Massachusetts House of Representatives
Bill Summary

Bill No: S 420

Title: An Act to Establish Collaborative Drug Therapy Management

Sponsor: Sen. Moore

Committee: Health Care Financing

Hearing Date: June 13, 2007

Similar Matters: None

Prior History: S 408 (2005-06) was reported favorably by the Joint Committee on Health Care Financing. It was redrafted as S 2691, and passed the Senate. House Ways & Means took no action.

Current Law: MGL ch. 112, §24 governs the registration of pharmacists.

Summary:

This legislation would authorize pharmacists to voluntarily engage in the initiation, monitoring, modifying and discontinuing of drug therapy under the supervision and direction of a physician. It requires a written collaborative practice protocol to be developed with a supervising physician or group of physicians. It calls on the Board of Registration in Medicine and the Board of Registration in Pharmacy to develop regulations to implement the provisions of this act.

The act adds pharmacists to the list of licensed practitioners who may dispense controlled substances for the purposes of treating disease or alleviating pain and suffering.

PDJ

Testimony of Massachusetts College of Pharmacy and Health Sciences
Before the Joint Committee on Health Care Financing
Boston, Massachusetts
June 13, 2007

RE: SB420 "An Act to Establish Collaborative Drug Therapy Management to Improve Pharmaceutical Care for Patients in Massachusetts"

Good morning. On behalf of the Massachusetts College of Pharmacy & Health Sciences (MCPHS). I thank you for the opportunity today to address you on behalf of MCPHS regarding Senate Bill 420 - An Act to Establish Collaborative Drug Therapy Management to Improve Pharmaceutical Care for Patients in Massachusetts.

The Massachusetts College of Pharmacy with campuses in Boston and Worcester is the largest college of pharmacy in the United States. Founded in 1823, the college has a 180 year tradition of educating health professionals. The School of Pharmacy offers a six-year program leading to a Doctor of Pharmacy (PharmD) degree as well as an accelerated three-year program out of our Worcester campus for students who already possess a bachelor' degree. Students follow a curriculum that combines general, specialized, and applied science courses with those in the liberal arts, preparing them for an increasingly visible role on the healthcare team. In addition, required experiential courses provide opportunities to learn while practicing in areas such as ambulatory, community, and institutional pharmacy, industry, long-term care, and regulatory agencies.

Senate Bill 420 provides an important opportunity for qualified pharmacists to more fully incorporate those skills which are being taught in today's pharmacy curriculum in order to more effectively serve the pharmaceutical needs of the patient. Most recently, the federal government recognized the value of pharmacists as an integral part of the health care team by allowing medication therapy management by pharmacists as part of the Medicare Modernization Act of 2003. We believe passage of CDTM in Massachusetts is consistent with this new initiative embraced by Congress.

At MCPHS, as in all pharmacy colleges around the country, we are preparing professionals who are uniquely qualified to provide enhanced pharmaceutical care, especially to many patients with chronic diseases who require continued monitoring and drug regimen review.

The proposed legislation is designed to create an expanded role for pharmacists in today's health care team. Collaborative Drug Therapy Management (CDTM) is a process whereby the pharmacist may engage in several activities that enhance the safety and cost effectiveness of medication therapy as well as greatly enhancing the quality of life for many patients. Under a voluntary agreement with a physician, pharmacists would be allowed to more effectively monitor and control the pharmaceutical care provided to many patients in Massachusetts. The net effect of this effort would be a reduction in unnecessary telephone calls, delays in treatments and frustration on the part of health care providers and patients.

Specifically we believe that CDTM will have the following direct benefits to Massachusetts residents:

- Improve Disease and Drug Therapy Management
- Reduce medication errors and enhance drug therapy monitoring
- Reduce preventable hospitalizations from Adverse Drug Events
- Reduce preventable nursing home admissions
- Reduce the cost of drug treatment
- Reduce the cost of unnecessary and dangerous drug therapies
- Improve quality of life and extent the ability of seniors to live in the community

As MCPHS is uniquely qualified to highlight the academic requirements of pharmacy students today, and you will hear more from several of our faculty members about the preparation and training of our students to participate in CDTM. Attached please find a listing of specific areas of training that are provided to our students to prepare them for graduation.

The Massachusetts College of Pharmacy and Health Sciences have been working with a coalition of supporters of this legislation, including members of the pharmacy and regulatory community to ensure passage of this vital piece of legislation. Over the past two years this coalition has worked very hard to specific areas of concern to ensure that the compromise piece of legislation before you offers additional assurances. These include the following: specific language regarding liability insurance; limitations for pharmacists working in community pharmacies to engage in selected disease states and additional language regarding qualifications of pharmacists who wish to engage in Collaborative Drug Therapy Management (CDTM).

Currently there are 43 states in the country that allow some form of Collaborative Drug Therapy Management. To date, despite many years of experience by many states that permit CDTM, there have been no documented cases of any negative outcomes, but rather, demonstrated cost savings and better patient outcomes as the result of this voluntary initiative between physicians and pharmacists at a time when patient safety and patient cost are paramount.

We believe that passage of enabling legislation is a critical first step to accomplish the abovementioned goals. Accordingly, we would encourage members of the Committee to support passage of Senate Bill 420.

Thank you for your consideration in this matter.

Katherine Keough, Executive Director, Government Affairs & Continuing Education

CDTM June 13, 2007
Academic Prospective

At MCPHS, the School of Pharmacy in Boston provides essential knowledge and skill sets necessary for our students to become qualified competent, providers of patient care. It is our responsibility to prepare students for practice as a pharmacist for today as well as the future. With this in mind, the national accrediting body for Schools of pharmacy asked all School of Pharmacy across the country to transition away from the Bachelor of Science degree as the entry level degree in pharmacy into a 6 year Doctor of Pharmacy program. With this transition in our curriculum came an added focus of providing patient care and managing a patient drug therapy. In this new curriculum students are engaged in:

Year 3

- Normal body functions (6 semester hours total)
- Abnormal functions and disease processes (3 semester hours total)
- Biochemistry (6 semester hours total)
- Drug Development (7 semester hours total)
- Managing a practice (2 semester hours total)

Year 4

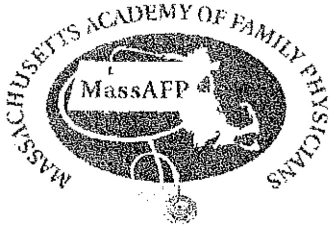
- Heath care ethics regulations and the laws governing the practice of pharmacy (5)
- Pharmacokinetics -The Science of Medication distribution within and removal from the body (5)
- Pharmacology – the study of how drugs work (8)
- Medicinal chemistry – The chemical structure of medications (6)
- Research methods (2)
- The study of viruses, bacteria and microbes (4)

Year 5

- Disease State Management (14)
- Poisons and substance abuse (2)
- Evaluation of medical literature (2)
- Practice Management (4)

<u>Clinical Experience</u>
Beginning in the fourth year students engage in preliminary activities in community and hospital pharmacy settings. This continues into the fifth year. In their last year students engage in 36 weeks of advanced clinical training in a variety of settings. Total experience then varies but correlates to about 1500 hours or more.

In conclusion, we believe the classroom preparation, combined with the advanced clinical requirements of our students provides more than enough training for our students to participate in CDTM in voluntary arrangements with physicians in the state.



MASSACHUSETTS ACADEMY OF FAMILY PHYSICIANS
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Testimony In Opposition to S.420
"An Act To Establish Collaborative Drug Therapy Management"
Committee on Health Care Financing
June 13, 2007

The Massachusetts Academy of Family Physicians (MassAFP) wishes to be recorded in strong opposition to S.420, "An Act To Establish Collaborative Drug Therapy Management". This bill is identical to H.2166, filed by Rep. Peter Koutoujian. That bill is in the Committee on Public Health, having been heard on May 2, 2007.

This bill would allow a pharmacist - practicing in a broad range of settings - to initiate, modify or discontinue a drug treatment prescribed by a physician, based on a collaborative agreement with a "supervising" physician *who may have never even seen the patient!*

Specifically, S.420 would allow pharmacists to enter into practice agreements with one or more supervising physicians to provide collaborative drug therapy management. Regulations to enforce the provisions of this bill would be promulgated by the Board of Registration in Medicine and the Board of Registration in Pharmacy.

The MassAFP is pleased to note the modifications to this bill from last year. S.420 is more limited in scope than the legislation before this body for consideration last year. It provides a more limited definition of practice settings, but still allows for collaborative practice agreements in hospitals, long term care facilities, ambulatory surgery centers, inpatient or outpatient hospice settings, and - for certain diseases – in community retail pharmacies. The Academy also appreciates the increased oversight by the Department of Public Health and the requirement that pharmacists entering into collaborative practice agreements have at least $1 million of professional liability insurance.

The MassAFP is fully supportive of collaboration between pharmacists and physicians. The Academy believes it allows for a healthy system of checks and balances. However, we are strongly opposed to pharmacists prescribing a scheduled drug without a one-on-one patient relationship, such as that between physicians and their patients. Pharmacists are not physicians, they did not go to medical school and they are not licensed by the Board of Registration in Medicine. While their education and training is laudable, it is not as comprehensive as that of a physician.

Other significant areas of concern for family physicians include communication of medical information, access to medical records and continuity of care. How are pharmacists to communicate necessary medical information to physicians in a timely manner and vice versa? If a change can occur without notifying the physician, a potential emergency decision could be made with inaccurate or incomplete information.

MASSACHUSETTS MEDICAL SOCIETY

Every physician matters, each patient counts.

Testimony of the Massachusetts Medical Society
In Opposition to Senate Bill 420
"An Act to Establish Collaborative Drug Therapy Management"
Before the Joint Committee on Health Care Financing
June 13, 2007

The Massachusetts Medical Society wishes to be recorded in strong opposition to Senate 420 because of our concerns about patient safety, quality of care and avoidance of the conflicts of interest that are inherent in a broad based expansion of the role of pharmacists. These proposed expansions raise clinical issues in a political forum. Public health is something that should never be politicized because, truly, people's lives are at stake. Therefore we ask you to consider this issue carefully on its merits.

This legislation would allow a pharmacist to "initiate, monitor, modify and discontinue a patient's drug therapy in accordance with a collaborative practice agreement".

A common provision in state laws that allow collaborative practice agreements is that the agreements are drafted by one physician, one pharmacist and one patient. They are a patient specific treatment plan to which the patient consents. In contrast, Senate 420 makes no mention of patient consent and does not limit agreements to one pharmacist and one physician.

This bill would allow a collaborative practice agreement between one physician and a dozen pharmacists. An agreement could allow a pharmacist to initiate treatment on patients the physician has never seen. It could allow pharmacists collaborating with one physician to change the treatment of patients being treated by a completely different physician without any "collaboration" with the patient or the patient's physician. The MMS has raised the issue of patient and physician consent in testimony on previous versions of this bill but this critical element is unchanged.

The bill says that a pharmacist may only practice within a collaborating physician's scope, but this provision is undefined and would have virtually no limits, particularly since the scope of practice of physicians is undefined in statute or regulation.

Senate 420 sets no standards for training. It allows collaborative practice by any pharmacist with three year's experience as a pharmacist, or it requires a Pharm. D.degree. The Pharm D is the only degree offered in the field these days so all new pharmacists will have this degree. Since Massachusetts trains many pharmacists and does not allow collaborative practice, how then do these newly trained pharmacists have the clinical experience necessary to diagnose patients?

Senate 420 purports to limit the sites where a pharmacist may practice, presumably as a patient protection concern. The sites are limited to:

- Hospitals
- Long term care facilities

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- Long term care facilities
- Inpatient or outpatient hospices
- Ambulatory clinics with on-site supervision by the attending physician, apparently excluding those with retail pharmacies.
- Community retail drug businesses, without requiring on-site supervision but only for the following diseases: asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV/AIDS, osteoporosis; and all co-morbidities associated with the primary diagnosis.

Whom exactly does this legislation protect? It seems as though a pharmacist could not work for a physician in a group practice, in an office setting or in a large group such as Harvard Vanguard. This seems to exclude the possibility of a real team approach such as is commonly used by physicians and nurse practitioners. However, this language would allow AIDS patients to seek treatment in a local drugstore. The site provisions in this legislation defy logic.

Section 2 of the bill mimics the language of existing statutes for prescription writing of nurse practitioners and physician assistants by requiring the commission of the Department of Public Health to issue regulations and register pharmacists for "prescription writing". This statutory language is appropriate for nurse practitioners and physician assistants who have well established histories of working with physicians. The legislation authorizing nurse and physician assistant prescribing developed gradually as clinical systems developed for the safe expansion of the roles of these professionals. The model was there in systems such as Harvard Community Health Plan that formed the basis for the legislative model that has worked so well in establishing the true collaborative practice model which serves us well. Pharmacists have no such existing model of service to patients.

Other sections of the bill call upon the Board of Registration in Medicine and the Board of Pharmacy to address the many potential areas of trouble that could come from the bill including: appropriate sites, qualifications, conflicts with employment, scope of diseases, documentation etc. The problem with this language is that many of these areas are specified previously in the proposed statute and would not be subject to regulation. A further problem is that it is unclear how conflicts among the Boards regarding these issues are to be resolved. Absent specific public protections, these sections guarantee a protracted regulatory battle with an uncertain result.

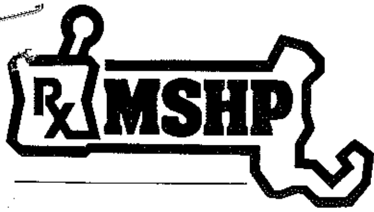
Finally we are seriously concerned about the ethical issues involved in allowing pharmacists who dispense medications for profit to actually choose the medication that is most appropriate. The conflict of interest inherent in such broad authority is readily apparent. The legislature has heard a great deal about the influence of the pharmaceutical industry on physicians recently. Imagine the influence they would exert on pharmacists. These conflicts are further increased when the pharmacist is in the employ of a pharmacy, long-term care pharmacy service or other entity with no established relationship with a patient or commitment to that patient's best interests. Will the employee pharmacist, perhaps supervised by an employee physician, do what is in the best interests of his patient or his employer?

Massachusetts has been prominent in its review of system flaws involved in medication errors. Much is being done to increase the review of appropriate medication choice and administration by a wide range of professionals. In no case does it make sense for a pharmacist to have the authority to initiate prescriptions or to change prescriptions without a prior review by the prescriber, as this legislation would allow.

In the worst-case scenario, this law would allow pharmacists to choose a drug for a patient, fill the prescription and administer the medication without ever having anyone else consider the decision. No system safety advocate is suggesting that such a lack of checks and balances is appropriate.

As dispensing is consistently moving into the arena of automation and minimally trained pharmacists assistants, pharmacists have a tremendous incentive to move up or be out of a job. However the public has a real need for pharmacists to stay involved in their core responsibilities which are the oversight of pharmacy technicians, preventing drug diversion and theft, safe dispensing of medication and the counseling of patients on potential side effects and utilization of their medication. Pharmacy needs to address the challenges of its own profession before it seeks new and unwarranted responsibilities.

The Massachusetts Medical Society urges the Committee on Health Care Finance not to support Senate 420.



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Written Testimony of the
Massachusetts Society of Health-System Pharmacists
Submitted to the Joint Committee on Health Care Financing
Senate Bill 420: An Act to Establish Collaborative Drug Therapy Management to Improve Pharmaceutical Care for Patients in Massachusetts
Submitted by: David E. Seaver, Chair, Legislative Committee of the Massachusetts Society of Health-System Pharmacists

June 13, 2007

The Massachusetts Society of Health-System Pharmacists ("MSHP"), on behalf of over 900 pharmacists and pharmacy technicians working in health care settings throughout the Commonwealth, submits this testimony in strong support of Senate Bill 420. We commend Senate Chairman Richard Moore for filing this important patient care legislation.

This bill seeks to add pharmacists to the groups of health care providers in the Commonwealth having dependent prescriptive authority, in collaboration with a supervising physician. The following mid-level practitioners enjoy dependent prescriptive authority, Physician's Assistants, Certified Nurse-Mid-wives and Psychiatric Nurse Mental Health Clinical Specialists. Forty-three states nation wide have granted pharmacists some measure of dependent prescriptive authority.

Collaborative drug therapy management (CDTM) is defined in S.420 as, "the initiating, monitoring, modifying and discontinuing of a patient's drug therapy by a pharmacist in accordance with a collaborative practice agreement. Collaborative drug therapy management may include: collecting and reviewing patient histories, obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration; and under the supervision of, or in direct consultation with a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and providing such evaluation does not include any diagnostic component." CDTM sets out a relationship between the pharmacist, physician and patient whereby the physician supervises the patient's therapy and the pharmacist manages the patient's medication treatment.

The relationship between the physician and the pharmacist is set by an agreement. The Collaborative Practice Agreement is defined in S.420 as, "a written and signed agreement, entered into voluntarily, between a pharmacist with training and experience relevant to the scope of collaborative practice and one or more supervising physicians that defines the collaborative pharmacy practice in which the pharmacist and supervising physician(s) propose to engage.

The collaborative practice must be within the scope of practice of the supervising physician(s). Each collaborative practice agreement shall be subject to review and renewal on a biennial basis." The voluntarily made agreement sets out the limitations under which the pharmacist may prescribe medications to the patients of the physician, under the supervision of the physician. The physician is responsible for the diagnosis of the patient's medical conditions and the pharmacist, within the bounds of the agreement and the scope of practice of the physician, is responsible for the medication management of that patient. The pharmacist may initiate, modify and discontinue medication therapy. The pharmacist may also order any relevant laboratory testing to monitor the medication therapy. The activities of the prescribing pharmacist are reported back to the supervising physician and documented in the patient's medical record. Each patient must be notified of and make an informed consent to this treatment.

The Massachusetts Medical Society has raised a concern that CDTM has been identified as a possible factor that could lead to higher medical malpractice premiums and increased legal risk to both physicians and pharmacists. Karl Williams, Assistant Professor of Pharmacy and Administrative Sciences at St. Johns University, researched this very issue. He found that in the twenty-five years CDTM has been practiced, there are no published cases of pharmacists or physicians being sued for malpractice, or any other legal theory, in the context of a collaborative drug therapy agreement. Indeed, the very existence of a CDTM agreement may in fact decrease malpractice risk. The agreements are typically based upon peer reviewed, evidence based criteria. The agreements are then subject to independent review by a regulatory agency. These added layers of protection help to assure the integrity, validity and rigor in the system. Despite the data that demonstrate CDTM prescribing practices are safer, each and every pharmacist participating in a CDTM agreement with a collaborating physician must carry a minimum of a million dollars of medical malpractice insurance.

A pharmacist would not be authorized to participate in a CDTM agreement without documented advanced training or the equivalent in experience. Pharmacists must have either earned a six-year Doctorate of Pharmacy degree or have earned a five-year Bachelor of Science in Pharmacy degree with an additional three years of work experience to practice in collaboration with a physician.