February 16, 2007

Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Medicaid Program; Prescription Drugs (71 Fed. Reg 77174, December 22, 2006)

Dear Acting Administrator Norwalk:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration.

As Chief Counsel for Advocacy, I am submitting comments on this rule because my office has received several oral and written contacts from small businesses, mostly small retail pharmacies and their representatives, that are concerned with the Centers for Medicare and Medicaid Services (CMS) proposed rule on prescription drugs.[1] The rule serves to codify requirements for drug manufacturers' calculation and reporting of average manufacturers price (AMP), and would revise existing regulations that set upper payment limits for certain covered outpatient drugs. While CMS certifies pursuant to the Regulatory Flexibility Act (RFA)[2] that the proposed rule will not have a significant impact on a substantial number of small pharmaceutical manufacturers participating in the Medicaid Drug rebate Program, and physicians and other practitioners that bill Medicaid for physician-administered drugs,[3] CMS correctly prepared an initial regulatory flexibility analysis (IRFA) and readily acknowledged that the rule will have a

[1] The rule was published in the *Federal Register* at 71 Fed. Reg. 77174 (December 22, 2006).
[2] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. § 612(a).
[3] 71 Fed. Reg. 77191 and 77192 (December 22, 2006).

significant impact on approximately 18,000 small retail pharmacies.[4] CMS admits that the savings expected to be garnered by the rule will largely be realized through lower payments to pharmacies and will likely reduce pharmacy revenues by about $800 million in 2007, increasing to $2 billion annually by 2011.[5]

The small retail pharmacy representatives who contacted Advocacy disagree with CMS' conclusion in the rule that "the aforementioned reductions in revenue, while large in absolute terms, represent only a small fraction of overall pharmacy revenues (less than 1 percent)."[6] CMS acknowledges that it was "unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."[7] While CMS should be commended for preparing an IRFA pursuant to the RFA, Advocacy believes that further analysis is required to determine how this rule will impact small retail pharmacies, especially in light of the fact that certain impacts of the rule cannot be adequately quantified.

Advocacy provides the following submission to CMS based on information provided by small pharmaceutical industry representatives:

1. **CMS should make every effort to analyze how the rule will affect small pharmacies and include the data in the final regulatory flexibility analysis.**

CMS is conceding there will be a significant impact on small independent pharmacies, but that there will only be a 1 percent impact overall on retail pharmacy revenues. The small pharmacy industry believes that this seemingly contradictory position stems from CMS analyzing retail pharmacy as a whole. CMS is not quantifying the impact specifically on small, largely independent pharmacies, especially rural independents. Since independents serve a disproportionate percentage of lower income Medicaid beneficiaries, the impact of the proposed rule is likely to be more pronounced.

2. **The application of a faulty AMP definition in calculating the Federal Upper Limits (FUL) will force many independent pharmacies to drop service to their Medicaid patients and some independents will close completely.**

The Government Accountability Office (GAO) has found that an "AMP-based federal upper limits (FULs) were, on average, 36 percent lower than average retail pharmacy acquisition costs."[8] This finding seems to validate the small pharmacy industry concern that AMP is not appropriate as a baseline for reimbursement and must be defined to reflect pharmacy acquisition cost. This lack of access to timely and safe prescription drug care will lead to additional costs of more doctor visits, emergency room care, hospital stays and long term care. Those pharmacies that remain in the Medicaid program

[4] Id. at 77191.
[5] Id. at 77192.
[6] Id.
[7] 71 Fed. Reg. 77193.
[8] See GAO report, GAO-07-239R.

may face a perverse incentive to dispense more profitable, higher-cost brand medicines, thus driving Medicaid costs higher.

3. **CMS must define AMP to reflect the actual cost paid by retail pharmacies, excluding all rebates and price concessions not available to pharmacies.**

Small pharmacy representatives told Advocacy that AMP is now to serve two distinct and contrary purposes under the proposed rule: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. GAO noted that AMP was never intended to serve as a baseline for reimbursement**,** and may not have been an effective measure for manufacturer rebates as outlined in the report "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States."[9] Small pharmacy representatives believe that all rebates and price concessions are appropriately included in "Best Price" but should not be included in AMP. Proper definition of AMP and "Best Price" will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

4. **CMS should redefine the term of art "retail pharmacy class of trade."**

Small pharmacy representatives recommended to Advocacy that the definition of "retail pharmacy class of trade" include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations. In order to be included in the definition of retail pharmacy class of trade, the prices used should be prices available to retail pharmacy and the prescriptions should be "publicly accessible." Under the suggested definition, sales to mail order facilities should not be included in AMP. Pharmacy Benefit Managers (PBMs) are not licensed to buy medications and should not be included in the definition of retail pharmacy class of trade. Mail order facilities are operated almost exclusively by PBMs, and as such they do not meet the above mentioned two criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

5. **If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the price actually paid by the retail pharmacy class of trade.**

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE[10] and to the Department of Veterans Affairs (VA). CMS also should also exclude rebates paid to PBMs from AMP calculation. The Medicaid drug rebate program was created for states to collect rebates from

[9] See GAO report, GAO-05-102**.**
[10] TRICARE is the health insurance program for military personnel and their families.

manufacturers in much the same way that PBMs receive manufacturer rebates on the market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive under Federal financial participation.

Conclusion

In summary, Advocacy requests that CMS give consideration to the issues raised by the small independent pharmacy industry herein and better analyze the possible affects of this regulation on that industry in the final rule. Advocacy appreciates being given a chance to provide CMS with these comments that are of great concern to small businesses in the pharmaceutical industry. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel, Linwood Rayford at (202) 401-6880, or www.linwood.rayford@sba.gov.

Sincerely yours,

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Cc: Steven D. Aitken, Acting Administrator, Office of Information and Regulatory Affairs