

January 2, 2008

Comments of the National Community Pharmacists Association

THREE COPIES HAND DELIVERED TO CMS WASHINGTON, DC OFFICE
(G. Hubert H. Humphrey Building, Room 445, 200 Independence Avenue, SW.,
Washington, DC 20201)

Re: 42 CFR Part 447

[CMS-2238-FC]

RIN 0938-A020

Medicaid Program; Prescription Drugs implementing the Medicaid Prescription
Drug provisions of the Deficit Reduction Act of 2005 (DRA)

The National Community Pharmacists Association (NCPA)¹ submits the following response to CMS' request for comments to the Average Manufacturer Price (AMP) and Federal Upper Limit (FUL) outlier sections of CMS-2238-FC (CMS' final AMP rule). An unaltered final rule will be in violation of the DRA and other AMP and Medicaid drug reimbursement statutes. Additionally, an unaltered final rule will result in significant negative economic impact upon independent pharmacy because CMS abdicated its responsibility for conducting a complete Regulatory Flexibility Act (RFA) analysis in either the proposed or final rule. In addition to our response to the CMS requested comments, NCPA includes an appendix that updates the RFA analysis in our CMS-2238-P comments submitted on February 20, 2007.

The following comments are written without regard to CR-05-151, *NACDS and NCPA v. US Dept. of Health and Human Services, et al*, in the U.S. District Court for the District of Columbia and does not alter the position of the plaintiffs in that litigation.

I. AMP Must Be Revised So That it Accurately Reflects, with Respect to a Covered Outpatient Drug of a Manufacturer for a Rebate Period, the Average Price Paid to the Manufacturer for the Drug in the United States by Wholesalers for Drugs Distributed to the Retail Pharmacy Class of Trade²

(under II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP* – at *Federal Register Vol. 72, No. 136, July 17, 2007 beginning at p. 39146 and Section 447.504 Determination of AMP, beginning at p. 39241*) (“*Federal Register, final rule*”).

¹ NCPA represents the nation's independent pharmacists, including the owners of more than 23,000 pharmacies, with 75,000 pharmacists, over 300,000 employees and millions of patients who rely on us for their prescription care.

² 42 U.S.C. Sec. 1396r-8(k) (1).

The DRA assigned CMS the task of making AMP serve two distinct purposes; 1) as a baseline for pharmacy reimbursement and 2) as an index for manufacturer rebates paid to states. CMS has the statutory authority, flexibility and opportunity under the DRA to properly define AMP, the retail class of trade and the outlier requirement in conformity with the DRA and other federal statutes regarding AMP and Medicaid pharmacy reimbursements. CMS also has the opportunity to accomplish savings through both increasing rebates and raising generic drug utilization rates by setting an accurate baseline for reimbursement limits.³

CMS now claims that it is balancing the interests of manufacturers and retail pharmacies while also ensuring the well being of retail pharmacists and the patients they serve. CMS did not, however, use its authority under the DRA to make policy choices that would balance the impact of the DRA. NCPA has consistently disagreed with CMS' assertion that its definition of AMP will have a minimal impact on independent pharmacy's ability to participate in the Medicaid program. CMS still has the opportunity to appropriately exercise its authority under the DRA to create definitions that reflect what actually happens in drug sales and reimbursements.

A. Correct definition of AMP

NCPA requests that CMS revise its definition of AMP, 44 CFR Sec. 447.504(a) to accomplish the Congressionally-mandated task of creating an appropriate AMP, as follows:

AMP means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include retail pharmacy⁴ sales only (chain and independent) and only adjustments that reduce the actual price paid by retail pharmacy. Prices extended to mail-order are excluded from the calculation of AMP.

CMS' final AMP rule violates the DRA by failing the requisite four-part test for determining whether a price may be included in AMP. Those requirements are that first, only prices paid to drug manufacturers may be included -- and not payments by a manufacturer to a third party, or payments by a manufacturer for separate services. Sales and rebates to PBMs, rebates and discounts "associated with" sales and low income patient programs should have been excluded under this first prong of the test.

³ NCPA supports CMS' decision to exclude prices to nursing home facilities and PBMs from AMP -- a policy choice that even manufacturers urged CMS to make.

⁴ Independent pharmacies are those that are not publicly traded. They can include franchise stores, but they are almost exclusively locally-owned and are not publicly traded corporations. For these comments, "retail pharmacy" refers to independent and chain (publicly traded) pharmacies. "Retail pharmacy class of trade" is defined later in these comments as the industry does, to include other forms of "brick and mortar" pharmacies.

Second, those prices must be paid by drug wholesalers, which industry practice defines as middlemen between manufacturers and providers who are licensed by States as wholesalers and do not dispense drugs to consumers. In contrast, CMS' final AMP rule considers patients, physicians, hospitals, retail pharmacies and virtually "any entity that purchases drugs from a manufacturer to be a "wholesaler" See CMS' final AMP rule at Sec. 447.504(f). This new definition runs counter to federal and state laws and regulations, and CMS' own policies.

Third, it is commonly understood in the industry that a retail pharmacy is an entity that is licensed (by a state) as a retail pharmacy, has a licensed pharmacist to dispense medications, and serves the general public. A specialty pharmacy, dialysis center, home infusion provider, mental health center, or mail order pharmacy or other provider only serves a subset of the public not the general public and thus fails to meet this part of the four-part test.

Fourth, a price paid for a drug may be included in AMP only if the drug is a "covered outpatient drug" See 42 U.S.C. Sec. 1396r-8(k)(1)(A). The Social Security Act defines "covered outpatient drug", and specifically excludes drugs provided to patients in connection with "physician services" or "outpatient hospital services" or "renal dialysis" 42 U.S.C. Sec. 1396r-8(k)(3). CMS' final AMP rule improperly includes in its AMP calculations sales of drugs to physicians, outpatient hospital pharmacies and clinics and sales to dialysis centers – these are sales of drugs that will ordinarily be provided to patients incident to physicians' services or outpatient hospital services or renal dialysis. CMS's final AMP rule also includes sales to surgical centers, ambulatory care centers and mental health clinics See *id.* at Sec. 447.504(g)(8), even though these drugs are ordinarily provided "incident to" physician's services.

In sum, CMS included in its calculations of AMP prices that are not paid to manufacturers by wholesalers for drugs distributed to retail pharmacies. The following are examples of sales that CMS' AMP rule improperly includes in calculations of AMP as the purchasers and entities or drugs at issue are one or more of the following: 1) not wholesalers; 2) not retail pharmacies; 3) the drugs will not be distributed to the retail pharmacy class of trade; or 4) not part of the "price paid to the manufacturer" for drugs:

CMS must exclude the following sales/fees/rebates that it includes in its final rule in the referenced sections:

- Direct sales to patients (*patients are neither wholesalers nor retail pharmacies, Sec. 447.504(g)(7)*)
- Sales to physicians (*physicians are neither wholesalers nor retail pharmacies, Sec. 447.504(g)(13)*)
- Sales to medical outpatient facilities, i.e. sales to dialysis centers, surgical centers, mental health facilities, ambulatory care facilities and physician clinics. (*are not sales to wholesalers, nor are they sales of drugs distributed to the retail pharmacy class of trade, Sec. 447.504(g)(8)*)
- Sales to retail pharmacies (*are not generally licensed as wholesalers, Sec. 447.504(g)(5)*)

- Sales to other manufacturers *(are not normally licensed as wholesalers and the drugs they buy are not necessarily distributed to retail pharmacies, Sec. 447.504(g)(2))*
- Specialty pharmacy sales *(are neither wholesalers nor retail pharmacies, Sec. 447.504(g)(11))*
- Sales at nominal price to any entity *(entity almost certainly not a wholesaler and drugs will almost certainly not be distributed to the retail pharmacy class of trade, Sec. 447.504(g)(4))*
- Sales to home health care providers *(are not sales to wholesaler, not distributed to retail pharmacy class of trade, Sec. 447.504(g)(12))*
- Sales to home infusion providers *(are not wholesalers, Sec. 447.504(g)(10))*
- Sales to hospital pharmacies, clinics or affiliated entities *(these entities are neither wholesalers nor are they retail pharmacies, Sec. 447.504(g)(3))*
- Sales and rebates to PBMs *(are not part of the “price paid to the manufacturer” for drugs and PBMs are not wholesalers, Sec. 447.504(g)(6))*
- GPO Fees *(are not prices paid to manufacturers; these fees are paid by manufacturers, often to non-purchasers, and GPOs are not normally wholesalers, Sec. 447.504(i))*
- Rebates and discounts “associated with” sales *(are not “prices paid to the manufacturers and are not linked to sales to wholesalers, Sec. 447.504(g)(14))*
- Sales reimbursed by third parties *(might not be sales to wholesalers, Sec. 447.504(g)(15))*
- Low income patient programs *(do not involve prices paid to manufacturers, Sec. 447.504(h)(9), (12), (16), (17))*
- Sales to mail order pharmacies *(are not normally wholesalers nor are they part of the retail pharmacy class of trade, Sec. 447.504(g)(9))*

B. Retail Pharmacy Class of Trade should be defined as only retail pharmacies. The definition should not include Pharmacy Benefit Manager (PBM) mail-order operations, which dispense almost no Medicaid prescriptions.

NCPA repeats its request that CMS change its proposed definition of retail pharmacy class of trade, 42 CFR Sec. 447.504(e) at Federal Register, final rule at p. 39241 as follows:

(e) Retail pharmacy class of trade means any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, traditional chain pharmacy – including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy.

This definition currently encompasses over 58,000 retail pharmacy locations.

In order then to be included in the definition of retail pharmacy class of trade, the prices must be prices available to retail pharmacy and the prescriptions must be “publicly accessible.”

Under this definition, sales to mail-order facilities would not be included in AMP. Mail-order facilities are wholly owned and operated almost exclusively by PBMs, and as such they do not meet the above mentioned criteria. Mail-order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are

1995) and limited AMP calculations to prices paid to manufacturers for the drug “in the State” by wholesalers. *Id.* at 48487.

The DRA did not alter this State availability requirement. Nonetheless, CMS’ rule discards the statutory requirement that the drug must be “sold or marketed in the State” and replaces it with language that the drug must be “sold or marketed in the United States. . . .” *See* CMS’ final AMP rule Sec. 447.502.

This is an important distinction because analogous to CMS including in its definition of AMP drug products that are not available to retail pharmacies but are available through other medical providers, (e.g. physicians, hospitals, clinics), CMS’ impermissible change in the State availability test will also result in inappropriately low FULs based upon prices for drugs that are not available to retail pharmacies in certain areas.

There are often situations when regional manufacturers, wholesalers and distributors sell drugs in parts, but not every state in the United States. These products may have low AMPs that are used to calculate FULs, even though pharmacies in other states cannot purchase those products at those low prices. Including AMPs of multiple source drugs that are sold anywhere in the country thus improperly lowers the reimbursements for those regionally-only available drugs.

II. NCPA Advocates that CMS Increase the Outlier requirement to 80%
(under II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs*, *Federal Register*, final rule at 39154 – 39156, *Outlier AMPs* at 39216 - 39217 and Sec. 447.514 at 39244)

CMS proposes to set the outlier limit at 40% - a modest increase from the 30% it announced in the proposed rule. CMS incorrectly reasons that this standard will “further safeguard to ensure” that “a very low AMP is not used by us [CMS] to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs.” *Federal Register*, *Proposed rule* at p. 77187.

The newly proposed requirement means that FUL could be calculated using an AMP that is a mere 40 percent of the second lowest AMP for that drug – so an AMP as low as \$4 could be used to calculate the FUL where the next lowest AMP was up to \$10.

CMS fails to address the issue of generic drug availability. Smaller generic manufacturers seeking to capture additional market share are willing to enter the market with a steeply discounted price in an effort to force pharmacies to buy their product. **The problem is manufacturing capacity.** Smaller generic manufacturers do not have the product inventories to serve more than just a small percentage of the Medicaid population.

In many cases there simply will not be enough supply for all pharmacists – particularly independent pharmacists. Independent pharmacists do not have access to the lowest AMP attached to a generic drug newly entering the market from a particular manufacturer. Independent

pharmacists will be unable to buy generics at that lowest AMP, no matter how diligently they try to buy drugs cheaply. There will always be buyers that will not be able to catch up to the best price of the generic drug seller. AMPs do and will vary dramatically among manufacturers and among what buyers can obtain.

CMS' use of a low outlier requirement, in the face of such an inability to meet the lowest price, is an undesirable manipulation of market forces. To allow the lowest generic AMP to set the benchmark for low rebates to states and as the benchmark for a low FUL when that generic is as low as 60% below the next lowest AMP would serve to permanently keep many independent pharmacies from providing patient access to Medicaid drugs.

CMS repeatedly asserts that the final rule will lead to adequate compensation for pharmacists. It has presented the outlier provision as a positive part of this overall rebate and reimbursement metric. For example, at two recent International Institute for Research conferences, CMS presented hypothetical AMPs for an unnamed representative class of drugs⁵:

AMP #1	\$15.00
AMP #2	\$10.00
AMP #3	\$3.90

Using these numbers, CMS stated that the FUL would be sufficient at \$25.00 (2.5 * \$10.00). What CMS failed to point out is that if the second lowest AMP for the representative drug was a mere 10 cents higher (\$4.00, as opposed to \$3.90), the maximum FUL would yield a reimbursement of only \$10.00:

But if AMP #3A	\$4.00	FUL would be \$10.00 (2.5 * lowest AMP as it is 40% or more of 2 nd lowest AMP)
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Many independent pharmacists will not be able to provide Medicaid medications to their patients if CMS retains the 40% outlier provision in the final rule. Here are similar numbers for a class of drugs whose second lowest AMP was \$15 and \$20, respectfully:

2nd lowest AMP at \$15.00

AMP #1	\$22.50	
AMP #2	\$15.00	
AMP #3	\$5.90	FUL would be \$37.50 (2.5 * AMP #2)
But if AMP #3A	\$6.00	FUL would be \$15.00 (2.5 * lowest AMP as it is 40% or more of 2 nd lowest AMP)

⁵ Deidra Duzor, CMS presentation July 26, 2007 in Baltimore, MD and September 25, 2007 in Chicago.

2nd lowest AMP at \$20.00

AMP #1	\$30.00	
AMP #2	\$20.00	
AMP #3	\$7.90	FUL would be \$50.00 (2.5 * AMP #2)
But if AMP #3A	\$8.00	FUL would be \$20.00 (2.5 * lowest AMP as it is 40% or more of 2 nd lowest AMP)

This simple mathematical illustration proves the 40% outlier policy to be grossly inadequate to ensure adequate pharmacy reimbursement. NCPA believes that an 80% outlier is a necessary step to keep from making acquisition of generic drugs under Medicaid unworkable for independent pharmacists.

Excluding from the calculation of the FUL those generic AMP prices that are 40% to 80% of the next lowest AMP will capture a much larger group of AMPs. The logical exclusion of AMPs that are less than 80% of the next lowest AMP will significantly move AMP to a much more realistic market based measure of the average manufacturers price for Medicaid generics.

Based on the findings of the GAO and OIG, independent pharmacies that have a high level of Medicaid beneficiaries will simply be unable continue servicing them at a financial loss. If CMS goes forward with this approach many pharmacies with a high percentage of Medicaid business will even be forced out of business.

III. Conclusion

For all the reasons outlined and to maintain patient access to independent pharmacy, NCPA requests that CMS:

- Adjust the definitions of AMP and retail pharmacy class of trade so that AMP is, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed only to the retail pharmacy class of trade, as the DRA requires and as such is consistent with our proposed revisions.
- Increase the outlier requirement to 80% so that the FUL allows for adequate pharmacy reimbursement consistent with market availability

We appreciate the opportunity to submit these comments on behalf of our membership.