products being available everywhere once a generic drug enters the market by adding the modifier ''nearly always.''

Response: Prior to the DRA revisions, we focused on applicability of the FULs based on the number of suppliers listed in a national published listing of average wholesale prices (such as Red Book, Blue Book, and Medi-Span). We have no reason not to believe that virtually all drug products are generally available in every State on a nationwide basis. However, we recognize there is a potential that certain drug products may not be generally available in every State and, as a result, we have established procedures which allow States to address such drug availability.

Comment: One commenter asserted that the States should be given an opportunity for an appeals process to address availability issues directly with CMS. They contend that this would support a more effective implementation of the new FUL pricing calculation by providing CMS with the ability to directly address unforeseen marketplace issues and ensure drug availability in each State across the nation.

Response: We do not believe that a formal appeals process will be needed. We continue to believe that the States are in the best position to determine drug availability and implement the process afforded in this rule when a covered outpatient drug has no equivalent that is generally available in the State. We have on going communication with the States, and through those discussions States may bring availability issues to our attention, or may bring availability issues to our attention in response to a pharmacy's complaint. We do not believe more formal appeals would be necessary as our source for setting FULs will be manufacturer submitted AMP data. Regardless, a State may disregard a FUL for a drug when it determines that the drug is not a multiple source drug within the State for the rebate period.

J. State Availability and Retail Pharmacy Definition

Comment: One commenter stated that CMS does not define ''retail pharmacies'' in the revised definition. However, CMS has included in the definition of the ''retail pharmacy class of trade'' many entities that do not constitute retail pharmacies. The commenter stated that determining that multiple source drug products are generally available in non-retail pharmacies would not be sufficient to satisfy the State availability standard.

Response: We appreciate the comment. However, the definition of retail pharmacies is outside the scope of this rulemaking.

K. Burden on States and Providers

Comment: Several commenters expressed concern about the burden that may be placed upon States and providers in determining whether a drug is a multiple source drug within the State.

Response: We believe that the effect on States and pharmacy providers will be small given our experience with the FUL program. To the extent a State would find, however, that a covered outpatient drug product is not a multiple source drug in that State, the effect will be to permit that State to disregard the FUL price for that drug, and apply appropriate pricing methodologies as set forth in the approved State plan.

Comment: One commenter expressed concern that there will be a substantial and ongoing burden on States because all retail pharmacies would have little choice but to notify the State that virtually any and every drug product may not be available as a multiple source drug in that State. Several commenters stated that a particular retail pharmacy will rarely if ever know whether a particular drug product is ''generally available to the public through retail pharmacies'' in a State. A commenter stated that, in practice, the most likely result would be that pharmacies would investigate only if they cannot buy enough inventory without losing more than they can afford. Another comment inquired how a State can confirm whether or not a multiple source drug is available from two sources.

Response: The statute provides that a drug product is considered to be sold or marketed in a State if the drug product appears in a published national listing of average wholesale prices, provided the listed product is ''generally available to the public through retail pharmacies in that State.'' In light of that standard, we see no reason why pharmacies would report that a substantial number of drugs would be generally unavailable; however, States have the authority to set reasonable standards for such reporting. We fully expect that pharmacies would report to their States information concerning any covered outpatient drug that is subject to a FUL but for which they cannot purchase an equivalent drug product.

Comment: One commenter stated that CMS is not only assigning States the burden of determining whether a multiple source drug is available in the marketplace (as listed in the Regulatory Impact Statement) but also of determining the adequacy of the FUL rates to cover pharmacy actual acquisition costs.

Response: We disagree. As we have previously indicated, we believe that the effect on States and pharmacy providers will be small. This rule does not require that States determine the adequacy of the FUL relative to the pharmacies' actual acquisition costs.

L. State Versus Federal Responsibility

Comment: CMS has given no guidance as to what the agency believes constitutes ''general availability to the public'' and what is considered by CMS to be a sufficient number of retail pharmacies that offer the drug product in sufficient quantities to be ''generally available to the public.''

Response: At this time we have not provided a definition of general availability to the public. The definition of multiple source drug has been in the statute since the amendments of the Omnibus Budget Reconciliation Act of 1990 and yet we have received very few complaints that drug products listed in the national compendia are not generally available, and the few complaints that we have received generally pertained to availability problems occurring nationwide, rather than availability problems unique to a particular State. We continue to believe that complaints regarding general availability will be infrequent and thus do not believe it is necessary to provide additional instructions to States at this time. However, if, after consultation with the States, we determine it is necessary to offer additional guidance, we will do so. We also note that the commenter has misconstrued this regulation which, in accordance with the statute, provides that the listed product be generally available to the public through retail pharmacies. General availability to the public is determined not by considering which drug products pharmacies have chosen to offer but by considering which drug

products are available for pharmacies to offer. We believe that if a drug is available to a retail pharmacy, then it will be available to the general public.

Comment: One commenter expressed concern that, if States cannot or will not act when pharmacies report a lack of availability of a drug, will CMS establish a process for pharmacies to directly petition CMS to remove a FUL? The commenter adds that CMS has not indicated that it will implement a timely process to remove the FUL on a product in a State.

Response: We have not established a separate Federal process for pharmacies to petition us for removal of a FUL and based on our experience with the FUL program, we see no need to add such a process at this time. We consider it the responsibility of the State to confirm the information provided by the pharmacies.

Comment: One commenter proposed that rather than having a process that has to be managed in 50 different States, it would be more efficient for CMS to establish a national process for States and providers to express their concerns.

Response: As discussed previously, we disagree. The statute and regulation provide that the listed product be generally available to the public through retail pharmacies in that State. We believe that States and pharmacies in those States are in a better position to assess the general availability of drugs in their areas.

M. Effects on Other Issues

Comment: We received an audit report entitled, Audit of Chain and Independent Pharmacies, Mass Merchandisers, Proprietary Stores and Foodstores with Pharmacies, March 2006, attached to a comment.

Response: We appreciate the report. However, the report did not address the provisions of this rule.

Comment: We received several comments regarding the definitions of AMP, wholesaler, and retail class of trade as well as comments regarding the outlier policy applied when setting FULs.

Response: The purpose of this rule is to define ''multiple source drug.'' The topics addressed by the commenters regarding AMP, wholesaler, retail class of trade, and outliers are not within the scope of this final rule.

Comment: One commenter stated that CMS must adopt a definition of ''multiple source drug'' that is based on the median or weighted AMP in order to ensure that such drug products are available to the public through retail pharmacies. One commenter urged CMS to clarify that when a drug product ceases to meet either the first or second prong of the ''multiple source drug'' definition (that is, there is not at least one other drug which is rated by the FDA as therapeutically equivalent in the most recent publication of the Approved Drug Products with Therapeutic Equivalence Evaluations and is pharmaceutically equivalent and bioequivalent as determined by FDA) that CMS will take Federal action to remove that drug from the FUL list and inform State Medicaid agencies to cease application of the FUL. Further, the commenter requested that CMS confirm that the State-by-State approach applies only in situations where the third prong of the ''multiple source drug'' definition is not satisfied—that is, where a generic equivalent is not ''sold or marketed in the State.''

Response: To the extent that a drug does not qualify as a multiple source drug, that drug is not subject to the FUL. Those comments concerning the revised definition of multiple source drug and the FUL methodology are not within the scope of the interim final rule with comment period.

Comment: One commenter asserted that updating AMPs and AMP based FULs monthly does not assure availability of drug products at the FUL rates, since corrections are not made to previously issued FULs. Another commenter stated that this proposed rule change does nothing to address fundamental shortcomings of using the currently proposed basis to set FULs.

Response: These comments are beyond the scope of this rulemaking document and will not be addressed in this rulemaking document.

IV. Provisions of the Final Regulations

This final rule incorporates the provisions of the March 2008 interim final rule with comment period with two changes.

In § 447.205, paragraph (3)(i) of the definition of multiple source drug, the term ''covered outpatient drug'' is revised to read ''drug product,'' and ''listed product'' respectively to reflect the statutory language.

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), Executive Order 13132 on Federalism, 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 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 the Secretary has determined that this final rule 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 final rule are small pharmacies. We believe that the effect will be small because we are unaware of any situation in which there are at least two FDA-approved, therapeutically, pharmaceutically, and bioequivalent drugs generally available in one State but not 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, therapeutically, pharmaceutically, and bioequivalent drug product is generally available in that State, the only effect will be to permit that State to disregard the FUL price for a drug that no longer qualifies as a multiple source drug in that State when determining the aggregate limit. To the extent this final rule has an effect on small retail pharmacies, that effect will be to increase payment rates to those pharmacies by allowing States to disregard FULs for certain drugs. Small pharmacies would only need to report when one drug in a two-drug group of therapeutically, pharmaceutically, and

bioequivalent drugs is unavailable. However, such reporting would clearly be in their interest. 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 the Secretary has determined that this final rule 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, therapeutically and bioequivalent drug 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 that are not multiple source drugs within the State, but this change is expected to increase reimbursement.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending on State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year of $100 million in 1995, updated annually for inflation. In 2008, that threshold is approximately $130 million. This final rule does not contain any mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of $130 million.

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 should determine whether the pharmacy's assertion of lack of general availability in the State is valid. The State, however, has no obligation to make an independent assessment of drug availability in the absence of such notification by a pharmacy. This final rule will only revise payment rates in those rare cases in which a particular FDA-approved therapeutically, pharmaceutically, and bioequivalent drug is not generally available to the public through retail pharmacies in a particular State and, as a result, only one therapeutically, and bioequivalent drug product is generally available to the public through those pharmacies. In this circumstance, a State would need to confirm the information received from its pharmacies regarding drug availability. 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, is confirming the interim rule published on March 14, 2008 (73 FR 13785) as final with the following changes:

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 the definition of ''Multiple source drug'' is amended by revising paragraph (3)(i) to read as follows:

§ 447.502 Definitions.

* * * * *

Multiple source drug * * *

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(3) * * *

(i) A drug product 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 that the listed product is generally available to the public through retail pharmacies in that State.

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

Dated: August 20, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 21, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–23653 Filed 10–6–08; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 070817467–8554–02]

RIN 0648–XK82

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Closure of the Limited Access General Category Scallop Fishery to Individual Fishing Quota Scallop Vessels

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that the Limited Access General Category (LAGC) Scallop Fishery will close to individual fishing quota (IFQ) scallop vessels until it re-opens on December 1, 2008, under current regulations. This action is based on the determination that the third quarter scallop total allowable catch (TAC) for LAGC IFQ scallop vessels (including vessels issued an IFQ letter of authorization (LOA) to fish under appeal), is projected to be landed. This action is being taken to prevent IFQ scallop vessels from exceeding the 2008 third quarter TAC, in accordance with the regulations implementing Amendment 11 to the Atlantic Sea Scallop Fishery Management Plan (FMP), enacted by Framework 19 to the FMP, and the Magnuson-Stevens Fishery Conservation and Management Act.

DATES: The closure of the LAGC fishery to all IFQ scallop vessels is effective 0001 hr local time, October 5, 2008, through November 30, 2008.

FOR FURTHER INFORMATION CONTACT: Christopher Biegel, Fishery Management Specialist, (978) 281–9112, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION: Regulations governing fishing activity in