



National Association of Chain Drug Stores (NACDS) – 12/22/08

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Note: Additional documents submitted online

**NACDS****NATIONAL ASSOCIATION OF
CHAIN DRUG STORES**

Pharmacy Provisions in President-elect Barack Obama's Plan for Healthcare Reform

The National Association of Chain Drug Stores (NACDS) thanks President-elect Barack Obama for making healthcare reform a top priority for his administration, and offers the following suggestions on pharmacy-related provisions in the President-elect's healthcare reform plan. NACDS and its member companies are ready to work with the President-elect and the new Congress to make an improved healthcare delivery system a reality for all Americans.

Availability and Use of Generic Drugs

President-elect Obama's plan for healthcare reform includes the call for increased availability and use of generic drugs in public and private healthcare programs. His proposal recognizes the need to address impediments to this goal, such as the current practice where brand drug manufacturers pay generic drug makers not to bring generic alternatives to the market.

NACDS applauds President-elect Obama's recognition of the value and importance of generic drugs in the healthcare reform debate. Generic drugs are therapeutically equivalent to brand name drugs; however, the average brand name drug costs over three times as much as its generic counterpart. We believe that brand manufacturers should have appropriate incentives to research and develop new drugs, and have sufficient time to recoup their investment and make a reasonable profit. However, these incentives must be balanced with encouraging generic manufacturers to bring competing products to the market, thereby expanding patient access to prescription medications and reducing healthcare costs. In addition, chain pharmacy has long advocated for policies that encourage providers to prescribe generic drugs whenever appropriate. Pharmacies have also worked tirelessly in the states to enhance the pharmacists' role in increasing generic drug utilization through patient and physician counseling. While our efforts have had measurable success as demonstrated by high generic drug utilization rates in the Medicare Part D program, we believe that President-elect Obama's proposal will lead to increased use of generic drugs and savings. These increased savings can be used to make needed improvements elsewhere in the healthcare system, including reducing the number of Americans without health insurance.

Pathway for Generic Biopharmaceuticals

President-elect Obama has stressed the need for the creation of an approval pathway for generic biopharmaceuticals. NACDS and its member companies have demonstrated that generic drug utilization is one of the most effective ways to control prescription drug costs. While community pharmacists work closely with patients and payers to encourage the use of traditional generic medications, they are limited in their ability to take similar actions with biopharmaceuticals since there is no clear regulatory framework for approval of generic versions of these products.

We urge the new Congress to make biogeneric pathway legislation a top priority for healthcare reform. The success of Hatch-Waxman, the groundbreaking law that created the regulatory pathway for generic versions of traditional pharmaceuticals, has clearly proven that incentives to reward innovation can be balanced with the need to ensure a competitive marketplace for prescription



drugs. We urge the President-elect and Congress to create a regulatory pathway for biogenetics that provides the FDA with the authority to make scientifically-grounded decisions to approve safe, comparable, and interchangeable biologic products. The added competition that a regulatory pathway will spur will help dramatically lower costs, helping to bring these cutting edge medicines within reach for millions of patients who need them.

Health Information Technology

President-elect Obama has called for lowering of healthcare costs through investment in electronic health information technology (HIT) systems. His proposal encourages the use of electronic systems for medical records and claims processing, and pledges necessary federal resources to make HIT fully integrated in the delivery of healthcare.

Pharmacies have long recognized the importance of HIT, including electronic prescribing, in the healthcare marketplace. Electronic prescribing has been proven to reduce medical errors and spending, and we urge the President-elect to build on the strong electronic prescribing provisions included in the Medicare Improvements for Patients and Providers Act to make electronic prescribing truly commonplace. One immediate need is to allow e-prescribing for controlled substances, which make up nearly 20 percent of new prescriptions. Antiquated regulations currently in place prevent e-prescribing of controlled substances, which poses a significant hindrance to physician adoption of e-prescribing.

In addition, pharmacists' access to critical patient information enables them to help patients make appropriate use of their medications. Accordingly, we also urge the President-elect to pave the way for interoperable HIT systems that provide pharmacists electronic access to critical patient healthcare information, including diagnosis and laboratory values that will help measure patient adherence, reduce medication errors, and enhance care coordination.

Finally, if HIT legislation is accompanied by additional measures to secure patient privacy, it will be imperative that those measures be carefully crafted to ensure that pharmacies and other health providers can continue to treat patients effectively and efficiently without undue administrative burdens or costs. While NACDS members are committed to protecting patient privacy, it would be unfortunate if additional privacy measures were so onerous as to discourage the uptake of HIT by health providers. Despite recent debate in Congress, consensus has yet to be reached among all relevant stakeholders on how best to address these complex privacy issues. Consequently, we believe it is premature for Congress to attempt to legislate in this area. Rather, if policymakers decide to pursue changes to existing privacy requirements, we believe a "negotiated rulemaking" process should be established instead of enacting legislation. With negotiated rulemaking, all relevant stakeholders have an opportunity for substantive input in the rulemaking process, which results in rules that work for both patients and providers.

Disease Management Programs

The President-elect recognizes the need to manage chronic diseases to address the rising cost of healthcare. Over 75 percent of total healthcare dollars are spent on patients with one or more chronic conditions such as diabetes, heart disease and high blood pressure. By some estimates, chronic diseases cost the healthcare system \$1.3 trillion annually. As part of his response to this growing problem, the President-elect has stressed the value of disease management programs in reducing costs related to chronic diseases.



NACDS also strongly believes that any healthcare reform proposal should include a clear plan to tackle the issues surrounding chronic diseases and urges policymakers to consider the role pharmacists can play in delivering and coordinating care. Access to appropriate medications and to the counseling of pharmacists has been shown to be critical in managing chronic diseases. Pharmacist-provided counseling and disease management programs have resulted in reduced mortality, morbidity and an appreciable reduction in healthcare spending. As the nation's most readily accessible healthcare providers, pharmacists are in a unique position to make disease management programs available to patients and help the system reap tremendous savings from pharmacists' interventions. Thus, we urge the new Congress to enact policies that ensure that pharmacists and pharmacies will be utilized and compensated for providing disease management services.

Negotiation Between Medicare and Drug Manufacturers

Given the strong desire to curb healthcare spending, some have called for a repeal of the non-interference clause in Medicare Part D to pave the way for the Department of Health and Human Services (HHS) to negotiate prices for prescription drugs in the Part D program. President-elect Obama has endorsed this proposal in an effort to address rising prescription drug costs.

We urge President-elect Obama and Congress to exercise caution as they consider the government's role in negotiation of drug pricing in the Medicare Part D program, as these proposals could inadvertently impact pharmacies. For example, proposals in the 110th Congress allowed the HHS Secretary to negotiate the prices "charged" to Medicare Part D plans for covered drugs. Since pharmacies, and not drug manufacturers, charge plans for prescription drugs through their reimbursement, this legislative approach left open to interpretation if the Secretary could dictate reimbursement terms to pharmacies, regardless of the price a pharmacy paid for a prescription medication. We urge President-elect Obama and Congress to be mindful of these issues as they examine the government's role in the negotiation of drug prices.

Re-importation of Prescription Drugs

President-elect Obama has indicated that he supports allowing consumers to purchase their medicines from other developed countries if the drugs are safe as a policy solution to address the rising cost of prescription drugs. Re-importing prescription drugs from other countries at first blush appears to be a sensible way to reduce drug spending; however, the idea of re-importation is at odds with the goal of ensuring the safety and efficacy of medicines in the marketplace.

Re-importation of prescription drugs raises numerous concerns that must be examined carefully before adopting such a drastic policy. International sources of prescription drugs may not be adequate or as consistently reliable as their US counterparts, resulting in wide variations in availability and prices of prescription drugs. American patients and pharmacies have come to depend on access to consistent, reliable, quality sources of medications, which may be threatened if re-importation is allowed. Further, introducing imported drugs with different shapes, sizes, colors, doses or trade names than those sold in the United States will confuse patients and health professionals. When a serious safety issue arises with an imported drug or the drug becomes subject to a recall, there is no current mechanism to notify consumers or healthcare providers of the dangers. Consequently, patient safety could be placed in grave danger with imported drugs. NACDS urges the President-elect to place Americans' safety as the paramount consideration in this debate and to reject proposals allowing for the re-importation of prescription medications. We



believe the most effective way to help Americans struggling to afford prescription drugs is to promote the approval and use of generic drugs and to ensure that more Americans have healthcare coverage.

**NACDS**NATIONAL ASSOCIATION OF
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Medicaid AMP: Support Fair Medicaid Payment to Retail Pharmacies
(November 2008)

- NACDS thanks members of Congress who supported H.R. 6331, which included several important provisions for pharmacies, including providing incentives for e-prescribing, delaying the competitive bidding program for durable medical equipment, and ensuring prompt payment under Medicare Part D.
- Most importantly, the legislation delayed devastating cuts to Medicaid pharmacy reimbursement for generic drugs until September, 2009. If Congress had not acted, over 11,000 pharmacies, representing more than 20% of pharmacies nationwide, could have closed and thereby seriously threaten access to prescription drugs and pharmacy services for millions of low-income patients. In addition, these cuts could have led to a loss of 300,000 jobs and \$31 billion in economic activity.
- Pharmacies across the country were fortunate last year when a federal district court issued a temporary injunction to halt these cuts, which gave Congress the time to pass the delay. However, it is absolutely critical that Congress pass a permanent legislative fix to this problem next year.
- Legislation was introduced in the 110th Congress by Senate Finance Committee Chairman Max Baucus (D-MT) and House Energy & Commerce Health Subcommittee Chairman Frank Pallone (D-NJ). The Fair Medicaid Drug Payment Act of 2007 (S. 1951/H.R. 3700) would create a fair Medicaid pharmacy reimbursement for generic drugs and ensure continued Medicaid beneficiary access to pharmacy services. S. 1951 currently has 49 bipartisan cosponsors and its House companion, H.R. 3700, has 57 bipartisan cosponsors.
- The legislation was endorsed by virtually all segments of the pharmaceutical supply chain, including chain and independent drug stores, generic drug manufacturers, drug wholesalers, and pharmacy benefit managers. The legislation was also endorsed by the U.S. Chamber of Commerce and the Food Marketing Institute. In addition, a number of patient advocacy and disease groups lent their support to the legislation.
- A private budget estimate of the bill indicates the bill will “score” at \$1.4 billion over five years. (The estimate was completed by a highly-regarded former staffer at the Office of Management and Budget (OMB) using CBO scoring methodology.) This is a small investment to ensure that Medicaid patients can continue to have access to local retail pharmacies of their choice.
- In addition, the Fair Medicaid Drug Payment Act has a built in offset – a requirement for prior authorization to prescribe anything other than a cost saving generic. This will encourage the use of cost saving and highly effective generic drugs, which will help control Medicaid spending.
- NACDS thanks the cosponsors of S.1951/H.R. 3700 for their support. As the 111th Congress convenes in January 2009, we urge Congress to make a priority of providing pharmacies with appropriate reimbursement for generic drugs in Medicaid.

For more information, contact the NACDS Department of Federal Government Affairs at (703) 549-3001.

**NACDS****NATIONAL ASSOCIATION OF
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Enhancing Medication Therapy Management in Medicare Part D

Background

The Medicare Modernization Act (MMA) requires Part D plans to establish Medication Therapy Management Programs (MTMPs). Under the MMA, these programs must be developed in cooperation with pharmacists and physicians, and care may be provided by pharmacists.

Medication therapy management (MTM) is a distinctive service or group of services that optimize therapeutic outcomes for individual patients. MTM includes a broad range of activities designed to improve patient care and outcomes, prevent medication errors, enhance communication between providers and patients, improve communication among providers, and enable patients to be more actively involved in medication self-management. In the pharmacy setting, MTM includes services such as review of the patient's prescription and over-the-counter medications, development of a personal medication record for the patient and a medication-related action plan in cooperation with his/her physician(s). As appropriate, MTMs involve further intervention, referral and follow-up care.

The inclusion of the MTM requirement in Medicare Part D demonstrates Congress' recognition of the importance and value of pharmacist professional services. Studies have clearly demonstrated that community-based MTM provided by pharmacists improves health care outcomes and reduces spending. 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. Another project involving pharmacist-provided care to patients with high cholesterol increased compliance with medication to 90 percent from a national average of 40 percent. Similar results have been achieved in several other demonstrations using community pharmacists.

Recognizing the benefits of MTM, the Medicare Part D program has the basic framework for MTM in place. However, Congress must strengthen and standardize the current requirements to ensure appropriate utilization, success and benefit to the Medicare program and its beneficiaries.

In addition, MTMPs should also evaluate provider performance through quality measures and provide incentives for improving outcomes. The Pharmacy Quality Alliance (PQA), an industry collaborative dedicated to improving quality, patient safety, and measuring performance at the pharmacy and pharmacist-levels, is an important source for quality measurement concepts.

Eligibility

Under the MMA, plans are required to make MTMPs available to targeted beneficiaries – those with multiple chronic conditions who take multiple prescription drugs, and whose drug spending is likely to reach a designated amount. In 2008, the set spending amount was \$4,000.



These vague requirements have resulted in the inconsistent availability of MTM services for Medicare beneficiaries nationwide. For example, one Part D plan might provide MTM services for a beneficiary with three chronic conditions and five prescriptions, while another Part D plan might elect to provide MTM services for beneficiaries with two chronic conditions and three prescriptions. This lack of standardization is unfair to Medicare beneficiaries and limits the potential of MTMPs to improve care and maximize savings to the Medicare program.

Availability

In addition to the lack of clear and consistent eligibility requirements, the MMA fails to provide sufficient guidance on how Medicare Part D plans should provide access to MTM services. NACDS strongly believes that MTM is most effective for patients when provided by licensed pharmacists, in a face-to-face, community-based setting. Most Medicare Part D beneficiaries obtain their prescription drugs and services from their local pharmacy. The convenience of the local pharmacy, as well as the access to a highly qualified medication expert – the pharmacist – makes retail pharmacies a logical, cost effective location for Medicare beneficiaries to access MTM services.

Reimbursement for Professional MTM Services

In most cases, Medicare Part D plans' payment to pharmacies is based on the cost of the drug and the cost to the pharmacy to dispense the drug. There is often no payment for other professional services such as MTM. The lack of a meaningful recognition of the value of these services creates a disincentive for pharmacies to provide this important care. As a result, utilization of these essential services at community pharmacies remains limited.

Chain Pharmacy's Recommendations for Improving MTM in Part D

NACDS is committed to improving the quality of MTM services and expanding their access in the Part D program. To that end, we urge Congress to make MTM a central piece of any health care reform legislation and make the following recommendations to improve MTMPs in the Medicare Part D program.

- *Congress should amend the definition of "target beneficiaries" to include those who have disease states which would benefit from medication therapy management interventions. The current requirement under the MMA that MTMPs be available to individuals suffering from multiple chronic diseases is unnecessarily restrictive. For example, despite widespread acceptance by the medical community that diabetes and hypertension are concomitant diseases, both diseases do not present themselves at the same time. There would be no reason to deny a diabetic patient access to MTM services simply because their high blood pressure is sub-clinical or their lipid profile has not crossed a certain threshold. Similarly, requiring that the patient is on multiple Part D medications to be eligible for MTM is limiting.*
- *MTMPs should be made available to any enrollee with a disease that is likely to increase federal health care spending whether or not the patient meets the annual cost threshold. Creating spending projection thresholds to determine eligibility for MTM places unnecessary limitations on access to MTM services, and creates disincentives for the use lower cost alternatives (e.g. generic drugs) as patients may take longer to reach the spending threshold while on these alternatives.*
- *Congress should specify a minimum package of MTM services that must be provided to each eligible enrollee, including a face-to-face annual medication review, by a licensed pharmacist or other health care*



provider with training in medication therapy management. Currently, plans are free to decide the scope of counseling and MTM services offered to its covered beneficiaries, resulting in an inconsistent and confusing menu of services between plans. Congress should define a minimum package of MTM services, including a face-to-face annual medication review for each enrollee.

- *Congress should mandate sufficient pharmacy access requirements to ensure wider availability of MTMs through community retail pharmacies.* Every licensed pharmacist employed at a community retail pharmacy is qualified to provide MTM services, offering beneficiaries unparalleled, convenient access to this essential Part D benefit. In order to guarantee beneficiary access to this important benefit, Congress should amend the current statutory language to require plans to meet TRICARE access standards for MTM services, just as they must meet these standards for their pharmacy network. Access standards would encourage MTM to be personalized and patient-specific, and allow pharmacists to monitor for adverse events unique to each person's medication(s) and history.

**NACDS**NATIONAL ASSOCIATION OF
CHAIN DRUG STORES**Summary and Concerns about Federal Privacy Proposals (December 2008)**

NACDS supports the passage of federal legislation to spur the development of health information technology (HIT) and has been in the forefront of the e-prescribing movement. We cannot, however, support any legislation that creates significant problems for the quality of care pharmacists provide to their patients. Our primary goal is to assure that any legislation does not interfere with pharmacies' ability to provide the communications necessary to ensure high quality patient care, while assuring adequate protections for protected health information (PHI.) The relevant provisions of the current HIPAA Privacy and Security Rules establish the appropriate standards for the protection and security of PHI. Both rules received significant public comment during the rulemaking process (over 50,000 comments), and provide patients with adequate protection.

Consent Requirement:

- ⇒ **For All Uses and Disclosures (Markey):** (1) one "informed consent" for treatment and payment; (2) second "informed consent" for all other uses and disclosures: Unlike the HIPAA privacy rules, which do not require written authorization or consent to use patient health information for treatment, payment or health care operations. A consent requirement was rejected as unworkable during the HIPAA rulemaking process.
- Would stop electronic prescribing and phoned-in prescriptions. No more phoned-in or electronic prescriptions, because pharmacists wouldn't know ahead of time if they have the patient's consent.
 - Pharmacists would need consents just to talk to customers. Pharmacists would need to obtain consents from patients before providing advice on any health care matter.
 - Only patients could pick up their own prescriptions. Only patients themselves would be able to pick up their filled prescriptions from the pharmacy, unless they provided explicit written consent ahead of time to allow other specific people to pick up their prescriptions.
 - Consent would have requirements nearly impossible to comply with: This consent requirement would be impossible to accomplish and even if were possible, would overwhelm patients with reams of paper and mostly useless information. Patients would be required to stand at the pharmacy counter sorting through this mountain of information before the pharmacist could even begin processing their prescription.
- ⇒ **For Use and Disclosure for Health Care Operations (E&C):** Providers that maintain electronic medical records would consent before using or disclosing PHI for the purposes of health care operations. The term "health care operations" includes many basic functions of health care providers that are integral to assuring appropriate payment, preventing fraud and abuse, and assuring quality of care. Since health care treatment and operations are intertwined, we might have to



obtain consent from patients even for just providing treatment. Both patients and consumers would find a consent requirement to be unnecessarily burdensome.

Accounting of Uses and Disclosures

⇒ **Accounting of Disclosures (E&C) (W&M)**: Expand accounting of disclosures requirement to non-oral information maintained electronically for treatment, payment, and health care operations.

Pharmacies make thousands of disclosures every day in order to process claims for payment and provide health care (e.g., sending a fax to a physician's office for a refill authorization). Our information systems have not been designed to comply with this type of requirement for the billions of transactions that would be required to be recorded and stored for a minimum of six years. Pharmacies would be forced to scrap all existing pharmacy systems for brand new systems that would comply with the mandate. This would be extremely costly and disruptive to the timely delivery of care.

Instead of requiring an accounting of all non-oral disclosures for the purposes of treatment, payment, or health care operations, NACDS seeks a provision that would require a covered entity to provide to a patient, upon request, a listing of examples to whom it discloses PHI for payment, treatment, and operations purposes. This would provide patients who are interested in an accounting of disclosures with the necessary information to illustrate to them with whom the pharmacy will disclose their information. Most of the disclosures made for treatment, payment, and operations are recognized as routine disclosures under the HIPAA privacy rules. As such, the same disclosures to the same entities occur repeatedly. We see little value in tracking and maintaining detailed information about all these repeated transactions.

Finally, we believe the vast majority of patients would be content with our proposal, as few patients have sought accounting of disclosures. The few patients who seek more details could talk with the pharmacist or corporate headquarters for more information.

⇒ **Accounting of Uses and Disclosures (Markey)**: Markey would expand the requirement to all uses and disclosures.

It would be nearly impossible and extremely expensive to track each and every use and disclosure, who made the communication, and to whom it was communicated. Pharmacists would spend their days documenting every conversation with a doctor, nurse, or patient and purpose of the conversation. There would be no time for patient care.

Marketing Issues (E&C) (W&M) (Senate) (Markey): Generally, would prohibit pharmacies from receiving remuneration for written communications to patients for the purposes of providing treatment, or for many activities that are considered health care operations (E&C); or would require an authorization to do so (W&M) (Markey). NACDS supports language that exempts from the definition of "marketing" all health-



related communications. These communications are treatment activities that save money and lives by urging patients to follow their doctors' prescriptions. This provision would worsen prescription noncompliance and its implications. This language would also stifle communications to patients that helps them better understand their health conditions and preventative care, and obtain optimal results from their treatments. These important communications empower patients to communicate more effectively with their health care providers and reinforce treatment regimens.

(W&M) (Markey): This essentially creates an "opt-in" requirement for these types of communications, which would essentially stop these programs, as consumers rarely "opt-in" to receive new communications, regardless of the potential benefit.

Breach Notification (E&C) (W&M) (Senate) (Markey): Note that E&C breach requirement excluded unintentional disclosures, W&M does not.

NACDS supports language that ensures individuals would have a right to be notified by a covered entity if that covered entity *wrongfully discloses PHI and such wrongful disclosure is materially expected to result in medical fraud or identity theft*. This language is contained in the bipartisan "Promotion of Health Care Information Act."

We would support language that protects patients by requiring notification for the types of breaches that could actually be harmful to patients and for which they should take remedial action. We would advocate the need for an objective standard that would provide clear guidance to health care providers about when breach notification should occur, and to patients as to why they are receiving such notification. Without such a standard, patients would be overwhelmed with meaningless notices for harmless disclosures.

Private Right of Action (Markey) and State Attorney General Enforcement Oversight (E&C) (W&M) (Markey): Would provide individuals and/or state attorneys general with the ability to bring civil actions in federal court to enforce the HIPAA rules.

This is unnecessary since the federal government (HHS) already has enforcement powers under HIPAA. States also already have enforcement powers under state privacy laws.

We fear this would lead to inconsistent and inequitable outcomes. Currently, enforcement exists under the authority of HHS. If individuals and states can bring actions in different district courts, it may lead to different interpretations. Moreover, this has the potential to result in a multiplicity of civil actions for the same incident and lead to costly and unnecessary litigation expenses. This is contrary to the legislative intent that HIPAA enforcement should be aimed at encouraging ongoing compliance and not punitive actions.

"Minimum Necessary" Requirement (Markey): HIPAA requires that health care providers only disclose the "minimum necessary" information to accomplish a particular task. Disclosures for treatment purposes are exempt from this "minimum necessary" requirement. HR 5442 would remove this exemption. This would throw health care into



chaos, with health care providers, including pharmacies, arguing with each other over what information is the “minimum necessary” to share to properly treat a patient. Not wanting to violate privacy laws, health care providers would err on the side of caution, and withhold potentially necessary information from each other. Patients would be harmed by health care providers not having complete information.

Prohibition on sale of PHI (W&M): Would prohibit the sale of PHI unless patient authorization is obtained. Would prevent the transfer of patient files from one pharmacy to another when pharmacies merge, or when one pharmacy acquires another, which occurs frequently. It would be impossible to obtain the authorization of every patient, resulting in having to destroy patient health records, which is prohibited by state pharmacy boards and DEA.

Monitoring Business Associates (W&M): A covered entity would have to monitor the activities of its business associates, and would be held responsible for the violations of business associates. We strongly believe that this is unnecessary and redundant regulation, as the legislation would bring business associates under the requirements of HIPAA. This would give both the federal and the several state governments the authority to penalize both covered entities and business associates for the same business associate violation.

“Opt-In” Requirement Would End Electronic Prescribing (Markey): A requirement for an “opt in” to the sharing of an individual’s information with a health information network or system. This would require pharmacies to block all electronic prescriptions for patients that have not opted in. This would be impossible without a unique patient identifier, as patients have similar names. Essentially, this would end electronic prescribing.

Patients Dictate Who May or May Not Access Information (Markey): The legislation would give patients the right to specify the particular person or class of persons not authorized to receive their information. This would be impossible for pharmacies to do. Health care providers work in teams, not in silos as this bill seems to imply. We cannot provide care with a maze of Chinese Walls separating health care providers.

Tiered Penalties (W&M) (Markey):

Rather than imposing new penalties, we recommend a requirement for a study to look at privacy violations. At this time, it is not known if many HIPAA violations are occurring; we should not assume that a problem exists. We believe that more resources should be given to OCR for enforcement and compliance activities, and then increase penalties if it is found that the existing penalties are not adequate.

**NACDS**NATIONAL ASSOCIATION OF
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NACDS PRINCIPLES OF HEALTHCARE REFORM

JUNE 2008

With transitions in government, the elevation of healthcare as a dominant issue, and the need to confront systemic challenges, an era of unique opportunity for healthcare reform may be at hand. NACDS is confident in pharmacy's ability to help improve the accessibility, affordability and quality of patient care. With the intent to build on the value of pharmacies as the "face of neighborhood healthcare," the Association has adopted and unveiled its Principles of Healthcare Reform.

About Pharmacy and NACDS

NACDS represents traditional drug stores, supermarkets and mass merchandisers with pharmacies. Its approximately 200 chain member companies include regional chains with a minimum of four stores to national companies. NACDS members also include approximately 1,000 suppliers of pharmacy and front-end products, and approximately 100 international members representing more than 30 countries.

Chains operate nearly 40,000 pharmacies, and employ more than 2.7 million employees, including 120,000 pharmacist positions. They fill more than 72% of prescriptions in the United States annually.

Retail stores with pharmacies post \$758 billion in annual sales, but their economic impact goes far beyond that. In fact, based on an analysis by NACDS, retail stores with pharmacies have a total annual economic impact of \$2.2 trillion. That is the equivalent of 16% of the gross domestic product.

Every one dollar spent in these stores creates a ripple effect of \$2.93 throughout other segments of the economy. That includes agriculture; manufacturing; construction; transportation and warehousing; finance and insurance; information technology; real estate; educational services; professional, scientific and technical services; and many more.

However, public policy can jeopardize the ability of pharmacies to perform their vital role in healthcare delivery, as well as their ability to help drive the economy. For example, pending Medicaid pharmacy reimbursement cuts for generic drugs would involve pharmacies selling medications below cost, which no business should be expected to do. These cuts could force the closure of more than 11,000 pharmacies. Patients rely on their neighborhood pharmacy and pharmacist as an easily accessible and trusted point of care, and the closure of these pharmacies would compromise the fulfillment of their healthcare needs. In addition, these more than 11,000 pharmacies generate more than 300,000 jobs and \$31.1 billion throughout the nation's economy.

Pharmacies. The face of neighborhood healthcare.



Pharmacy and Healthcare Delivery

The case for pharmacy's role in healthcare policy is logical, and consideration of the state of chronic care provides a vivid illustration:

- In addition to its dramatic human costs, chronic disease is responsible for the vast majority of healthcare spending.
- Pharmacist-provided care can improve outcomes for patients with chronic disease, and reduce costs.
- Therefore, public policy strategies should incorporate the value of pharmacy, and certainly should not jeopardize the viability or accessibility of pharmacies.

Chronic Disease and Healthcare Costs

The Partnership to Fight Chronic Disease in May 2008 released a report that included these findings about chronic diseases: they affect more than 130 million Americans annually, they are responsible for 7 in 10 deaths, and they account for more than 75 cents of every healthcare dollar.

In October 2007, the Milken Institute released a report that indicated the seven most common chronic diseases in the nation inflict a \$1.3 trillion annual drag on the economy. The report estimated the economic drag could reach nearly \$6 trillion by the middle of the century.

An August 2007 report by the National Council on Patient Information and Education cited economic analysis that failure to take medications as prescribed costs an estimated \$177 billion annually in direct and indirect healthcare costs.

The Medication Expertise of Pharmacy and Improved Patient Outcomes

The *Medicare Prescription Drug, Improvement and Modernization Act of 2003* defines medication therapy management (MTM) as “drug therapy management programs provided to ensure that drugs are used appropriately in order to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.”

In March 2008, the National Association of Chain Drug Stores (NACDS) and the American Pharmacists Association (APhA) released *Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model Version 2.0*. This resource says, “MTM services are built upon the philosophy and process of pharmaceutical care that was first implemented in pharmacy practice in the early 1990s. As pharmacy education, training, and practice continue to evolve to a primarily clinical ‘patient-centered’ focus, pharmacists are gaining recognition from other healthcare professionals and the public as ‘medication therapy experts.’ Recognizing the pharmacist’s role as the medication therapy expert, the pharmacy profession has developed a consensus definition for medication therapy management and is increasingly using this term to describe the services provided by pharmacists to patients.”



The five core elements of MTM services in pharmacy practice include:

- conducting a medication therapy review (MTR), a consultation between a patient and a pharmacist,
- development of a personal medication record (PMR), a comprehensive record of a patient's medications,
- development of a medication-related action plan (MAP), which a patient can use to track progress,
- intervention and/or referral to work with a physician or other healthcare professional to resolve medication-related problems, and
- documentation and follow-up.

Studies have shown that utilization of pharmacists' medication expertise delivers positive results for patient outcomes and healthcare costs. One of the most commonly cited programs is the Asheville Project. This initial experiment in North Carolina is being replicated nationwide. A five-year study involving diabetes patients and 12 community pharmacies found decreases in average direct medical costs of \$1,200 to \$1,872 per patient per year. Employers also cited the benefits of better health and fewer sick days for employees.

"...utilization of pharmacists' medication expertise delivers positive results for patient outcomes and healthcare costs."

Another Asheville Project study involving 620 patients and 12 community and hospital pharmacy clinics over six years focused on hypertension and high cholesterol. The study found a reduction in cardiovascular events by nearly 50%, and a reduction in average cost per cardiovascular event from \$14,343 to \$9,931. While cardiovascular medication use increased almost 300%, savings for other medical costs exceeded the medication and program costs by nearly 13%.

A study of MTM programs with 186 patients through Blue Cross/Blue Shield of Minnesota found reductions in healthcare costs per person of 31.5%, from \$11,965 to \$8,197. Interestingly, prescription claims increased 19.7%. The total cost of the MTM services was an estimated \$49,490, but total healthcare expenditures for all patients were reduced by 31.5%, from \$2,225,540 to \$1,524,703. The return on investment was \$12.15 per \$1.00 of MTM services provided.

Yet another study evaluated the effects of pharmacist care on heart failure, a leading cause of hospitalizations. One review of 2,000 patients from 1998 to 2007 found a 29% reduction in all-cause hospitalization and a 31% reduction in heart-failure hospitalizations.



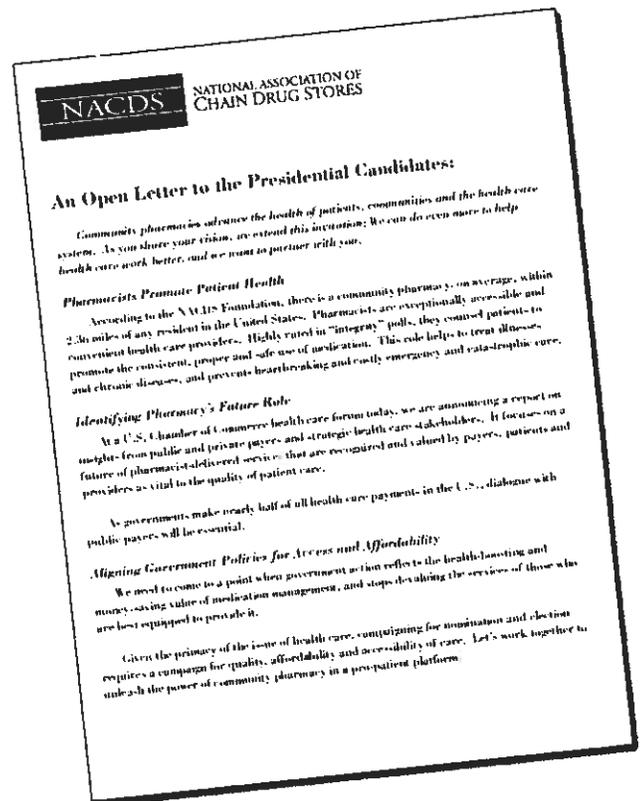
NACDS: Advancing the Role of Pharmacy in Healthcare

Backed by substantiated demonstrations of the value of pharmacy, NACDS is vigorously communicating the role of pharmacy in the healthcare system, as well as the Association's commitment to engaging in the healthcare reform debate. In November 2007, NACDS demonstrated this commitment by publishing in *The Washington Post* an open letter to the Presidential candidates, encouraging them to incorporate the value of pharmacy into their healthcare positions. In 2008, NACDS launched a Washington, D.C. initiative to communicate to policymakers and opinion leaders the role of pharmacies as "the face of neighborhood healthcare."

NACDS Principles of Healthcare Reform

To build on pharmacy's success in improving healthcare, NACDS supports the following principles of healthcare reform:

- Providing high quality, affordable and accessible healthcare coverage to as many Americans as possible should be the goal of any healthcare reform proposal.
- The reformed healthcare infrastructure should consist of a combination of private insurance plans augmented by existing public insurance programs, rather than a single-payer model.
- The value of prescription drugs and retail pharmacy professional services should be recognized in health care reform, and patients should be able to choose where to obtain their prescription medications and pharmacy services.
- Financing mechanisms for reform initiatives should be broad-based, fair, and proportionate. They should be crafted to avoid negative consequences, such as creating excessive burdens on employers that might lead to the elimination of jobs, raise the prices of consumer goods, and negatively affect the overall economy. The flexible and nationally uniform framework for employer provision of healthcare benefits through the Employee Retirement Income Security Act (ERISA) should be maintained.
- Patients should have access to the most appropriate cost-effective medication to treat their particular medical condition. Lower cost, equally effective generic medications should be encouraged when appropriate.



NACDS launched its outreach on the healthcare reform issue with an ad in The Washington Post.



- Preventive services, such as medication therapy management, should be encouraged. The medication and healthcare expertise of the pharmacist should be reflected in any efforts to facilitate collaboration in patient care.
- Methods of evaluating the costs of legislation and regulations should take into consideration the role of pharmacy professional services in preventing poor health and acute healthcare events that result in more costly forms of care.
- Cost-sharing, such as patient co-payments, should be set at affordable levels that encourage the use of the most cost effective medications. However, cost sharing should not prevent patients from seeking appropriate medical care, or create barriers to accessing providers.
- Reimbursement to healthcare providers should be equitable to prevent access limitations that result when providers are forced to reduce or eliminate services. In the case of pharmacies, reimbursement should include those costs related to dispensing medication and pharmacist-provided care, as well as medication costs, both of which should be determined fairly.
- Non-pharmacy health care and educational services such as in-store clinics and healthy living presentations should be explored, in collaboration with other healthcare providers including the physician community.
- A robust and standardized health information technology system, including e-prescribing and electronic medical records, should be the backbone of healthcare reform. Speeding the adoption of this technology will increase the likelihood that patients will take their medications as prescribed, helping to prevent medication errors, and enhancing medical decision-making and collaboration.

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Representing its members – which serve as the face of neighborhood healthcare – NACDS looks forward to working with all policymakers and stakeholders as an active partner in healthcare reform efforts.

For statistical and study references, or for more information, please feel free to contact NACDS at healthcarereform@nacds.org.

www.NACDS.org

**NACDS**NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

The 2008 election provides Congress with a rare opportunity to pass legislation to dramatically reform our nation's health care system. American citizens spoke loudly and clearly on November 4th, expressing a clear desire for change, and calling upon elected officials to work collectively to address the challenges facing our nation.

The flaws of the current health care system are clear:

- 45 million Americans have no health insurance.
- 25 million additional Americans have health coverage but are considered underinsured because their policies offer minimal coverage.
- Total spending on health care represented around 16% of the Gross Domestic Product (GDP) in 2007, and the Congressional Budget Office (CBO) estimates spending will rise to a quarter of GDP by 2025.
- Health information technology (HIT) has not been widely adopted.

While the opportunity for health care reform is here, current fiscal restraints require investment in initiatives that improve health care outcomes while at the same time controlling costs. Furthermore, accessibility and convenience of providers is critical to the success of any reform effort. With this mindset, a logical course of action is to expand the role of pharmacists in providing health care.

Pharmacists play a key role in helping patients take their medications as prescribed. When patients adhere to their medication therapy, it is possible to reduce higher-cost medical attention, such as emergency department visits and catastrophic care, and the preventable human costs that impact patients and those who care for them. Specifically, pharmacists are uniquely qualified as medication experts to work with patients to manage their medications and chronic conditions. Pharmacists also provide prevention and wellness services, such as immunizations, and promote lower cost alternatives, such as generic drugs, when in the best interest of the patient.

The benefits of increased adoption of HIT are numerous, and include safer, more timely, and more cost-effective delivery of care. Pharmacy was a leader in HIT even before the term was widely known and used. Electronic prescribing is recognized as a necessary building block for HIT adoption, and more than 95% of the nation's retail community pharmacies have the capability today to receive electronic prescriptions. Further adoption of HIT is critical to allowing pharmacies and pharmacists to increase their involvement in the clinical care of patients. Incentives for HIT adoption serve the dual goals of decreasing overall health care costs and improving patient care.

Evidence of the value of the pharmacist in the delivery of healthcare includes:

The Patient Self-Management Program (PSMP) for Diabetes, implemented in 2003, offers employees of five nationally known companies scheduled consultation with pharmacists to receive counseling on management of their diabetes. The PSMP program resulted in a mean total



healthcare cost reduction of \$918 (10.8%) per patient per year from the employers' projected expenditures.¹

Pharmacist-Delivered Immunizations Impact Public Health

Pharmacists provide patients with convenient access to immunizations and forty-nine states now allow pharmacists to administer vaccinations. Each year, more than 50,000 adults and 300 children in the United States die from vaccine-preventable diseases or their complications.² Meanwhile, immunizations, including those administered by pharmacists, help prevent 14 million cases of disease and 33,000 deaths every year.³

America's Medication Use Experts Are Guardians of Patient Safety

Failure to take medications as prescribed costs over \$177 billion dollars annually.⁴ As medication use experts, pharmacists help patients every day by counseling on proper use of medications, checking for possible side effects, drug interactions or allergies, and helping to coordinate insurance benefits. Pharmacists providing pharmaceutical care to patients with high cholesterol in their community improved patient compliance with medication from a national average of 40% to 90%.⁵

As Congress and the Administration look to reform our nation's health care system, improve access to vital health care services, control costs, and improve outcomes, NACDS urges policymakers to expand the role of the pharmacist. Trusted by patients, trained as medication experts, and accessible in virtually every community, pharmacists are a critical resource to our health care system.

¹Garrett DG, Bluml BM. Patient self-management program for diabetes: first-year clinical, humanistic, and economic outcomes. *J Am Pharm Assoc.* 2005 Mar-Apr;45(2):130-137.

²Institute of Medicine Report. Shaping the Future for Health – Calling the Shots – Immunization Finance Policies and Practice. Accessed at: http://books.nap.edu/html/calling_the_shots/reportbrief.pdf, October 26, 2008.

³Department of Health and Human Services, Fiscal Year 2008. Centers for Disease Control and Prevention. Justification of Estimates for Appropriation Committees. Accessed at: http://www.317coalition.org/documents/cdc_fy2008budget_immunization.pdf, October 26, 2008.

⁴Ernst FR, Grizzle AJ. Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model. *J Am Pharm Assoc.* 2001 Mar-Apr;41(2):192-199.

⁵Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in Project ImPACT: Hyperlipidemia. *J Am Pharm Assoc.* 2000 Mar-Apr;40(2):157-165.