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Hearing before the House Committee on Small Business Regarding Legislation to Improve the Regulatory Flexibility Act

Good Morning, Madam Chair and other members of the Committee. Thank you for conducting this hearing and providing us an opportunity to share our support and recommendations for this legislative proposal to improve the Regulatory Flexibility Act ("RFA").

My name is Charles Sewell, Senior Vice President of Government Affairs for the National Community Pharmacists Association, or NCPA. I am honored to testify today on behalf of our members, their employees, and most importantly our patients. NCPA represents the nation's community 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.

Independent pharmacists provide vital prescription services in rural, inner-city and urban areas, including services offered almost exclusively by independents, such as compounding, medication therapy management, durable medical equipment and home delivery. The nation's independent pharmacies dispense nearly 40% of the nation's retail prescription medicines.

Because of the face-to-face relationship with their local independent pharmacist, patients are more likely to take their medicines on-time, more likely to take them properly, more likely to refill meds before they run out and more likely to avoid harmful drug interactions. Patient access to their trusted independent pharmacist helps to lower health care costs by promoting patient health every day.

We are also small businesses, with small profit margins that suffer disproportionately from unnecessary administrative burdens. NCPA therefore applauds the initiative of this Committee in holding the November 15 hearing on the burdens of the Regulatory Flexibility Act (RFA) upon small business and drafting legislation to amend the RFA to improve its protection of small business in the face of government agency action.

Government is the independent pharmacist's largest partner as the Medicare Part D and Medicaid programs cover an average of half of our prescription volume.. A robust RFA is therefore important to our success. Simply put, the Regulatory Flexibility Act was created to ensure that government agencies must examine the impact of their actions on small business and make their findings public. As the Committee knows all too well, this vital oversight and transparency help to preserve the small businesses which are the backbone of our economy.

From our perspective, the Regulatory Flexibility Act should serve as a shield for small business from the adverse effects of government agency actions. It is an absolute imperative that real economic analysis of small business impact be taken into consideration before a government agency implements new public policy.

NCPA PROPOSALS:

We support the draft "Small Business Regulatory Improvement Act of 2008", including its major provisions which:

1) clarify when agency reviews of existing rules are to take place;
2) require agencies to consider indirect impacts to small business; and
3) codifies Section 3 of Executive Order 13272 (August 13, 2002) which require agencies to notify the SBA Office of Advocacy of proposed rules that may impact small businesses before such rules are published in the Federal Register. These are sensible and helpful reforms.

We believe, however, that they can be strengthened and be made to have an even greater potential impact.

The three major reforms that we support are:

1) **For at least all major rules, an agency may not issue a final regulation unless it specifically analyzes the "significant impact" that implementation of the rule will have on small businesses. Agencies should not be able to hide behind the excuse of having a "lack of evidence." In order to proceed, agencies must affirmatively demonstrate that there is no significant adverse impact on small business. If studies exist which show the rule will cause a significant impact, the agency cannot simply dismiss the studies and proceed with implementation.**
2) **Once there is a finding of significant impact upon small businesses (a loss of 3% or more of gross revenues), the agency should not be able to implement the rule for the small business sector.**
3) **A private person or entity or governmental entity can make a regulatory challenge of an agency that releases a final rule which the person or entity believes was done in violation of the RFA. The regulatory challenge would be an abbreviated administrative action adjudicated through the SBA. Failure to obtain relief in the SBA process would not preclude the challenger from filing a subsequent, nor would it negate a simultaneous lawsuit.**

NCPA believes from its experience with government agencies that such strong measures are necessary to ensure that agencies truly examine the impact of their actions upon small businesses.

A recent and key example is the final CMS rule implementing the Medicaid reimbursement provisions of the Deficit Reduction Act of 2005 (DRA). The DRA and subsequent regulatory rule will be devastating to community pharmacy. CMS, however, used a technical reading of the DRA to

ignore the significant economic impact of the rule upon pharmacies under both HHS and SBA standards.

INDEPENDENT PHARMACIES ARE VITAL AND VIBRANT PARTS OF THEIR COMMUNITIES AND ARE SMALL BUSINESSES THAT HAVE BEEN HARD HIT BY MEDICARE PART D AND WILL BE FURTHER DAMAGED BY IMPLEMENTATION OF THE FINAL RULE BY CMS

Through attentive patient care and dedication to their communities, independent pharmacies have been able to compete with chains and mass merchants. In fact, the independent pharmacy sector was quite stable in the 5 years prior to Medicare Part D. Independent pharmacists have considerable staying power: A full 68% have been in business for more than 20 years.

Pharmacies are closing: Part D and CMS' AMP

In 2006, however, 1,152 independent pharmacies were sold or permanently closed. This net loss of three independents per day is directly attributable to Medicare Part D, chiefly from payment delays, lower reimbursements, and patients being unfairly steered into mail order and away from their community pharmacy.

It can easily be said that the Federal government maintains the controlling interest in the operation of every independent pharmacy. This is not by our choosing. Between Medicare and Medicaid, the average independent will see half our patients' care controlled by government programs.

The giant Pharmacy Benefit Managers or PBMs who administer the Part D program have long used their size and market power to foist take-it-or-leave-it contracts upon independent pharmacies. Medicare Part D has tremendously strengthened the big PBMs. All Medicaid prescriptions for dual-eligibles are now paid by PBMs under Part D. The government and third parties now dictate the reimbursement for 92% of all retail prescriptions.

This level of third-party involvement, especially the share controlled by government programs, means that any regulatory changes will have a great impact upon the health and welfare of small business independent pharmacy. RFA was intended specifically to ensure small businesses in this position are not adversely impacted by government action.

To make matters worse, CMS has just published the final rule on Average Manufacturers Price, or AMP. AMP will serve as the new reimbursement basis for the Federal Upper Limit (FUL) on generic drugs dispensed under the Medicaid program. These changes were among the many onerous provisions of the Deficit Reduction Act of 2005.

The original purpose of AMP was to serve as an index for manufacturer's rebate liability. CMS acknowledges that their AMP will now serve these two distinct purposes, but fails to reconcile the definition of AMP so that it is appropriate as an accurate benchmark for reimbursement. CMS

also did not include any policing of manufacturers calculating or reporting process thereby giving manufacturers the opportunity to minimize their rebate liability by underreporting AMP.

CMS' AMP is simply not appropriate for pharmacy reimbursement. Period.

The DRA sets the new FUL at a maximum of 250% of the lowest AMP for therapeutically equivalent and nationally available generics. This 250% is a best-case scenario as some states will likely set reimbursement below the FUL. The HHS Office of Inspector General 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 is considered.

Retail pharmacy cost-to-dispense averages $10.50 nationwide according to a 2007 study by the international accounting firm Grant Thornton. The dispensing fee paid under state Medicaid programs is far lower at an average of $4.50. 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 are consistent with 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.

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

No economic analysis of the impact on small business pharmacies was ever really conducted by CMS despite overwhelming evidence. This is proof as to why the RFA should be amended to allow affected parties the opportunity to challenge agencies as they issue rules which impact small business.

THE UPCOMING SIGNIFICANT IMPACT UPON INDEPENDENT PHARMACY AND CMS' CURSORY DISMISSAL OF THAT IMPACT SHOW THE NEED TO ADOPT NCPA'S SUGGESTED REFORMS

In both its proposed and final rule, CMS failed to examine the negative impact the rule would have upon community pharmacy – and in particular upon independent community pharmacy. Instead, CMS states on page 522 of the final rule (CMS-2238-FC):

> Although it is clear that the effects will be small on the great majority of pharmacies, whether chain or independent, we are unable to estimate quantitatively effects on "small" pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. We received general comments that these pharmacies will be greatly impacted by the provisions of this rule; however, we did not receive documented estimates of these effects. Because of the lack of evidence as to the true effect, we have retained our prior conclusion that this proposed rule is likely to have a "significant impact" on some pharmacies. *[CMS refused to provide the industry with AMP data to review]*

CMS has shirked its responsibilities under the Regulatory Flexibility Act's requirement for analysis of significant economic impact by not analyzing that impact in either its proposed or final rule. CMS has admitted that there will be a significant impact upon small pharmacies, yet it has twice chosen not to analyze that impact because it was not presented with "documented evidence." OIG and GAO have both documented the "significant impact" upon community pharmacy, yet CMS continues to contend that the impact cannot be determined. NCPA believes that CMS has violated at least the spirit and intent of the Regulatory Flexibility Act. **Under NCPA's proposed additions to the "Legislation to Improve the Regulatory Flexibility Act", CMS would be violating the letter of the RFA.**

It is CMS' position that under the Regulatory Flexibility Act and the standard for HHS regulations, CMS is required to analyze the impact upon small businesses if implementation of the regulatory rule will result in a negative impact upon gross revenues of 3% or more. For the case of AMP, CMS looked at the impact on prescription drug revenues. Even if one accepts this standard, based on data from the 2007 NCPA Digest, the rule will have at least that amount of impact upon the median independent pharmacy. The impact will be greater upon rural independent pharmacies and those independent pharmacies serving a higher than average number of Medicaid patients.

Even under HHS/CMS' high standard of loss of gross revenues, those projected losses under CMS' AMP demonstrate that CMS should have found a significant impact

More than 50 percent of the business of some ten percent (10%) of independent pharmacies is from Medicaid, with the majority of those prescriptions being filled as generics. The average amount of Medicaid business for an independent pharmacy is 14%. These independent pharmacies and their patients will be disproportionately affected.

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. (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). Because profit margins are higher with generic drugs, the implementation of the rule will affect independent pharmacists to a much greater degree than might be assumed based on gross revenue calculations. More importantly, reimbursements below acquisition costs will depress generic utilization rates, leading to higher costs as more brand name drugs are dispensed. This shift will ultimately hurt taxpayers.

Any revenue projections must assume that all other prescription sales and non-prescription sales will stay constant after implementation of the rule. This is an assumption made not in the belief that all other sales will stay flat, but rather for the sake of making as uncomplicated a calculation as possible. In reality, for those stores that can stay in business, a loss of Medicaid patients would mean, for example, a loss of those patients that also acquire diabetic and related Medicare Part B supplies. The impact upon the business is difficult to measure, but it surely must reach beyond the linear loss of Medicaid generic drug reimbursements.

More importantly, the dramatic loss of net profits (SBA standard) under CMS' AMP is unacceptable and further supports the needs for NCPA's proposed reforms

Under Small Business Administration (SBA) standards, CMS can and should have considered the effect on profits of small pharmacies by the proposed and final rules. Under that standard, it is even clearer that small independent pharmacies will suffer significant economic impact under the final rule.

SBA standards for implementing Executive Order 13272, which President Bush signed on August 13, 2002, (reassigning responsibility of duties under Executive Order 12866), gave new direction for federal agencies in their efforts to assess the impact of their proposed rulemakings on small business and other small organizations under the Regulatory Flexibility Act, and directed the SBA's Office of Advocacy to provide agencies with information on how to comply with the President' directive. In that rule, the SBA directed federal agencies to look to the impact upon profits of small entities caused by a new rule.

Under the standard of impact upon profits, small independent pharmacies will indeed suffer significant economic impacts which CMS acknowledged, but did not analyze. Once again, assuming that all other prescription and non-prescription sales would stay constant, implementation of the final rule would cause the total net profit of the average independent pharmacy to fall by nearly 79%. No business can stay in business for very long without making at least a small profit.

CMS did not take into account the resulting harm to the Medicaid program, beneficiaries and taxpayers

The new FUL will force states to underpay pharmacies for many generic drugs. This will in turn force pharmacies from the Medicaid program and severely reduce patient access. Many independents will close their doors entirely. We expect to lose over 2,300 pharmacies with high Medicaid volume (over 50%) almost immediately when this CMS scheme goes into effect.

CONCLUSION

NCPA thanks the committee for the opportunity to discuss with it the inadequacies of the current RFA. In analyzing the impact of its implementation of the DRA, CMS took advantage of a technical reading of the RFA to ignore the significant economic impact that implementation of the

rule will have under both the logical SBA standard of loss of profit, and also under the broader HHS/CMS standard of loss of gross revenue.

This testimony discusses just one example of a government agency subverting the positive public policy intentions of the Act. In order to protect the interests of small businesses and the communities they serve, NCPA requests that in addition to the reforms contained in the draft "Legislation to Improve the Regulatory Flexibility Act", the Committee support and introduce three other reforms, previously detailed and now summarized below:

1) **For at least all major rules, an agency may not issue a final regulation unless it specifically analyzes the "significant impact" that implementation of the rule will have on small businesses.**

2) **Once there is a finding of significant impact upon small businesses (a loss of 3% or more of gross revenues), the agency may not implement the rule as it applies to the affected small business sector.**

3) **A private person or entity or governmental entity can make a regulatory challenge of an agency that releases a final rule which the person or entity believes was done in violation of the RFA.**