



American Pharmacists Association[®]

Improving medication use. Advancing patient care.

APhA

January 4, 2010

The Honorable Harry Reid
Senate Majority Leader
United States Senate
Washington, DC 20510

The Honorable Steny Hoyer
House Majority Leader
United States House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Senate Minority Leader
United States Senate
Washington, DC 20510

The Honorable John Boehner
House Minority Leader
United States House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Speaker of the House of Representatives
United States House of Representatives
Washington, DC 20515

RE: Pharmacist's Perspective on Health Care Reform (House H.R. 3962/Senate H.R. 3590)

Dear Senate Majority Leader Reid, Senate Minority Leaders McConnell, Speaker Pelosi, House Majority Leader Hoyer, and House Minority Leader Boehner:

As you consider merging the House and Senate health care reform proposals, the American Pharmacists Association (APhA) appreciates the opportunity to provide you the perspective of our nation's pharmacists. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first established and largest association of pharmacists in the United States. APhA members provide care in all practice settings, including community pharmacies, health systems, long-term care facilities, managed care organizations, hospice settings, and the uniformed services.

Medications are the first line of defense and have been proven to be our most important weapon in the fight against disease, including chronic diseases. However, under the current system, the United States incurs more than \$177 billion annually in mostly

avoidable health care costs to treat adverse events from inappropriate medication use. [i] The proper use of medication becomes even more important as treatment of chronic disease costs the health care system \$1.3 trillion annually, or about 75 cents of every health care dollar.[ii] A 2006 Institute of Medicine report requested by the Senate Finance Committee estimated "that there are at least 1.5 million preventable ADEs [adverse drug events] that occur in the United States each year. The true number may be much higher." [iii] Clearly, more must be done to address this crisis. To that end, appropriate medication use is APhA's top priority for health care reform.

While each bill you will be merging includes many proposals that would affect the practice of pharmacy, the following comments focus on the areas of primary concern to us.

Again, thank you for the opportunity to participate in this important dialogue. We strongly support efforts to improve medication use through broader patient access to pharmacist services and applaud you and your staff for your efforts. We would welcome the opportunity to discuss our comments and recommendations. For additional information, please contact Kristina Lunner, APhA Vice President of Government Affairs, at klunner@aphanet.org, 202.429.7507 (w), or 202.497.5953 (c).

Best regards,



Thomas E. Menighan, BSP Pharm, MBA, FAPhA
Executive Vice President & CEO

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cc: Members of the United States House of Representatives and the United States Senate

[i] Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. J Am Pharm Assoc. 2001;41:192-9.

[ii] "An Unhealthy America: The Economic Burden of Chronic Disease," Milken Institute, Oct. 2, 2007.

[iii] Preventing Medication Errors: July 2006, Institute of Medicine.

The American Pharmacists Association's Health Care Reform Conference Committee Recommendations

Access to Pharmacy Products and Services

House Section 531/Senate Section 9003

APhA opposes limiting medication reimbursements from Archer medical savings accounts, health flexible spending accounts and other similar accounts to expenses incurred for prescribed drugs or insulin. **Such limitations could negatively impact a patient's ability to access necessary medications. We recommend** deleting this restriction.

Senate Section 1201 (new Section 2706)

APhA opposes removing the provider and patient choice protections (often referred to as "any willing provider" laws) that many states have enacted. To protect these current rights, we strongly **recommend** deleting the language that states that a group health plan or health insurance issuer is not required to contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer. The language we recommend removing protects insurance companies but does nothing to lower costs or improve care. In fact, disrupting and limiting patients' choice of their pharmacists is a detriment to good care.

House Section 1712/Senate Section 4107

APhA supports coverage of and removing cost-sharing for tobacco cessation counseling and pharmacotherapy (prescription and over-the-counter FDA-approved products) for pregnant women in the Medicaid program. However, we are concerned that the proposal would limit pharmacists' ability to provide these services because while pharmacists are well trained providers of these services, they are not defined as "providers" in many Medicaid programs. Excluding pharmacist-provided tobacco cessation counseling services would be short sighted. Patients are likely to obtain their tobacco cessation products at a pharmacy; and pharmacists, as one of the most accessible health care providers, are readily available and legally authorized to counsel these patients. Examples exist today in the public and private sector where pharmacists have successfully conducted smoking-cessation management programs. **We recommend** adding assurances that pharmacists would be authorized to provide these services in Medicaid programs.

Compounding

House Section 1451/Senate Sections 6002, 6004

Compounding is a cornerstone of pharmacy practice and an important component of contemporary practice that has been recognized by all legislative and regulatory agencies as separate and distinct from manufacturing. Therefore, APhA is deeply concerned about detrimental language that would inadvertently include the practice of pharmacy compounding under the definition of manufacturer.

We **recommend** reconciling the three varying definitions of manufacturing that are contained in the House and Senate bills to ensure consistency in federal law and to mitigate any possible confusion with regard to the definition of a manufacturer. Specifically, we **recommend** including language that reads as follows (as excerpted from H.R. 3590, as amended by the Senate) with one change to the language (as indicated by the strikethrough on the word "retail"):

Such term does not include a wholesale distributor of drugs or a ~~retail~~ pharmacy licensed under State law.

This language will clarify the intent of the legislation and ensure that the final bill is consistent with current law while not redefining manufacturer in current law.

Diabetes

House Section 1313

APhA supports establishing Medicare payment for certified diabetes educators for outpatient self-management training services and **recommends** their inclusion in the final bill. These services are essential tools for patients trying to manage their diabetes.

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

House Section 1147/Senate Section 3109

APhA supports exempting certain pharmacies from the current Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation and surety bond requirements. These requirements place undue burdens on pharmacies that may only sell limited products and do not reflect that pharmacies and pharmacists are already highly regulated by state boards of pharmacy and the Drug Enforcement Administration. Unlike other sellers of these products who may not be licensed, pharmacies and pharmacists are licensed by their state. This licensure should be sufficient for pharmacies and pharmacists to provide DMEPOS. The proposed exemption will better ensure continued patient access to DMEPOS. We **recommend** including these exemptions in the final bill.

Hospital Readmissions

House Section 1151/Senate Sections 3025, 3026

If medications are involved, pharmacists should be part of the care. APhA supports efforts to reduce preventable hospital readmissions. Because readmissions are often caused by medication misuse, we strongly support ensuring that transition-of-care activities address an individual's medication therapy. However, we are concerned that the provision does not explicitly reference pharmacists. Excluding pharmacists from providing medication reviews and MTM excludes the health care provider trained exclusively in medication use. To ensure that pharmacists may engage in these activities, we **recommend**:

- Explicitly listing pharmacists when referring to medication-related activities ("pharmacist-provided MTM services").

- Including pharmacist-provided medication reconciliation activities in discharge planning.
- Clarifying that nothing precludes a hospital from utilizing services not otherwise covered by Medicare Part B, such as pharmacist clinical services.
- Clarifying that pharmacists may provide these services and have their services compensated through Medicare Part B.

Integrated Care Models

House Sections 1301, 1302, 1312, 1722, 1730A, 1907, 2534/Senate Sections 2703, 2704, 2706, 3021, 3022, 3023, 3024, 3502

APhA supports efforts to facilitate the establishment of health teams [such as medical home, community care team, accountable care organization (ACO), etc.] to better address and coordinate the care of individuals, particularly those with chronic illness. However, we recommend several amendments to recognize that their medication expertise uniquely positions pharmacists to undertake MTM activities, to better ensure that patient medication use is addressed, and to better ensure that pharmacists may engage in these efforts as part of a patient's health care team. Absent Medicare Part B payment for pharmacist services, we question whether pharmacists will have the opportunity to engage on all care teams. Specifically, we **recommend**:

- Section 2703: adding "pharmacist-provided medication therapy management services" to the list of home health services; adding pharmacists to the list of health care professionals.
- Section 2704: including "pharmacist-provided medication therapy management services" in the list of services to include in the bundled payments for integrated care.
- Section 2706: including pharmacists in the list of pediatric medical providers in the pediatric accountable care organization demonstration project.
- Section 3021: amending the clause "utilize medication therapy management services" by adding "provided by pharmacists or other qualified providers with expertise in medication use" to ensure that providers of MTM services are qualified; requiring at least one of the programs that utilize MTM services to measure the impact of pharmacist-provided MTM services; testing more than one model that utilizes MTM services, at least one of which must be provided by pharmacists; requiring community-based health teams to support small-practice medical homes by assisting primary care practitioners in providing chronic care management activities including pharmacist-provided MTM services.
- Section 3022: adding pharmacists to the list of professionals who may participate in an ACO; clarifying that pharmacists, who lack Medicare Part B recognition as providers, are not precluded from participating in an ACO; ensuring that pharmacists providing patient care services in an ACO may share in any incentive payments; ensuring that Medicare Part B payment is available for pharmacist-provided MTM services provided through these programs.
- Section 3023: adding pharmacist-provided medication therapy management services to the list of "applicable services."

- Section 3024: adding, "improved medication use" to the list of what the proposed model must test.

Long-Term Care Pharmacy

House Section 1183

We support the proposal to repeal the current law (scheduled to being 1/1/10) requiring pharmacies located in or contracting with long-term care facilities to submit claims to a Part D sponsor within 90 days. We **recommend** the inclusion of this change in the final bill.

House Section 1187/Senate Section 3310

APhA supports efforts to reduce medication waste in any setting. However, in an effort to ensure that the mandated utilization management techniques meet the goals of reduced waste without negatively impacting patients, pharmacists, or pharmacies, we recommend assurances that:

- Pharmacies that serve long-term care facilities will have a single approach to address utilization management (rather than a different one for every Part D plan) to which they must comply.
- Pharmacies, like other health care providers under the stimulus package, will have access to grant funding to assist them with the likely increased costs associated with acquiring new technology and more frequent deliveries of routine medications.
- Dispensing fees will be paid for each prescription dispensed, regardless of the number of dosage units dispensed.
- The Secretary will take into consideration the significant regulatory barriers to remote dispensing in some states.
- Enough time will be provided for pharmacies to implement these changes. For example, piloting any recommendations before they are fully implemented.

Medicaid Payment

House Section 1741/Senate Section 2503

We support efforts to "fix" the average manufacturer price (AMP) formula used to calculate pharmacy reimbursement for generic medications in the Medicaid program. Recognizing that both proposals take important steps in the right direction but are imperfect, we **recommend**:

- The 175% Senate multiplier, though it is too soon to know whether it is sufficient.
- Removing the Senate requirement to publicly post the AMP and retail survey price (RSP) amounts. These postings provide no real value to either payers or consumers and have the potential to distort the marketplace and reduce incentives for manufacturers to discount drug prices.

Medicare Part D

Coverage Gap

House Sections 1181, 1182/Senate Sections 3301, 3315

We support efforts to reduce Medicare Part D beneficiary out-of-pocket expenses related to their prescription drug coverage by reducing and/or eliminating the coverage gap ("doughnut hole"). However, we remain concerned with the potential financial and administrative burdens that may be applied to pharmacies and pharmacists to effect these changes and **recommend** language directing the Secretary to take this potential impact into consideration when implementing this provision.

Medication Therapy Management Services

House Section 2528/Senate Sections 3021, 3201, 3503, 10328

APhA supports providing financial incentives for Medicare Advantage plans to conduct MTM programs that are more extensive than what is required under Medicare Part D. APhA also supports improvements to the Medicare Part D MTM programs as proposed in the Manager's amendment.

Finally, APhA strongly supports establishing a grant program to implement medication management services provided by licensed pharmacists, as a part of a collaborative, multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The covered services and description of targeted beneficiaries will provide an opportunity to test the models that have proven to be successful in both the public and private sectors. However, we are concerned with the lack of funding for this proposal and the reference to Federal programs because the practice of pharmacy, like other health professions, is regulated primarily at the state level. Therefore, we **recommend**:

- Authorizing appropriations necessary to implement the program.
- Amending the following clause as follows "such other patient care services as are allowed under pharmacist scopes of practice **in state law or regulation, or** in use in other Federal programs that have implemented MTM services."

Pain Care

House Sections 2561, 2562, 2563/Senate Section 4305

We support efforts to increase the recognition of pain as a significant public health problem in the United States, evaluate the adequacy of pain care, identify barriers to pain care, and to improve basic and clinical research on the causes of and potential treatments for pain. We **recommend** the inclusion of these provisions in the final bill.

Quality

House Sections 1441, 1442, 1443, 2401/Senate Sections 2717, 1311, 3011, 3012, 3013, 3014, 3015, 3501, 3508

We support efforts to improve health outcomes. In particular, we support efforts to include medication compliance activities. As outlined above, medication misuse is costly yet often avoidable when patients are more aware of their medication use. We also support efforts to include schools of pharmacy in efforts to develop and implement academic curricula that integrate quality improvement and patient safety in the clinical

education of health professionals. We **recommend** the inclusion of these proposals in the final bill.

Transparency

House Section 233/Senate Section 6005

APhA supports the establishment of pharmacy benefit manager (PBM) transparency requirements. Though there is no guarantee that greater transparency will lead to fair treatment of community pharmacies or a level playing field, we believe that greater transparency is a step in the right direction. To ensure that pharmacy's interests are considered, we **recommend** that the proposed annual report assess the overall impact of PBMs on:

- Community pharmacies;
- Patient choice of pharmacy; and
- Patient choice of medication therapy management service provider.

Vaccines

House Sections 1310, 1725, 2524/Senate Sections 2713, 4204

APhA supports efforts to expand access to vaccines. However, efforts to include stakeholders in any of these efforts must include pharmacists. Pharmacists' current efforts to provide adult immunizations have proven to be extremely successful. By the end of 2009, over 88,000 pharmacists were qualified and legally authorized to administer vaccines. Pharmacists in every state will have administered a total of well over 5 million vaccinations in 2009. In addition, pharmacists provide a variety of screening and prevention programs in the community. APhA **recommends** that Congress build upon these successes to expand awareness of, and utilization and access to preventive services offered by Medicare.

Workforce

House Section 2211, 2252/Senate Sections 5101, 5305, 5315, 5403

We support efforts to address our nation's health workforce shortages and the development and operation of interdisciplinary training programs for health professions. In particular, we strongly encourage the inclusion of the House proposal (Section 2211) to establish a loan repayment program, similar to the National Health Service Corps Loan Repayment program, for frontline health care providers (including pharmacists). We also strongly support inclusion of pharmacists and schools of pharmacy in any workforce strategies. However, we are concerned with two proposals:

- Senate Section 5101: the definition of health professionals, which includes "clinical pharmacists" is too narrow, poorly defined and does not reflect the goal of expanding access to pharmacist services. Therefore, we **recommend** removing the reference to "clinical."
- Senate Section 5315: we are concerned with the number of slots allotted for pharmacists in the proposed United States Public Health Sciences Track. The proposal lists the minimum number of students the Track must graduate annually. While most student minimums are set at 100 (the medical student minimum is

150; the nursing student minimum is 250), the pharmacy student minimum is set at 50 students annually. To place such a low priority on pharmacists does not reflect the role of pharmacists in communities and often as the first point of entry to the medical system for patients - thereby often the first to notice public health issues. We **recommend** increasing the number to 100.