

Statement of:

National Association of Chain Drug Stores

On:

Comprehensive Health Reform Discussion Draft

To:

**U.S. House of Representatives
Committee on Energy & Commerce
Subcommittee on Health**

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Introduction

Chairman Pallone, Ranking Member Deal and members of the Subcommittee, the National Association of Chain Drug Stores (NACDS) is pleased to have this opportunity to testify on the House Health Reform Discussion Draft. I am Carol Kelly, Senior Vice President, Government Affairs and Public Policy.

The National Association of Chain Drug Stores represents the nation's chain pharmacies, advocating for pro-patient and pro-pharmacy public policy. Chain pharmacies operate more than 39,000 pharmacies, employ 118,000 pharmacists and a total of more than 2.6 million employees, and fill nearly 2.5 billion prescriptions yearly – about 72 percent of U.S. prescriptions.

Pharmacies are the face of neighborhood healthcare. Millions of Americans rely on their local pharmacy every day for prescription drugs and pharmacy services. In addition, pharmacies provide patients with convenient access to preventive services such as immunizations. Legislation has passed in all fifty states to allow pharmacists to administer immunizations such as flu and pneumococcal.

NACDS shares in the common goal of providing accessible, affordable and high quality healthcare coverage to as many Americans as possible. There is a community pharmacy, on average, within about two miles of every American, making pharmacies among the most accessible healthcare resources. We believe patients should have access to the most cost-effective medications to appropriately treat their particular medical conditions. In addition, patients should have the freedom to choose where to obtain their pharmacy services and prescription medications. Pharmacists play a key role in helping patients take their medications as prescribed and offer a variety of pharmacist-delivered services, such as medication therapy management (MTM), to improve quality and outcomes. When patients take their medication as prescribed, it is possible to reduce utilization of costly medical services, such as emergency department visits and unnecessary physician visits, and enhance their quality of life. Failure to take medications as prescribed – which is known as “non-adherence,” has been estimated to impose \$177 billion annually in direct and indirect healthcare costs.¹

Maintaining Access to Local Pharmacies

Fair and accurate reimbursement to providers is key to maintaining access to healthcare services. NACDS appreciates the recognition of the Subcommittee of this important link. In particular, we are grateful for the leadership of Chairman Pallone on this issue. As the primary sponsor of H.R. 3700, the Fair Medicaid Drug Payment Act, legislation from the 110th Congress to reform pharmacy reimbursement for generic drugs in the Medicaid program, Chairman Pallone understands the importance of maintaining patient access to their local pharmacy. We also appreciate the many members of this Subcommittee who co-sponsored this critical legislation, and we applaud the inclusion of several critical provisions in the House Health Reform Discussion Draft.

¹ Ernst FR and Grizzle AJ, “Drug-Related Morbidity and Mortality: Updating the Cost of Illness Model.” *J Am Pharm Assoc.* 2001;41(2):192-9.

While we are appreciative of the Subcommittee's efforts, we do believe that additional improvements are needed in House health reform legislation in order to create a fair and accurate reimbursement system for generic drugs in the Medicaid program.

The Deficit Reduction Act of 2005 (DRA) required the use of average manufacturer price (AMP) to set federal upper limits (FULs) to determine maximum pharmacy reimbursement for generic drugs in the Medicaid program. Because AMP was created to determine manufacturer rebates, and was never intended to be used as a benchmark for pharmacy reimbursement, several policy changes are needed to ensure it will result in payment to pharmacies that cover their costs to acquire and dispense medications, and make a reasonable return. Several government studies have revealed that the reimbursement policy created by the DRA would result in reimbursement to pharmacies that is on average below their costs to obtain prescription medications.²

We believe the most important component of a reformed average manufacturer price-based reimbursement system is an accurately defined AMP. The AMPs currently reported to CMS by drug manufacturers do not reflect the AMP definition, which is the average price paid by wholesalers for drugs distributed to the retail class of trade. If AMP is to be used for pharmacy reimbursement, it should not include rebates, discounts and sales that are not part of the retail class of trade. For example, pharmacy benefit manager (PBM) rebates should not be included in the AMP definition, as they are used to drive formulary placement and are not available to retail pharmacies. In addition, sales to entities that are not part of the retail class of trade, such as physicians, surgical centers, and mental health centers, should not be included in the AMP definition. These entities obtain discounts and rebates not available to retail pharmacies. We urge Congress to include an accurately defined AMP in its health reform legislation.

Furthermore, NACDS believes AMP-based federal upper limits should be determined by using the weighted average AMP rather than the lowest AMP. Use of the lowest AMP, required by DRA, fails to take into account the wide range of market prices for generic drugs. Moving to weighted average prevents reliance on the prices of small generic suppliers. Use of these AMPs would obviously result in market prices that are not widely and generally available to retail pharmacies. NACDS applauds the provision in the House Health Reform Discussion Draft to move from lowest to weighted average AMP to set federal upper limits.

The Deficit Reduction Act required FULs to be set when there are two sources of supply – the brand and one generic – for a prescription medication. Previously, FULs were created when there were three sources of supply – the brand and two generics. Setting FULs when there are only two sources of supply is premature. FULs should not be established until there is a steady and consistent supply of generic drugs available to all retail pharmacies nationwide. Drug shortages are relatively common. When the first generic enters the market, particularly in cases when it is brought to the market by a small manufacturer, there may not be a sufficient supply for all retail pharmacies. We believe setting FULs when there are three sources of supply ensures all retail pharmacies have access to a generic, while still providing CMS with the ability to establish federal upper limits appropriately. We urge final healthcare reform legislation to include a provision moving back to the original policy of waiting until there are three sources of supply.

² GAO-07-239R Medicaid Federal Upper Limits

One of the most difficult aspects of creating a fair and accurate AMP-based reimbursement system is determining an appropriate multiplier – that is, an appropriate “mark up” above the cost of a product to cover pharmacies’ costs and make a reasonable return. Determining the correct multiplier is challenging since average manufacturer price data is not publicly available, and because an AMP that accurately reflects the average price paid by wholesalers for drugs distributed to the retail class of trade is not currently being reported to CMS. Because of these uncertainties, NACDS believes that multiplier proposed in the House Health Reform Discussion Draft – 130% - may not be sufficient to ensure that pharmacies are being reimbursed fairly.

While a “mark up” of 30% may appear to be generous, it is important to keep in mind the low cost of generic medications. For example, a generic drug with a per unit AMP of 3.67¢ would yield a markup of 1.1¢. Calculating this on a per prescription basis, an AMP of \$5.75 would yield a “mark up” of \$1.72.

There are two components of pharmacy reimbursement – product reimbursement as well as a dispensing fee - to cover the costs of dispensing a medication. While the federal government determines maximum reimbursement for drug product through federal upper limits, states make determinations about an appropriate dispensing fee – although proposed increases and decreases to pharmacy reimbursement must be approved at the federal level by CMS. Currently, the average dispensing fee in the Medicaid program is a wholly insufficient \$4.40. A national study conducted by the accounting firm Grant Thornton found that the actual cost to dispense is approximately \$10.50, more than twice the average dispensing fee. When determining reimbursement for pharmacies, it is critical to consider both of these components.

NACDS understands the desire by policymakers to create a system where reimbursement for drug product closely reflects pharmacy’s cost to acquire prescription medications. However, we urge the Subcommittee to keep in mind the importance of fair and accurate reimbursement for *both* product and dispensing fee. During consideration of the Deficit Reduction Act, Congress was clear that if pharmacy reimbursement for product was reduced, dispensing fees would need to be increased. Despite clear guidance by Congress, CMS has not acted on any state plan amendments (SPAs) to increase pharmacy dispensing fees. Just yesterday, the Federal Register published a notice of a denial by CMS of a state plan amendment to implement a 4 to 6 cent increase in retail pharmacy dispensing fees in Washington State. Rejection by CMS of even the most minimal increases to pharmacy dispensing fees – which are already below the average cost to dispense – prevents comprehensive reform of pharmacy reimbursement in the Medicaid program.

NACDS appreciates the provision in the House Health Reform Discussion Draft to strike the requirement of the DRA to post brand and generic AMPs on a public website. The House rightfully recognized that this provision of DRA does not meet the goal of greater transparency in prescription drug pricing. Instead, it would only result in the posting of flawed and inaccurate data. Before any AMP data are publicly posted, it is critical that AMP is defined accurately. When AMPs are collected based on an accurate definition, NACDS supports the public posting of a weighted average AMP.

We are committed to continuing to work with this Subcommittee and all Members of Congress to create a pharmacy reimbursement system that results in fair and accurate reimbursement to pharmacies, assists in controlling prescription drug costs, and encourages generic utilization in the Medicaid program.

Value of Medication Therapy Management in Improving Health and Reducing Costs

As Congress has debated healthcare reform, we have been pleased that policymakers have realized the importance of addressing the problem of poor medication adherence. The failure of patients to adhere to medication therapy has been associated with an estimated \$47 billion each year for drug-related hospitalizations³, as many as 40 percent of admissions to nursing homes and an additional \$2,000 a year per patient in medical costs for visits to physician offices.⁴

As highly accessible medication experts, community pharmacists, working in partnership with physicians and other health providers, can greatly improve patient adherence to medication therapy. NACDS thanks the Subcommittee for highlighting the importance of medication therapy management (MTM) and the role of non-physician practitioners, such as pharmacists, in the Medical Home Pilot Program.

In addition, we think there are other opportunities to expand access to medication therapy management, thereby improving health outcomes and reducing costs. For example, although medication therapy management (MTM) programs are currently in operation in Medicare Part D, they remain limited. Part D requires MTM for certain Medicare beneficiaries using multiple and costly medications. We believe that the MTM requirements in Part D should be strengthened and expanded in order to improve health outcomes for Medicare beneficiaries and reduce costs for the program. The Medicare MTM benefit should include services such as an annual comprehensive medication review for eligible beneficiaries, and eligibility standards should be broadened to include dual eligible beneficiaries enrolling in Medicare for the first time, and beneficiaries in transition, such as those recently discharged from a hospital or other institutional setting. These beneficiaries are likely to have had new medications introduced, and would benefit from a targeted intervention by a pharmacist.

Studies have clearly demonstrated that community-based MTM provided by pharmacists to senior populations improves healthcare outcomes and reduces spending. In North Carolina, the ChecKmeds NC program, which offers eligible seniors one-on-one MTM consultations with pharmacists, saved an estimated \$10 million in healthcare costs and avoided numerous health problems in the first year of the program for the more than 15,000 seniors receiving MTM.⁵

³ Johnson JA, Bootman JL. Drug-Related Morbidity and Mortality. A Cost-of-Illness Model. Arch Intern Med. 1995 Oct 9;155(18):1949-56.

⁴ Medication Compliance-Adherence-Persistence Digest. American Pharmacists Association. 2003.

⁵ North Carolina Health and Wellness Trust Fund. NC Health and Wellness Trust Fund's ChecKmeds NC Program Serviced Over 15,000 Seniors in First Year news release. Accessed at <http://www.healthwellnc.com/hwtfc/pdf/PressChecKmedsNC10-30-08.pdf>, March 25, 2009.

Results from MTM programs and related interventions that were not limited to seniors have been equally promising. For example, five-year outcomes of the Asheville Project – a diabetes program designed for city employees in Asheville, North Carolina, and delivered by community pharmacists – revealed a decrease in total direct medical costs ranging from \$1,622 to \$3,356 per patient per year, a 50 percent decrease in the use of sick days, and an increase in productivity accounting for an estimated savings of \$18,000 annually.⁶

Similar results have been achieved in numerous demonstrations of community pharmacist-delivered interventions and services. The Minnesota Medication Therapy Management Care Program – a program designed for low-income residents who are taking four or more prescription medications to treat or prevent two or more chronic medical conditions – generated total savings of approximately \$2.11 million, with the state share estimated at \$1.05 million, in 2006-2007. Approximately 62.2 percent of the total savings were the result of overall decreases in the number of hospitalizations, clinical office visits, emergency department visits, and urgent care visits.

Ensuring Access to Durable Medical Equipment

The Centers for Medicare and Medicaid Services (CMS) is requiring suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) to obtain accreditation and a \$50,000 surety bond per location to serve Medicare beneficiaries. While NACDS supports the efforts to curb fraud and abuse in Medicare, these requirements will reduce beneficiaries' access to prescribed drugs and supplies and could cause disruptions in their healthcare.

DMEPOS includes such items as diabetic testing supplies and monitors, walkers, hospital beds, wheel chairs and oxygen tents. Many beneficiaries rely on their local pharmacies for their DMEPOS, particularly diabetes testing supplies. In fact, nearly two-thirds of older diabetic patients obtain their diabetes test strips from community pharmacies where they have readily available access to these products and counseling from their trusted pharmacists. These relationships help patients better manage their diseases and save Medicare resources.

These requirements are unnecessary for pharmacies as they are heavily regulated by state boards of pharmacy and numerous state and federal laws. In addition, each pharmacist employed by a community pharmacy must graduate from an accredited school of pharmacy and be licensed in the state where they practice. These assurances obviate the need to require accreditation and surety bonds from licensed pharmacies.

These rules also place Medicare beneficiaries' health at risk by reducing access to medications, supplies and pharmacists' counseling if pharmacies are unable to continue providing services as a result of accreditation and surety bond. The costs of obtaining accreditation and a surety bond add to the expenses pharmacies already face to participate in Medicare Part B, making it exceedingly difficult for many pharmacies to continue to serve Medicare beneficiaries. According to CMS' own estimate, over 25,000 suppliers will exit the Medicare program due to these requirements, reducing access to drugs and supplies for many Medicare patients.

⁶ Cranor, CW, Bunting BA, Christensen DB. The Asheville project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc.* 2003;43(2):173-84.

These requirements will also have a spill-over effect on Medicaid patients. Several state Medicaid programs require DMEPOS suppliers to be enrolled in Medicare in order to provide DMEPOS to Medicaid patients. If pharmacies in these states are unable to withstand the costs of accreditation and surety bond requirements, they will be forced to turn away vulnerable Medicaid patients in addition to Medicare beneficiaries.

Pharmacies need to be in compliance with accreditation by September 30, 2009, and must obtain bonds before October 2, 2009. Therefore we strongly urge Congress to immediately provide an exemption to state-licensed pharmacies from these unnecessary and disruptive requirements. NACDS has endorsed H.R. 616, sponsored by Rep. Marion Berry, which provides conditional exemptions to pharmacies and pharmacists from Medicare accreditation requirements in the same manner as the exemption applies to other professionals. We have also endorsed H.R. 1970, introduced by Rep. Zack Space, which exempts pharmacies with positive histories with the Medicare program from surety bond requirements. We urge these bills to be incorporated in health reform legislation.

Conclusion

Chairman Pallone, Ranking Member Deal, and Members of the Subcommittee, thank you for this opportunity to testify today. NACDS is grateful for the opportunity to share our views on how to reform our nation's healthcare system. We commend you for your leadership and look forward to working with you to advance healthcare legislation that protects patient access, improves health outcomes, and reduces costs.