



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



April 14, 2008

Delivered by hand and
submitted electronically

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-IFC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-2238-IFC – Medicaid Program; Multiple Source Drug Definition

To Whom It May Concern:

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) submit the following comments regarding the revised definition of “multiple source drug” set forth in an interim final rule recently promulgated by the Centers for Medicare and Medicaid Services (CMS). *See* 73 Fed. Reg. 13785 (March 14, 2008). The definition of “multiple source drug” is important to pharmacies because CMS imposes Federal Upper Limits (FULs) reducing Medicaid reimbursement when pharmacies dispense multiple source drug products.

NACDS and NCPA represent virtually all of the retail pharmacies that provide critical drugs and services to Medicaid patients. NACDS represents nearly 180 of the nation’s leading retail pharmacy chains, including traditional pharmacy chains, supermarket chains that operate pharmacies and mass merchandisers that operate pharmacies. NACDS’s members operate more than 38,000 retail pharmacies, employ approximately 114,000 pharmacists, and dispense more than 2.3 billion prescriptions each year. NCPA is a national association of independent community retail pharmacies and pharmacists organized and existing under the laws of the Commonwealth of Virginia. Founded in 1898 as the National Association of Retail Druggists, NCPA represents the owners, managers, and employees of 25,000 independent community retail pharmacies (not publicly held) across the United States, including independently owned chains and franchises. The more than 65,000 independent pharmacists nationwide dispense 1.5 billion prescriptions annually.

We appreciate the fact that CMS has revised its definition “to better conform with the statutory provisions.” The basic statutory definition of “multiple source drug” has existed since 1990, and it is important for CMS to implement that definition.

Unfortunately, NACDS and NCPA have identified two sets of important legal problems with the new rule that revises the definition of multiple source drug. First, the rule was not promulgated in accordance with the rulemaking requirements of the Administrative Procedure Act. Second, the rule does not comply with the Social Security Act’s “State availability” standard, which requires CMS to confirm whether particular drug products are generally available to the public through retail pharmacies in each State. As a result of these and other problems discussed below, Medicaid reimbursement to pharmacies for multiple source drugs will be improperly reduced and a major new burden will be imposed on pharmacies and States.

A. The Rule Was Not Promulgated In Accordance With The Administrative Procedure Act

Problems with the new rule could have been avoided if CMS had accepted comments on a proposed revision to the definition of multiple source drug before issuing the final rule. Unfortunately, CMS did not issue a proposed rule and go through the normal notice and comment rulemaking process. Instead, CMS issued an “interim final rule with comment” which provides that the revised definition is final as of April 14, 2008. As CMS acknowledges, the rule is “not being issued in response to public comments....” 73 Fed. Reg. at 13786.

When establishing rules, CMS must ordinarily follow the formal notice and comment rulemaking process established by the Administrative Procedure Act (“APA”). This process requires CMS to provide public notice, issue a proposed rule, allow time for the public to submit comments, review and assess public comments, and then issue a final rule with a statement of basis and purpose that responds to public comments. *See* 5 U.S.C. § 553(b).

CMS asserts that it is not obligated to follow the formal notice and comment rulemaking process because the new rule is “an interpretive rule, a general statement of policy, and/or rule of agency procedure or practice.” 73 Fed. Reg. at 13787. The new rule is not merely interpretive. Rules such as this which are included in the Code of Federal Regulations are considered “substantive” rules, not interpretive rules that need not go through the notice and comment rulemaking process. That is especially true where, as here, a rule amends another substantive rule subjected to notice and comment rulemaking. Rules such as this which affect methodologies for calculating federal funding levels are substantive rules that are subject to notice and comment under the APA. At any rate, as discussed below the language of the rule fails to follow the language of the statute because the rule does not properly distinguish between drugs and drug products. Similarly, CMS’s assumption that drug products are nationally available does not “interpret” the statute, it contradicts the statute.

Moreover, the new rule is not merely interpretive because, as discussed below the rule establishes significant new burdens on pharmacies and States regarding the State availability standard that have never been imposed by either the statute or CMS. These new burdens are not

internal “agency procedures,” they are substantive new burdens that CMS has for the first time imposed on entities that are not part of the agency.

CMS also asserts even if notice and comment was required the agency has “good cause” to waive this statutory process and proceed directly to issuing a final rule. *Id.* CMS had no good cause to impose a final rule with new burdens on pharmacies and States without first issuing a proposed rule, allowing the public to comment on that proposal, and then analyzing and responding to those public comments in a preamble to a final rule. By implementing these new burdens CMS is reversing many years of implementation of the statutory definition of multiple source drug, and the agency should not have done that without following formal rulemaking procedures. 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.

CMS has no need to avoid the rulemaking requirements of the APA. CMS would not be harmed by taking the time to go through notice and comment rulemaking. As CMS acknowledges, the rule cannot be enforced due to a federal court injunction. *Id.* at 13786. CMS had time to go through notice and comment rulemaking.

B. The Rule Does Not Comply With The Statute’s State Availability Standard

The Social Security Act provides that a drug is not a multiple source drug unless two or more equivalent drug products are “sold or marketed in the State.” The statute explains that “a drug product is considered to be 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.” 42 U.S.C. § 1396r-8(k)(7).

CMS may establish a FUL on reimbursement for a drug only if the drug satisfies the definition of “multiple source drug.” *Id.* at § 1396r-8(e)(4). Therefore, a FUL cannot apply in a State unless two or more equivalent drug products are generally available to the public through retail pharmacies in that State. FULs may only be based on the average manufacturer prices of products that satisfy the State availability standard.

CMS has not complied with this State availability standard in five important ways. First, the new rule improperly applies the State availability standard to drugs rather than drug products. Second, CMS assumes nationwide availability of all drug products without a legal or factual basis for that assumption. Third, CMS does not satisfy its statutory duty to confirm whether drug products are generally available to the public through retail pharmacies in each State. Fourth, CMS improperly imposes new burdens on pharmacies and States regarding the State availability standard. Fifth, 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.

1. The Revised Rule Improperly Applies The State Availability Standard To Drugs, Not Drug Products

The distinction between drugs and drug products is important. Simply put, a drug is a chemical ingredient contained in one or more drug products. The same drug may be included in several distinct drug products marketed by different manufacturers. When two or more equivalent drug products include the same drug ingredient, those products may, under certain circumstances, be considered multiple source drug products. A “drug” is defined as an “active ingredient” in a drug product, whereas a “drug product” is “a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance....” 21 C.F.R. § 314.3.

This distinction between drugs and drug products is built into the statute’s State availability standard. The statute requires CMS to confirm whether “a drug product” appears in a published national listing of average wholesale prices, and whether that “listed product” is generally available to the public through retail pharmacies in that State. 42 U.S.C. § 1396r-8(k)(7).

The new rule does not implement the statute’s careful focus on the general availability of drug products in each State. Instead, the rule applies the State availability standard to a “covered outpatient drug” rather than to individual drug products. *See* 73 Fed. Reg. at 13788 (paragraph 3 of the revised definition of multiple source drug).

It is important to maintain the proper distinction between drugs and drug products. A drug may be generally available to the public through retail pharmacies in a State even though no individual drug product is generally available to the public through retail pharmacies in a State. For example, if retail pharmacies in a State sell ten different drug products that contain the same drug ingredient, then the drug may be generally available to the public but each of the ten individual drug products may not be sold in sufficient quantities to be generally available to the public. It would be improper to apply a FUL to any of those ten drug products unless at least two of those products are generally available to the public through retail pharmacies in that State. *See* 42 U.S.C. § 1396r-8(e)(4), (k)(7).

To comply with the statute, CMS must replace “covered outpatient drug” with “drug product” in paragraphs 3(i) and 3(ii) of the definition of multiple source drug. Otherwise, FULs may be applied improperly.

2. CMS Should Not Assume Nationwide Availability

In the preamble to the amended rule, CMS simply assumes that equivalent multiple source drug products are, and will remain, available nationwide. CMS states that “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.” 73 Fed. Reg. at 13787. *See also id.* at 13786 (“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.”) As a result, CMS declines to make any effort to

confirm whether drug products are generally available to the public through retail pharmacies in a State. *Id.* at 13786, 13787-88.

a. CMS Has No Legal Basis For Assuming National Availability

The statute does not authorize CMS to assume that equivalent drug products will be available nationwide. Instead, the statute establishes a specific and detailed process that CMS must follow to confirm that drug products are generally available to the public through retail pharmacies in each State. If Congress had intended CMS to 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. An assumption that all drug products are available nationwide would render the statute's State availability standard completely superfluous.

As a federal court has already indicated, this assumption of national availability does not comply with the statute. The same assumption of national availability was contained in CMS's original definition of multiple source drug, which looked to whether drug products were available "in the United States" rather than in each State. *See* 72 Fed. Reg. 39142, 39240 (July 17, 2007). A federal court enjoined implementation of that definition because it violated the "crystal clear" provisions of the statute's State availability standard. *NACDS, NCPA v. HHS*, No. 1:07-cv-02017 (RCL) (District Court for the District of Columbia), Transcript of Hearing on Motion for Preliminary Injunction, December 14, 2007 ("Hearing Transcript"), at 43, 55-56.

Having lost in court, CMS has changed the rule's definition of multiple source drug in an attempt to parrot the statute's State availability standard, but CMS has made it clear that the agency will continue to ignore the statute's State availability standard. Despite the court's ruling, CMS will continue to assume that all drug products are available nationally. Pharmacies and States may enforce the statute's State availability standard, but CMS will not.

CMS should not repeat the State availability standard in its revised rule and then announce that it will take no steps to comply with the plain language of the statute, which requires CMS to determine on a case-by-case basis that two or more equivalent drug products are "generally available to the public through retail pharmacies in that state." To comply with the law CMS must do more than simply repeat the statutory language in a rule, CMS must actually implement that statutory language by not applying FULs unless it has first confirmed State availability as mandated by the statute.

b. CMS Has No Factual Basis For Assuming National Availability

There is also no factual basis for CMS' assumption of nationwide availability. CMS cites no evidence that all drug products are generally available to the public through retail pharmacies in every State. CMS refuses to confirm which drug products are generally available to the public through retail pharmacies in each State, so the agency has not compiled evidence to justify its assumption of national availability. CMS appears to agree that an assumption of national availability is not always justified. *See* 73 Fed. Reg. at 13786 (stating without evidence that drug products are "nearly" always available).

In contrast, one of the nation's leading pharmaceutical industry experts has determined that there is no factual basis for assuming nationwide availability of drug products. Dr. Steven Schondelmeyer, who on several occasions has served as CMS's expert regarding pharmaceutical industry matters, has identified two basic reasons why it is incorrect to assume that all drug products are generally available to the public through retail pharmacies in every State:

202. There are at least two reasons why drug products can not be assumed to have national availability: (1) regional manufacturers, marketers, distributors, and wholesalers, and (2) certain drug products, at the NDC level, may be sold exclusively to entities in a specific class of trade and thus may not be "generally available" to any, or all, pharmacies in a given state or to the general public.

203. First, small regional manufacturers, marketers, or wholesalers may re-package and re-label drug products with a new NDC number and charge a price that is only available within the geographic scope of the firm's limited distribution market. These regional NDCs may be listed in the national price compendia (e.g., First DataBank, MediSpan, or Red Book), but they may not be available outside of the geographic region served by the firm. Because there are certain regional marketers and wholesalers, who list in the national compendia, one can not assume that all prices listed in these national compendia are available to all pharmacies across the nation. Consequently, the drug products and prices that are actually available "in the State" may vary from the drug prices that are listed in national price compendia.

204. A second situation may lead to drug products being listed in the national drug compendia, but not being available to all types of pharmacies nationwide. Certain NDCs are sold only to a certain class of trade (e.g., some NDCs are sold only to physicians). These limited 'class of trade' NDCs may still be listed in the national price compendia, but no pharmacy can order or purchase these drug products. This practice of having specific NDCs for a specific 'class of trade' is used as a way to implement class of trade discriminatory pricing and to track sales to certain classes of trade.

205. In those cases where an NDC is limited to a specific class of trade, the special class of trade typically gets a much lower price, thus lowering the AMP with prices from an NDC that is not available to traditional retail pharmacies (independent, chain, mass merchandise, or food & drug store pharmacies) in the state or the nation.

NACDS, NCPA v. HHS, No. 1:07-cv-02017 (RCL) (District Court for the District of Columbia), Plaintiffs' Motion for Leave to Supplement the Record, November 15, 2007, Exhibit A, Expert Report of Stephen W. Schondelmeyer, Pharm.D., Ph.D. (November 13, 2007) ("Schondelmeyer

Report”), ¶¶ 202-205.¹ CMS has never refuted, or even disputed, the portions of the Schondelmeyer report quoted above.

3. CMS Should Satisfy Its Statutory Duty To Confirm Availability In Each State

Rather than simply assume national availability, the statute does not allow CMS to reduce reimbursement to pharmacies by applying FULs until it has confirmed that equivalent drug products are generally available to the public through retail pharmacies in each State. The statute unambiguously imposes these duties on “the Secretary” and his agents within CMS.

Unfortunately, CMS has announced that it will apply FULs without making an effort to confirm the availability of drug products or otherwise satisfy the statutory State availability standard. CMS makes it clear in the preamble to the revised rule that it will do nothing to confirm whether particular drug products are generally available to the public through retail pharmacies in each State.

Despite the plain language of the statute’s State availability standard, CMS asserts that “We do not interpret the law to require us to continually survey drug availability in the retail pharmacies of every State....” 73 Fed. Reg. at 13786. This is quite different from what a federal court recently indicated CMS must do. In the lawsuit challenging the original definition of multiple source drug, CMS told the court that NACDS’s and NCPA’s interpretation of the statute’s State availability standard “would essentially require CMS to go out in every rebate corridor and look at all the retail pharmacies in every state and make a determination about whether they’re generally available” and if availability varies then “you’d be setting your Federal Upper Limit at – based on the lowest price equivalent available in that state....” Hearing Transcript at 43. In response, the Court suggested that is exactly the type of investigation and implementation process Congress wanted CMS to conduct before establishing FULs. *See id.* (“THE COURT: Isn’t that what Congress said?”). Ultimately the Court held that CMS’s failure to implement the State availability standard violated the “crystal clear” requirements of the statute’s State availability standard. *Id.* at 54-55.

We do not believe the federal court will condone continued refusal to confirm the availability of drug products in each State. Copying the words of the statute’s State availability standard into a rule is not sufficient. CMS must actually implement those words by not calculating and applying FULs unless it first confirms that equivalent drug products are generally available to the public through retail pharmacies in each State.

¹ The Schondelmeyer Report is attached hereto and incorporated into these comments and the administrative record.

4. CMS Has No Authority To Shift the Burden of Investigating State Availability To Pharmacies and States

Rather than comply with its statutory duty to ensure State availability, CMS has attempted to shift that burden to pharmacies and States. The burden will be placed on pharmacies and States to satisfy CMS's statutory obligation to determine in each State whether drug products satisfy the State availability standard.

CMS leaves it to pharmacies to notify a State when pharmacies suspect that “a drug on the CMS FUL list may not be available as a multiple source drug in that State.” 73 Fed. Reg. at 13787. CMS states that “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.” *Id.* at 13787-88. CMS acknowledges this is a new “burden” that CMS has imposed on States. *Id.* See also *id.* at 13786 (CMS will assume “all outpatient drugs to be generally available in a State”; this assumption may be rebutted if a State can “confirm” notifications by pharmacies “that a drug cannot be purchased in that State”).

The statute does not authorize CMS to calculate and apply FULs and then impose on pharmacies and the States the burden of investigating whether particular drug products satisfy the State availability standard. The federal statute clearly discusses the duty of “the Secretary” to apply FULs to multiple source drug products that satisfy the State availability standard. The statute never states, nor even hints, that CMS may place this burden on pharmacies and States. Nothing in the statute or its legislative history suggests that Congress intended the statute to impose this duty on pharmacies and States.

CMS has never before interpreted this longstanding statutory standard to impose an obligation on pharmacies and States. Similarly, CMS never suggested to the court that the State availability standard imposes a burden on pharmacies and States. Eighteen years after the State availability standard was enacted, CMS should not now interpret that standard as imposing a new burden on pharmacies and States.

The new burden that CMS is imposing on pharmacies and States will be substantial and ongoing. It will be a major burden on States because retail pharmacies would have little choice but to notify each State that virtually any and every drug product “may not be available as a multiple source drug in that State.”

For two reasons, 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. First, a retail pharmacy knows which drug products it sells, but it does not ordinarily know which drug products its competitors sell. Equivalent drug products are interchangeable and substitutable, so one retail pharmacy may fill a prescription for a drug with one drug product but a competing retail pharmacy may fill the same prescription for the same drug with a different drug product from a different manufacturer.

Second, CMS has given no guidance as to what the agency believes constitutes “general availability to the public” in a State. Therefore, even if a pharmacy knows that other pharmacies sell a particular drug product, the pharmacy will not know whether CMS would believe that a sufficient number of retail pharmacies offer that drug product in sufficient quantities to be “generally available to the public.”

As a result, pharmacies will lack sufficient information to determine whether particular drug products are generally available to the public through retail pharmacies in a State. To protect their interests and ensure that FULs are not applied incorrectly, retail pharmacies would have to notify each State that virtually all drug products on the FUL list may not satisfy the general availability standard.

According to CMS, each State must then investigate the availability of thousands of drug products to confirm whether those products satisfy the State availability standard. This massive undertaking will be complicated by the fact that CMS has given no guidance as to what the agency believes constitutes “generally available to the public.” Moreover, this series of notifications and investigations will have to be repeated every rebate period, which may be every three months. See 42 U.S.C. § 1396r-8(k)(8). This unfunded mandate does not satisfy the requirements of Executive Order 13132 regarding agency policies that have substantial direct effects on the States, and an agency’s resulting obligation to consult with the affected States “early in the process of developing the proposed regulation.” See Exec. Order No. 13132, 64 Fed. Reg. 43,255 (Aug. 10, 1999).

5. CMS Incorrectly Instructed Pharmacies and States That The State Availability Standard Focuses On Whether Drugs Are Unavailable To Pharmacies

The statute provides that a drug qualifies as a multiple source drug in a State only if two or more equivalent drug products are “generally available to the public through retail pharmacies in that State.” 42 U.S.C. § 1396r-8(k)(7). CMS repeats that language in the revised rule. 73 Fed. Reg. at 13788.

However, in the preamble to the revised rule CMS instructs pharmacies and States not to follow that statutory standard in two ways. First, the statute focuses on whether drug products are available to the public, but CMS focuses on whether drug products are available to pharmacies. Second, the statute focuses on whether drug products are generally available, but CMS focuses on whether drug products are completely unavailable.

CMS states that “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.” *Id.* Similarly, elsewhere in the preamble CMS indicates that pharmacies will need to notify States that “that a drug cannot be purchased in that State,” and the State will then need to “confirm that to be the case.” *Id.* at 13786. See also *id.* at 13787

(indicating that the impact of the revised rule will be minimal because it will apply in a State only when “no FDA-approved equivalent product is available in that State”).

These instructions to pharmacies and States are a critical misapplication of the statute that goes to the heart of the statute’s State availability standard. The crystal clear statute requires CMS to confirm whether drug products are generally available to the public through retail pharmacies. The statute does not require States to determine whether drug products are completely unavailable to retail pharmacies. CMS’s instructions to pharmacies and States do not conform to the plain meaning of the statute.

Finally, another misapplication of the State availability standard concerns the definition of “retail pharmacies.” CMS uses but does not define that term in the revised definition of multiple source drug. However, CMS has incorrectly included in the definition of the “retail pharmacy class of trade” many entities that do not constitute retail pharmacies. Schondelmeyer Report at 23-27, 68-70, 96-121, 123. Determining that multiple source drug products are generally available in non-retail pharmacies would not be sufficient to satisfy the State availability standard. CMS should implement the plain meaning of the statutory phrase “retail pharmacies.”

C. Conclusion

NACDS and NCPA believe the revised definition of multiple source drugs does not properly implement the State availability standard established by the Social Security Act. In addition, the rule was not promulgated in accordance with the notice and comment rulemaking requirements of the Administrative Procedure Act. NACDS and NCPA ask CMS to reconsider and withdraw the rule.

Sincerely,



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President and Chief Executive Officer
NACDS



Bruce Roberts
Executive Vice President
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