January 2, 2008

APPENDIX to 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)

Under a Regulatory Flexibility Act ("RFA") analysis, CMS is clearly setting an unrealistic threshold for Outlier Prices in the FUL calculation. The FUL Outlier should be changed to 80%.

(**II. Provisions of the Proposed Regulations –** *Upper Limits for Multiple Source Drugs, Section 447.514 at p. 39244 and discussed at pgs. 39154 – 39157 and pgs. 39216 - 39127)*

CMS' definition of AMP, including the definition of retail pharmacy class of trade, combined with the 40% outlier provision, will have a significant negative impact upon independent pharmacists and will impact patient access to Medicaid drugs. Our RFA analysis shows that the definition of AMP and the outlier requirement must be substantially adjusted.

I. Regulatory Flexibility Act

Cuts to pharmacy are much greater than CMS' characterization of a "1% loss of drug revenues"

(**II. Regulatory Impact Analysis –** B.3. Effects on Retail Pharmacies at p. 39233)

CMS misleadingly, and erroneously, claims that the effect of implementation of the rule will be less than "1 percent" of prescription drug revenues. CMS wrote in the proposed rule that:

> First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as prescription drug sales. Second, pharmacies have the ability to mitigate the effects of the proposed rule by changing purchasing practices. . . . Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs. *CMS-2238-P, Federal Register, Vol.71, No. 246, December 22, 2006, pgs. 77192 – 77193 ("Federal Register, Proposed rule") (emphasis added).* CMS repeats the last assertion in *Federal Register, Final rule at p. 39233.*

CMS' assertions are simply wrong. NCPA offers the following rebuttal:

First some 92% of independent pharmacy revenues are from prescription drug sales. The negative effect of CMS-2238-FC will be tremendous on independent pharmacies, which are disproportionately located in rural and urban areas. This negative impact will not be abated by the small portion of non-pharmaceutical sales that occur at these pharmacies.

Second, in claiming only a 1 percent loss of revenues, CMS looks at gross revenue sales figures for all of pharmacy (chain and independent), and fails to look at the percentage of Medicaid business per pharmacy. Based on analysis of 2006 data, Medicaid comprises 15% of the average independent pharmacies' business—approximately double the Medicaid business of a typical chain location. For over 10% of independent pharmacies, Medicaid represents 50% or more of their business. If Medicaid reimbursements will be significantly below acquisition costs, as government oversight organizations have projected, then many independent pharmacies will have to suspend their participation in the Medicaid program or close their doors, thus restricting patient access, increasing health care costs, and deteriorating beneficiary/patient health.

Because of these qualitative differences between independent pharmacies and chain pharmacies, and because of the newly estimated negative impact of the final rule upon independent pharmacies, *infra*, NCPA repeats its request for an exemption from the new definition of AMP for either: 1) small business as defined by the Small Business Administration (SBA) definition based on gross dollar of business - $6.5 million or less annual; or 2) pharmacies that have a 10% or higher volume of Medicaid business.

A. The OIG and the GAO have stated that FUL will be insufficient

The DRA sets the new FUL at a maximum of 250% of the lowest AMP for therapeutically equivalent and nationally available generics. This 250% ceiling is a best-case scenario as states will be unlikely to set reimbursement at the FUL (many states currently reimburse below the FUL). The OIG recently reported that even with the 250% multiplier, the FUL would still fall below pharmacy acquisition cost for 19 of the 25 high-expenditure generic drugs studied. For 5 of the other 6 drugs in the study, the pharmacy would only cover the cost of the drug, but would still realize a loss once the cost-to-dispense (pharmacy operational costs) is considered.

Retail pharmacy cost-to-dispense averages $10.50 nationwide according to a comprehensive 2007 study by the international accounting firm Grant Thornton. The dispensing fee paid under state Medicaid programs is far lower at an average range of $3.00 - $5.00. When these numbers are applied to the findings of the OIG study, only 1 of the top 25 high-expenditure Medicaid drugs would post a meager profit under the new FUL.

These findings confirm those of a December 2006 GAO study (released January 2007) which found that the new FUL would fall below acquisition cost for 59 of the 77 generics profiled. The AMP-based FUL was 65% below acquisition cost for the 27 high-expenditure drugs studied,

15% below acquisition for the 27 most-frequently prescribed generics, and an average of 36% below pharmacy acquisition cost across the entire sample.

B. On average, independent pharmacists stand to lose nearly 80% of total net profits under the new AMP – patient access will decline

CMS did not undertake a substantive RFA analysis in either its proposed or final rules. CMS dismissed the findings of the OIG and GAO. CMS then claimed a lack of evidence to substantiate the significant economic impact of the final rule. CMS then went on to state ". . . we [CMS] have retained our prior conclusion that this proposed rule is likely to have "significant impact" on some pharmacies." *Federal Register, Final Rule at 39233*.

CMS is not technically required to conduct an RFA analysis if it does not find evidence of a significant economic impact, however NCPA believes the intent of the RFA was violated when CMS dismissed the evidence offered by the OIG and GAO. NCPA does not understand how CMS can say that if finds no evidence of a significant economic impact in light of these data and analyses. In addition to a comprehensive review of the OIG and GAO studies, CMS should also consider the following NCPA analyses based on newly acquired 2006 data.

Based on recently acquired 2006 data, NCPA estimates that implementation of the AMP-based FUL will lead to a 79% reduction in net profits of the average independent pharmacy. This estimate: 1) assumes that sales from other drugs and products at the pharmacies stays constant, and 2) uses the GAO's projection of pharmacists being reimbursed for the average Medicaid drug under CMS' new AMP-based FUL at 36% below the acquisition cost – even if that reimbursement is at the maximum FUL of 250% of AMP. Due to the changes that CMS has made to its definition of AMP, reimbursements could even be lower.

Using those assumptions, NCPA estimates that the average total revenues from Medicaid will reach $104,326 in the first year that AMP is implemented. Projected average total Medicaid expenses of $180,222 will therefore exceed the average total revenues by $75,896. The total net profit of the average independent pharmacy in 2006 was $96,030. The projected $75,896 reduction in net revenue, to $20,134, equals a 79% drop from 2006 net revenue.

In addition, while the average amount of Medicaid business for an independent pharmacy is 15%, for some ten percent (10%) of independent pharmacies, over half of their business is from Medicaid, with the majority of those prescriptions being filled as generics. These high Medicaid volume business independent pharmacies and their patients will be greatly negatively impacted by the final rule.

The total revenue from generic Medicaid prescriptions is low relative to the total median independent pharmacy business because generic drugs are significantly cheaper than brand name

drugs.[1] Because net profits per prescription are much lower for generic drugs than they are for brand name drugs, implementation of the final rule will affect independent pharmacists to a much greater degree than might be assumed based on gross revenue calculations. Simply put, a relatively small cut in federal Medicaid expenditures on generic drugs will cause significant profit losses for some independent pharmacies. Because they will lose money on most Medicaid generic prescriptions, many will have to discontinue dispensing Medicaid prescriptions and some will have to shut their doors.

1. National Average

Table 1 (assuming an average $4.50 state dispensing fee)

Projected independent pharmacy revenue losses under new CMS AMP – assuming GAO's projection of reimbursement at 36% below acquisition cost
Except as noted, data expressed as projected revenues for the average independent pharmacy with $3,612,000 in annual sales (2006 average)

	Dollar Value at 15% Medicaid business	Dollar Value at 30% Medicaid business	Dollar Value at 50% Medicaid business
New Generic Medicaid Revenues			
Drug Product Reimbursement	$82,060	$164,119	$273,532
Dispensing Fee Revenue	$22,266	$44,532	$74,221
Total Revenues	$105,326	$208,652	$347,753
Expenses			
Cost of Goods Sold	$128,218	$256,437	$427,394
Cost to Dispense	$52,004	$104,008	$173,347
Total Expenses	$180,222	$360,445	$600,741
Net Loss	**(-$75,896)**	**(-151,793)**	**(-$252,988)**
Average Independent Pharmacy Total Net Profit (2006)	$96,030	$96,030	$96,030

[1] Based on CMS data from January to June 2006, the average prices paid for a generic and brand name drug under Medicaid are $21.92 and $155.98, respectively. NACDS' *The Chain Pharmacy Industry Profile 2007* at page 69 lists the average price for all generic drugs as $32.23 and the average price for all brand name drugs as $111.02. The $32.23 value was used in calculating the figures found in Table 1, *infra*.

Total Projected Net Profit/Loss of average independent pharmacy under new CMS AMP	$20,134 (**Drop of 79% from 2006)**	**(-55,763) (Drop of 158% from 2006)**	**(-$156,958) (Drop of 263% from 2006)**

2. Even an example independent pharmacy that does a modest volume of Medicaid business would be hurt by CMS' AMP and would likely stop servicing Medicaid beneficiaries

An NCPA member whose pharmacy's Medicaid sales total only 2.08% of its total drug revenues and whose net profit margin is almost identical to the national independent average net profit margin provided us with data regarding its Medicaid business that shows that even independents with a small volume of Medicaid business will be hurt by CMS' AMP rule and will have financial incentive to stop servicing Medicaid beneficiaries.

In the last year, the sample independent shows a 2.743% net profit margin of which $2,614.61 was generated from its Medicaid generic drug sales. Under the GAO projection of reimbursements at 64% of costs, and including dispensing fees, the independent pharmacy calculated that it would incur a $20,410 loss of Medicaid generic drug sales revenue if it were to continue servicing Medicaid beneficiaries under CMS' new AMP.

If the sample independent were to terminate its Medicaid contract, however, the calculated net loss would only be $13,069. This calculation also takes into consideration losing ancillary prescriptions filled by family members or care givers that are not covered by Medicaid. The sample independent is thus trying to accurately project -- and not minimize -- the anticipated loss from dropping out of the Medicaid program.

This sample independent calculates, as many others will, that terminating their Medicaid contract will be less harmful than continuing to serve Medicaid patients under CMS' AMP. A few independent pharmacies with a small volume of Medicaid business may decide to absorb the losses as a courtesy to needy Medicaid beneficiaries. Those independent pharmacists with a larger volume of Medicaid business will not have that option and will either drop out of the Medicaid program or be forced out of business.

Table 2 shows the sample independent's projected losses for continuing or discontinuing service in the Medicaid program based on the current and hypothetical levels of Medicaid business:

Table 2 (assuming a $4.00 dispensing fee)

Percentage of business as Medicaid business	Net loss if sample independent pharmacist remains in Medicaid program	Net loss if sample independent pharmacist terminates Medicaid contract
2.08%	(-$20,410)	(-$13,069)
15%	(-$146,181)	(-$93,944)
30%	(-$292,129)	(-$187,794)
50%	(-$486,875)	(-$313,022)

3. CMS's criticisms of the GAO and OIG reports are unfounded and its reference to state power to address reimbursements is not realistic

CMS has disputed the findings of both the OIG and GAO reports; however, the methodologies used by each agency are congruent with provisions contained in the rule. CMS failed to refute any of the reports specific findings, instead using sweeping generalizations to dismiss two independent government agency reports as flawed and irrelevant. The HHS Secretary also offered wholesale rejection of the GAO study during testimony before the House Committee on Energy & Commerce without providing any specific refutation of the study's findings.

CMS suggests states should examine dispensing fees as well as estimated pharmacy acquisition cost to ensure that pharmacy costs are sufficiently covered. CMS even included a cost-to-dispense definition similar to the definition within Medicare Part D for state's consideration. CMS did not, however, provide any guidance or incentive for states to ensure pharmacy operational and acquisition costs are covered.

While CMS incorrectly claims that the new FUL will sufficiently cover acquisition costs, CMS makes it clear that states are free to pay pharmacies more than what the federal government will give to the states. CMS acknowledges that the states need to make up the difference between this new metric and what pharmacists have received in the past from state Medicaid programs. Where are the states supposed to find this new funding? This amounts to another unfunded mandate being handed to the states.

Last year the Louisiana Legislature passed a measure which would have increased dispensing fees to $10 for brand name prescriptions and to $15 for generic medicines, which would cover pharmacy's operating costs and encourage generic utilization. In July of this year, CMS rejected the Louisiana plan. This does not bode well for states hoping to preserve patient access by covering pharmacy's cost to dispense. CMS' approach of leaving the problem to the states to solve, when it apparently will not approve plans that will substantively address the problems in the new AMP, is one other reason CMS must adjust its definitions and the outlier requirement.

II. Conclusion

Not only must CMS significantly adjust its final AMP rule to correspond with federal statutory requirements regarding AMP and Medicaid pharmacy reimbursements (see NCPA's comments), but it must also conduct a meaningful RFA analysis of the impact of its final rule on retail pharmacies, particularly upon independent pharmacies and those that currently service a high volume of Medicaid beneficiaries. A review of NCPA's RFA analysis should prompt CMS to act appropriately to safeguard community retail pharmacies and their patients.