

January 6, 2010

The Honorable Nancy Pelosi  
Speaker  
United States House of Representatives  
Washington, D.C. 20515

The Honorable Harry Reid  
Majority Leader  
United States Senate  
Washington, D.C. 20510

**Subject: Conference on H.R. 3962 and H.R. 3590, the Affordable Health Care for America Act and Patient Protection and Affordable Care Act**

Dear Speaker Pelosi and Majority Leader Reid:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide our views on the provisions that we would like to see included in a final conference report on H.R. 3962 and H.R. 3590. We appreciate all the hard work on behalf of community pharmacy that has gone into health care reform legislation in this Congress. It presents many opportunities to improve the use of prescription medications, reduce health care costs, and enhance patient care through an expansion of pharmacist services. NCPA represents the approximately 23,000 owners and operators of independent community pharmacies in the United States.

**NCPA Supports Senate Medicaid Pharmacy Reimbursement Provisions:** NCPA strongly encourages that the final conference report include important reforms to the Medicaid Average Manufacturer Price (AMP)-based reimbursement system for generic drugs that was originally enacted in the Deficit Reduction Act (DRA) of 2005. These reforms, which have important bipartisan bicameral support, are critical to ensuring the continued dispensing of lower cost generic medications, and the viability of small independent community pharmacies. These reforms are also critical because Medicaid will become an even larger payer for prescriptions in the future, given the expansions envisioned in both the House and Senate bills.

We support the language in the Senate bill which would: 1) appropriately redefine AMP and community pharmacy so that only retail pharmacy prices would be included in the definition of AMP; 2) revert the definition of “multiple source drug” back to the pre-DRA definition, (that is, a drug having three or more sources of supply rather than two sources of supply); 3) require CMS to only use nationally-available generic products when calculating the AMP, and incorporate the use of a smoothing process to minimize monthly fluctuations in AMP; 4) set FULs at no less than 175% of the weighted average AMP for a multiple source drug, rather than 250% of the lowest AMP; and, 5) eliminate the requirement that CMS post individual AMPs in favor of weighted average AMPs for brand name and generic medications. We also support the Senate bill’s revision of the “retail survey price” definition.

Setting the FUL at a minimum of “no less than 175% of the weighted average AMP” is critically important for independent and small community pharmacies. While we absolutely appreciate the modifications made to the AMP-based reimbursement system in the House bill, reimbursement at 130% of the weighted AMP, combined with the low dispensing fees paid by states, could negatively impact generic dispensing and reduce Medicaid patients’ access to community pharmacies.

For most independent community pharmacies, 90 percent or more of their revenues are derived from prescription sales. Independents also serve a higher percentage of Medicaid recipients than other pharmacies. Many independents operate pharmacies in rural and urban locations where most Medicaid recipients live.

We believe that the colloquy included in the *Congressional Record* by Senators Lincoln and Baucus should remain in the conference report language because it describes the circumstances under which CMS would set an FUL for a generic drug at higher than 175% of the weighted average AMP. One such situation described is where independent community pharmacies would be paid at a higher FUL to assure that Medicaid patients had access to pharmacy services, especially in rural areas.

Moreover, we strongly urge that you consider an annual incentive-based payment to small and independent pharmacies beyond the base Medicaid pharmacy reimbursement rate. For example, we support the Senate language that would establish a grant program to states for health care providers that serve a disproportionate share of Medicaid patients and those that provide health care in medically-underserved areas. Independent community pharmacies should be eligible for this program.

With respect to implementation, we believe that further setting of FULs by CMS should be suspended until the new, reformed AMP-based system is in place. For example, the House bill would not have FULs go into effect until January 2011. Further, we urge that CMS be required to publish a proposed rule – not an interim final rule – to implement these new requirements. We believe that it is critical that all affected parties have an ample opportunity to comment on a proposed regulation before it becomes final. CMS should collect several months of new AMP data to allow manufacturers and others to adjust to making the new calculations. This will assure more uniformity in AMP calculations among manufacturers. This is critically important before CMS uses any AMP data to set FULs or before any AMP data become public.

We also support inclusion of Senator Bennet’s amendment requiring that the GAO conduct a study of the costs of dispensing Medicaid prescriptions by state. This study is needed to help states better understand how their current dispensing fee payments compare to the actual cost of dispensing, so they can consider any needed adjustments.

**NCPA Supports Blend of House and Senate PBM Transparency Language:** We strongly support the provisions included by Congressmen Berry and Weiner in the House bill, and Senator Cantwell in the Senate bill, which would begin the process of creating transparency requirements for pharmacy benefit managers (PBMs) that are used by health insurance plans in the exchange.

Having this important information will empower plan sponsors to make sure that PBMs are putting the best interests of the plan sponsor and its enrollees ahead of the self-serving financial interests of the PBMs.

The House PBM transparency language would require at least an annual disclosure of the information by the PBMs, and will provide greater protections for plans and patients. In addition, the House language would require plans to disclose their generic dispensing rates in community pharmacies, as compared to mail order outlets; indicate how much of the aggregate rebates and discounts the PBMs obtain from drug manufacturers are not shared with the plan sponsors; indicate whether the PBM charges the plan more for the prescription than it pays to the pharmacy; and disclose drug switching policies to plans, particularly when a higher cost drug is used rather than lower cost drug.

We urge the application of these PBM transparency requirements to Medicare Part D plans as well, as included in the Senate language. Finally, we support the language in the House bill that would give the Commissioner of the exchange the ability to apply these provisions to other qualified health plans not being offered in the exchange to maximize the benefits of transparency.

PBMs will argue that these provisions will reveal sensitive financial information about individual drugs that will compromise their ability to negotiate with pharmaceutical manufacturers. In truth, the language does not require PBMs to pass through rebates or disclose sensitive pricing information. It simply requires disclosure of aggregate information on some of the most basic key elements of how PBMs work so that payers can help assess if they are getting a good deal. In addition, CBO has indicated that the provision will have no cost. Many public and private plans have reduced costs significantly through PBM transparency.

**Lack of Specifics on Public Option/Senate Multi-State Plan Option Concerns NCPA:** NCPA has consistently remained concerned about the impact of a “public insurance option” on patient care. For example, it is not clear how a small independent pharmacy would be able to effectively “negotiate” with the Secretary of HHS. Inadequate reimbursement could close many small pharmacies, thereby reducing access to prescription medications. Payments to pharmacies should include reimbursement for the pharmacy’s cost of product as well as a dispensing fee, based on annual cost of dispensing surveys.

To maximize cost savings, Congress should adopt a model used by the state Medicaid programs or the DOD TRICARE program, where a “pharmacy benefits administrator” (PBA) is used and all manufacturer rebates are passed through to these programs. To ensure patient choice in the public option, mandatory or coerced mail order requirements for prescription drugs should be prohibited. Without these concerns being addressed, the public option approach has and will continue to raise serious apprehensions with community pharmacies.

With respect to the possibility of multi-state or national health insurance plans being overseen by the Office of Personnel Management (OPM), any prescription drug benefit under these plans should be administered by a PBA rather than a PBM.

Recent Congressional hearings demonstrate that OPM has done a relatively ineffective job in managing the FEHBP's PBM-administered prescription drug benefits. The program receives fewer manufacturer rebates than other Federal government prescription drug benefit programs. Further, the PBMs administering the programs are not disclosing important information to OPM that would help determine whether Federal employees and retirees are getting a good deal. Any PBM transparency requirements for plans operating in the exchange should also apply to these plans. The plan should also get full pass through of manufacturer rebates.

**NCPA Supports Senate Language on Medicare DMEPOS Accreditation Exemption:** We are extremely appreciative of the provisions in both the House and Senate bills that would modify the DMEPOS pharmacy accreditation requirements. As state-licensed health professionals, these redundant and costly accreditation requirements will only serve to reduce beneficiary access to these important health care products.

The language in the House bill would exempt pharmacies from accreditation if they provided only diabetes testing supplies, canes and crutches to Medicare beneficiaries. The Senate language would exempt pharmacies if their total Medicare DMEPOS billings are 5 percent or less of their total prescription sales. The Senate language would also exempt all pharmacies from the accreditation requirements until 2011. NCPA supports the Senate language because it would give pharmacies flexibility in the types of items they could provide to Medicare beneficiaries and sets a reasonable DMEPOS accreditation threshold.

Should conferees adopt the House approach, we ask that a pharmacy accreditation exemption be granted until 2011, as the Senate bill does. We also ask that the list of items included in the House bill be expanded to include other non-complex DMEPOS items commonly provided by pharmacists, such as ostomy supplies, walkers and accessories, therapeutic shoes, bedpans, and urinals. This will give Medicare beneficiaries access to a wider range of medical products that they commonly obtain from community pharmacies. We also ask that the language give the Secretary authority to expand the list through program instruction rather than through legislative or regulatory changes.

We also support inclusion in the conference report of the pharmacy surety bond exemption included in the House bill. This provision will further reduce onerous regulatory requirements on pharmacies in order to maintain access to DMEPOS. At a minimum, the Senate's language that would permit the Secretary to set the bond amount based on a provider's DMEPOS billings should be adopted.

**NCPA Supports Expansion of Pharmacist Patient Care Services:** We are pleased that both House and Senate bills recognize the importance of an expanded patient care role for pharmacists through the delivery of medication therapy management (MTM) services and coordination of care with other health care providers. We strongly support provisions that will help assure more appropriate medication use and result in a decrease in medication-related problems, which cost the nation's health care system more than \$290 billion annually.

Specifically, we support: 1) the MTM grant program that would test new innovative ways to deliver MTM services; 2) provisions that allow for pharmacists to play a vital role as part of transitional care activities, the management of chronic disease, integrated care models, and accountable care organizations; and 3) provisions included by Senator Hagan’s amendment that would codify changes made by CMS to the Medicare Part D MTM program. We urge that all these provisions be included in the conference report.

**NCPA Opposes Medicare Part D Long Term Care Pharmaceutical Waste Proposal:** Both bills contain provisions that require Medicare Part D plans to utilize specific drug dispensing techniques, such as weekly, daily, or automated dose dispensing, to reduce waste associated with 30-day prescription fills in long term care facilities. Many of these facilities receive pharmacy services from NCPA members.

Reducing pharmaceutical waste and promoting appropriate disposal of unused medications is very important. However, these limited dispensing technologies are not in widespread use at this time, and small pharmacies may have more difficulty accessing or paying for this new technology. The possibility exists that each Part D plan could require a different dispensing technique which would prove untenable for our members, thus decreasing access to long-term care pharmacy services in many rural areas. NCPA respectfully requests that careful consideration be given to the ultimate effect of this provision on pharmacy services and safety in long term care facilities. In addition, any reduced costs from shorter dispensing cycles would be offset by the need to pay pharmacies more frequently to dispense these medications to long term care facilities.

Alternatively, we suggest that a significant amount of Part D savings could be found if the CMS and Part D plans focus instead on waste in mail order dispensing. Studies estimate that anywhere from 3 to 4 percent of all mail order prescriptions are “wasted” either because the patient does not need or cannot fully use a 90-day supply of medications.

NCPA also urges conferees to amend Section 1860D(12)(b)(4) of the Social Security Act – which is the Medicare Part D pharmacy prompt pay section – so that these requirements also apply to prescriptions dispensed by pharmacies to long term care facilities. There is no reason why community pharmacies, many of whom also serve long term care facilities, should wait any longer for payment for prescriptions dispensed to long term care patients versus ambulatory Medicare patients.

**NCPA Supports House “Any Willing Provider” Laws:** NCPA supports provisions that would maintain state-based “any willing provider laws.” Federal laws should not pre-empt these laws, which have been instrumental in protecting patients against discriminatory health insurance and PBM practices. We particularly want to make sure that state AWP laws apply to plans that operate in the exchange, including the public insurance option or the multi-state OPM administered plans.

We believe that the House language is stronger and should be adopted regarding this issue. The Senate's language is confusing since it appears to require plans to allow any provider into a network that is acting within the scope of his or her state licensure. The language then indicates that the plan is not required to accept any provider in the network willing to abide by the terms of the plan.

**NCPA Opposes Moving Medicare Vaccinations to Part B:** The House bill would move coverage for all Medicare vaccinations to Medicare Part B, including those new vaccinations that were recently covered through Medicare Part D. NCPA encourages that all Medicare vaccinations be moved to Medicare Part D, rather than Medicare Part B. Community pharmacies are among the most accessible health care providers, and pharmacies are able to immunize in all 50 states. However, not as many pharmacies participate in Part B as do Part D due, in part, to administrative challenges. For this reason, a shift in all Medicare vaccinations to Part B would lower the overall immunization rates for Medicare beneficiaries. We urge that this provision be dropped in conference or that a study be done to assess the impact of such a move on Medicare beneficiaries' access to immunizations.

**NCPA Supports Limitations on Use of "340B" Program Drugs:** Both House and Senate bills would substantially expand the number of entities eligible to obtain pharmaceutical discounts under the 340B program. These 340B entities are supposed to provide discounted prescription medications to uninsured individuals. However, many NCPA members report that eligible entities are using these 340B drugs for ineligible patients, such as a hospital's own employees and for patients that have good insurance.

We believe that the 340B program is in need of significant overhaul to assure that these drugs are only being provided to eligible patients. Limiting the eligibility for these discounted drugs to truly uninsured patients is a good start. In 2007, HRSA issued a notice that would narrow the definition of patient so that only those individuals that were truly needy were eligible for these discounted drugs. While not perfect, the proposed definition represented a good start. We believe that a definition of eligible patient should be finalized before any expansion of this program is allowed to occur. This new definition should apply to all eligible facilities. We also believe that eligibility for these discounts among facilities must be tightened.

The bottom line is that the 340B program's purpose - that is, to help the indigent and uninsured - is being undermined and threatened. Appropriate legislative safeguards should be included in the conference report to protect against the diversion of these drugs to ineligible patients or inappropriate use by the facilities that receive them.

**NCPA Concerns with Secretary Negotiations for Part D Drug Prices:** We have concerns with the House bill's provisions that provide the Secretary with the authority to negotiate lower prices directly with drug manufacturers for medications provided under Medicare Part D and the public plan. Some of the language implies that negotiation could be directed at retail pharmacies. For example, the language indicates that the "...Secretary shall negotiate with pharmaceutical manufacturers the prices...that may be charged to PDP sponsors and MA organizations for covered Part D drugs for Part D eligible individuals who are enrolled under a prescription drug plan or under an MA-PD plan."

Similarly, under the public plan option, "the Secretary shall negotiate with pharmaceutical manufacturers the payment rates...that may be charged for prescription drugs for individuals who are enrolled under the public health insurance option and shall establish a particular formulary for prescription drugs under such option." Drug manufacturers do not "charge" PDP sponsors, MA organizations, or individuals for prescription drugs. Pharmacies charge the plans for the drugs that they purchase.

Plans negotiate with manufacturers for additional rebates, which are used to affect the benefit cost and to increase the plans profitability. If the goal is to negotiate with drug manufacturers to reduce drug prices, it is critical to make sure that these negotiations are not directed at retail pharmacies. We respectfully ask for clarification in the conference report of the intent of this language to mitigate the potential adverse consequences that it could have on community pharmacies and beneficiary access to prescription drugs and pharmacy services.

**NCPA Supports House Language on Part D “Donut Hole” Discount Program:** Both the House and Senate bills start to close the Medicare Part D donut hole, in part, through contributions from pharmaceutical company discounts for brand name drugs. We prefer the structure of the House bill, which operates the program through the Part D plans, rather than a separate third-party administrator. Administration of the program directly through the plans should save administrative costs for Medicare, as well as avoid additional transaction fees for pharmacies.

We also ask that the final bill clarify that the new MIPPA “prompt pay” provisions included in 1860D-12 (b)(4) apply to payments from plans to pharmacies under this program for these claims. Moreover, we want to make sure that Part D plans cannot contend that language in the MIPPA provisions prevents them from paying timely because the claims are not clean. A clean claim is one that is free from “defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.”

Part D plans may claim that a “particular circumstance exists” because they are waiting for payment from manufacturers for these drugs, that they therefore do not have to pay pharmacies in a timely manner. We urge that final language be included that does not allow Part D plans to circumvent the pharmacy prompt pay requirements with respect to the discounted drugs provided in the donut hole.

**NCPA Concerns with Fraud, Waste, and Abuse Sections:** Both House and Senate versions of health care reform contain a number of elements designed to combat fraud, waste and abuse in the Medicare and Medicaid programs. NCPA supports such efforts. However, there are two such requirements present in both proposals that we feel are not practicable to impose on certain providers, such as independent community pharmacists.

First, the House version would require a screening process for all new providers and the Senate version would require a screening of all providers. Provider screening should only be required in those situations or providers classes with a demonstrable risk of fraud, waste, and abuse, the approach adopted by the Senate.

Studies have shown that independent pharmacists are not a significant source of fraud, waste and abuse in the Medicaid and Medicare programs. The imposition of extraneous procedures and fees on low-risk providers would only increase the administrative and financial burdens on both the providers and the federal government with no realistic expectation of a tangible return. In addition, many pharmacies have just recently completed an expensive and exhausting accreditation process and have also had to obtain surety bonds.

Second, both bills also contain a provision that would require providers to establish a compliance program to deal with fraud, waste and abuse. The House version would require all providers to establish such a program, which we believe is unnecessary. Independent pharmacists have not been a significant source of fraud, waste and abuse and are primarily small business owners. We do not have an abundance of resources to establish or maintain these programs. The Senate version would require only certain providers or suppliers (to be determined by the Secretary) to establish and maintain a compliance program to combat fraud, waste and abuse.

We are also concerned about provisions that would prohibit providers from participating in Medicaid if they voluntarily terminate from Medicare participation. Pharmacies participate in both Medicare Part B and Medicare Part D, with the overwhelming majority of services being provided by pharmacies under Medicare Part D. However, many pharmacies may not be voluntarily participating in the Medicare Part B DMEPOS program because of the new onerous accreditation requirements. Some that are not participating in the DMEPOS program, however, remain in the Part B drug program. Pharmacies should not be prohibited from participating in Medicare Part D and their state's Medicaid program if they voluntarily choose not to participate in Medicare Part B programs.

**NCPA Concerns with Health Insurance Requirements on Small Businesses:** Small businesses, including independent pharmacies, will continue to be critical to the nation's economic recovery. For that reason, NCPA remains concerned about any additional mandates, taxes or penalties that might be levied on small businesses at this crucial juncture. Health care reform should be targeted toward lowering the cost of health care and making it more affordable for small businesses to provide it to their employees. Legislation that sets overly burdensome national employer-provided coverage standards could lead to thousands of small independent pharmacies having to close their doors.

We appreciate the attempts by the House and Senate to provide tax credits to small businesses in the early years to ease the burden of transition under pending legislation. However, NCPA is concerned that these tax credits will not aid a large majority of our members. Because we employ highly-trained professionals, including pharmacists and pharmacy technicians, we tend to have higher average wages than other small businesses. However, we also employ lower-end wage earners as well. Moreover, unlike other small businesses, our average annual after tax profit is about 2 percent, while other small businesses average about 5 percent.

For these reasons, we ask that you make these tax credits available to some small businesses, which may have higher than average annual salaries, but which also may have a mix of skilled and unskilled employees and lower than average net profit margins. Such small businesses should not be denied assistance based on the high level of training their employees are required to receive in order to operate these small businesses.

---

Speaker Pelosi and Majority Leader Reid, we appreciate your hard work and that of all the Members of Congress on health care reform. We also appreciate the support you have shown for patients and community pharmacies which have more day to day interaction with patients than any other health care provider. We look forward to working with you as the conference report is developed and toward implementation of these health care reform provisions. Thank you again.

Sincerely,



Bruce T. Roberts  
Executive Vice President and CEO

cc:

The Honorable Steny Hoyer, Majority Leader, US House of Representatives  
The Honorable Jim Clyburn, Majority Whip, US House of Representatives  
The Honorable John Boehner, Minority Leader, US House of Representatives  
The Honorable Henry Waxman, Chairman, Committee on Energy and Commerce  
The Honorable Joe Barton, Ranking Member, Committee on Energy and Commerce  
The Honorable Charles Rangel, Chairman, Committee on Ways and Means  
The Honorable Dave Camp, Ranking Member, Committee on Ways and Means  
The Honorable Frank Pallone, E+C Health Subcommittee Chairman  
The Honorable Nathan Deal, E+C Health Subcommittee Ranking Member

The Honorable Richard Durbin, Majority Whip, US Senate  
The Honorable Mitch McConnell, Minority Leader, US Senate  
The Honorable Max Baucus, Chairman, Committee on Finance  
The Honorable Charles Grassley, Ranking Member, Committee on Finance  
The Honorable Chris Dodd, Chairman, Committee on Banking  
The Honorable Tom Harkin, Chairman, Committee on Health, Education, Labor and Pensions  
The Honorable Mike Enzi, Ranking Member, on Health, Education, Labor and Pensions