SENATE, NO. 2706

[Senate, May 15, 2008 - Substituted by amendment by the Senate (Moore) for Senate, No. 420]

The Commonwealth of Massachusetts

IN THE YEAR OF TWO THOUSAND AND EIGHT

AN ACT ~~TO~~ ESTABLISH COLLABORATIVE DRUG THERAPY MANAGEMENT.

Be it enacted by the Senate and House of Representatives in General Court assembled, And by the authority of the same, as follows:

SECTION 1. Subsection (g) of section 7 of chapter 94C, as appearing in the 2006 Official Edition, is hereby amended by adding the following 3 paragraphs:–

The commissioner shall issue regulations that provide for the registration of pharmacists, who have been duly registered in accordance with section 24 ½ of chapter 112, to engage in collaborative drug therapy management and to issue written prescriptions in accordance with the provisions of said section 24 ½ and guidelines mutually developed and agreed upon by the supervising physician and the pharmacist in a collaborative practice agreement, as defined in section 24 ½ of chapter 112, established in accordance with regulations of the board of registration in medicine and board of registration in pharmacy. Prior to issuing such regulations, the commissioner shall consult with the board of registration in medicine and the board of registration in pharmacy with regard to those schedules of controlled substances for

which a pharmacist may be authorized to prescribe within the scope of his collaborative practice.

The commissioner may gather patient outcome and cost-savings data if available from objective sources and review community retail drug business-based collaborative drug therapy management. If the commissioner finds that sufficient data and funding sources exist to conduct a valid study, he shall conduct a study within 2 years after that finding. The study shall include representatives of the board of registration in medicine and the board of registration in pharmacy. In conducting the study, the commissioner shall hold at least 1 public hearing to receive testimony from the public, including representatives of pharmacy and medicine and other concerned parties.

SECTION 2. Said chapter 94C is hereby further amended by striking out section 9, as so appearing, and inserting in place thereof the following section: –

Section 9. (a) A physician, dentist, podiatrist, optometrist as limited by sections 66 and 66B of chapter 112 and paragraph (h) of section 7 of this chapter, nurse practitioner and psychiatric nurse mental health clinical specialist as limited by paragraph (g) of said section 7 and section 80E of said chapter 112, physician assistant as limited by said paragraph (g) of said section 7 and section 9E of said chapter 112, certified nurse-midwife as provided in section 80C of said chapter 112, pharmacist as limited by said paragraph (g) of said section 7 and section 24B½ of said chapter 112, or veterinarian when registered pursuant to said section 7, may, when acting in accordance with applicable federal law and any provision of this chapter which is consistent with federal law and in good faith and in the course of a professional practice for the alleviation of pain and suffering or for the treatment or alleviation of disease, possess

controlled substances as may reasonably be required for the purpose of patient treatment and may administer controlled substances or may cause the same to be administered under his direction by a nurse.

(b) Notwithstanding section 17, a physician, physician assistant, dentist, podiatrist, optometrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist as limited by said paragraph (g) of said section 7 and section 24B½ of said chapter 112, or veterinarian registered pursuant to said section 7, may, when acting in good faith and in the practice of medicine, dentistry, podiatry, optometry, nurse-midwifery, pharmacy or veterinary medicine or as a nurse, as the case may be, and when authorized by a physician, dentist, podiatrist, optometrist, nurse practitioner, physician assistant, certified nurse-midwife, psychiatric nurse mental health clinical specialist or veterinarian in the course of such nurse's professional practice, dispense by delivering to an ultimate user a controlled substance in a single dose or in a quantity that is, in the opinion of such physician, dentist, podiatrist, optometrist, nurse practitioner, physician assistant, certified midwife, psychiatric nurse mental health clinical specialist or veterinarian, essential for the treatment of the patient. The amount or quantity of any controlled substance dispensed under this subsection shall not exceed the quantity of a controlled substance necessary for the immediate and proper treatment of the patient until it is possible for the patient to have a prescription filled by a pharmacy. All controlled substances required by the patient as part of his treatment shall be dispensed by prescription to the ultimate user in accordance with this chapter.

This section shall not prohibit or limit the dispensing of any prescription medication that is classified by the department of public health as schedule VI and that is provided by the

manufacturer as part of an indigent patient program or for use as samples if the prescription medication is: (i) dispensed to the patient by a professional authorized to dispense controlled substances pursuant to this section; (ii) dispensed in the package provided by the manufacturer; and (iii) provided at no charge to the patient. The department shall promulgate rules and regulations governing the dispensing of medication pursuant to this section. These rules and regulations shall include, but not be limited to, those concerning the types and amounts of medications that may be dispensed and the appropriate safeguards for the labeling and dispensing of such medications.

(c) A nurse who has obtained from a physician, dentist, physician assistant, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian a controlled substance for dispensing to an ultimate user pursuant to paragraph (b) or for administration to a patient pursuant to paragraph (a) during the absence of the physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian, shall return to the physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian any unused portion of the controlled substance which is no longer required by the patient.

(d) Every physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian shall, in the course of a professional practice, keep and maintain records, open to inspection by the commissioner during reasonable business hours, which shall include the following: the names and quantities of any controlled substances in schedules I, II or III received by the

practitioner; the name and address of each patient to whom such controlled substance is administered or dispensed; the name, dosage and strength per dosage unit of each such controlled substance; and the date of such administration or dispensing.

(e) Notwithstanding paragraph (b), a physician, nurse practitioner, physician assistant, pharmacist as limited by paragraph (g) of section 7 of this chapter and section 24B½ of said chapter 112 or certified nurse-midwife, when acting in good faith and providing care under a program funded in whole or in part by 42 U.S.C. 300, or in a clinic licensed by the department to provide comparable medical services or a registered nurse, registered pursuant to section 74 of chapter 112 and authorized by such physician, nurse practitioner, physician assistant, pharmacist as limited by said paragraph (g) of said section 7 and section 24B½ of said chapter 112, or certified nurse-midwife, may lawfully dispense controlled substances pursuant to schedule VI to recipients of such services in such quantity as needed for treatment and shall be exempt from the requirement that such dispensing be in a single dosage or as necessary for immediate and proper treatment under subsection (b). A registered nurse shall dispense under this subsection only as provided in section 17. The department may establish rules and regulations controlling the dispensing of these medications, including, but not limited to, the types and amounts of medications dispensed and appropriate safeguards for dispensing.

SECTION 3. Chapter 112 of the General Laws is hereby amended by inserting after section 24B the following 2 sections:-

Section 24 B½. (a) As used in this section, the following terms shall have the following meanings unless the context clearly requires otherwise:

"Collaborative drug therapy management", the initiating, monitoring, modifying and discontinuing of a patient's drug therapy by a pharmacist in accordance with a collaborative practice agreement; provided, however, that "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 when the evaluation shall not include a diagnostic component.

"Collaborative practice agreement", a written and signed agreement between a pharmacist with training and experience relevant to the scope of the collaborative practice and a supervising physician that defines the collaborative practice in which the pharmacist and supervising physician propose to engage. The collaborative practice shall be within the scope of the supervising physician's practice. Each collaborative practice agreement shall be subject to review and renewal on a biennial basis. A collaborative practice agreement shall include individually developed guidelines for any prescriptive practice of the pharmacist.

"Patient", a person who is referred to a pharmacist by his supervising physician for the purpose of receiving collaborative drug therapy management services from the pharmacist. The supervising physician shall assess the patient and include a diagnosis when referring the patient to the collaborating pharmacist. The patient shall be notified of and consent to the collaborative drug therapy management services in the retail drug business setting. Individual referral and consent shall be recorded by the pharmacist and the supervising physician in the patient's record.

(b) In order for a pharmacist to enter into a collaborative practice agreement, the pharmacist shall: (1) hold a current license to practice pharmacy in the commonwealth and currently be engaged in pharmacy practice in the commonwealth; (2) have at least $1,000,000 of professional liability insurance; (3) have earned a doctor of pharmacy degree or have completed 5 years of experience as a licensed pharmacist or the equivalent; (4) agree to devote a portion of his practice to the defined drug therapy area that the pharmacist shall co-manage; and (5) agree to complete, in each year of the agreement, at least 5 additional contact hours or 0.5 continuing education units of board-approved continuing education that addresses areas of practice generally related to collaborative practice agreements.

(c) Collaborative drug therapy management shall only be allowed in the following settings: (1) hospitals licensed pursuant to section 51 of chapter 111, subject to approval by the medical staff executive committee at a licensed hospital or designee; (2) long-term care facilities licensed pursuant to section 71 of chapter 111, subject to approval by the long-term care facilities' medical director or designee; (3) inpatient or outpatient hospice settings licensed pursuant to section 57D of chapter 111, subject to approval by the hospice's medical director or designee; (4) ambulatory care clinics licensed pursuant to section 51 of chapter 111, with on-site supervision by the attending physician and a collaborating pharmacist, subject to approval by the ambulatory care clinic's medical staff executive committee or designee, or medical director or designee; (5) a collaborating pharmacist in a retail drug business, as registered in section 38 of chapter 112 and limited by this section, with supervision by a physician according to the terms of his collaborative practice agreement and limited to the following: patients 18 years of age or older; an extension by 30 days of current drug therapy prescribed by the supervising physician; administration of vaccines or the modification of dosages of medications

prescribed by the supervising physician for asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV or AIDS, osteoporosis and co-morbidities identified by the supervising physician for the individual patient along with the primary diagnosis. The collaborative practice agreement shall specifically reference each disease state being co-managed. A patient shall be referred by a supervising physician to that physician's collaborating pharmacist and shall be given notice of the collaboration and consent to the collaboration. No collaborative practice agreement in the retail drug business setting may permit the prescribing of schedule II through V controlled substances, as defined in section 3 of chapter 94C. A pharmacist in the retail setting, who has a collaborative practice agreement with a supervising physician which specifically allows initial prescriptions for referred patients of the supervising physician, may issue prescriptions for schedule VI controlled substances, as defined in subsection 6 of section 3 of chapter 94C. Such prescriptions shall be for a patient diagnosis specified in the supervising physician's individual referral of that patient. A copy of the prescription shall be sent to the supervising physician within 24 hours.

(d) A retail drug business practicing in collaborative drug therapy management under this section shall not be required to register as a Health Facility under 105 CMR 700.004(A)(2)(d).

(e) A physician or a physician group may hire pharmacists for the purpose of practicing collaborative drug therapy management under a collaborative practice agreement, as defined in subsection (a), for the benefit of a patient of that physician or physician group. No retail pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement with a patient. Nothing shall prohibit a retail pharmacy from hiring a physician or licensed medical practitioner for the purpose of conducting quality

assurance reviews of its pharmacists that are engaged in the practice of collaborative drug therapy.

Section 24 B¾. The board of registration in medicine and the board of registration in pharmacy shall issue rules and regulations to implement collaborative drug therapy management pursuant to section 24 B½ of this chapter and sections 7 and 9 of chapter 94C. To aid in the implementation, the board of registration in medicine and the board of registration in pharmacy shall consult with at least 1 individual from each of the following groups: the department of public health; the Massachusetts Society of Health-System Pharmacists; the Massachusetts chapter of the American Society of Consultant Pharmacists; the Massachusetts Pharmacists Association; the Massachusetts Independent Pharmacists Association; the Massachusetts Chain Pharmacy Council; the Massachusetts College of Pharmacy and Health Sciences; the Bouvé College of Health Sciences at Northeastern University; the Massachusetts Medical Society; the Massachusetts Academy of Family Physicians; the Massachusetts Chapter of the American Academy of Pediatrics; the Massachusetts Psychiatric Society; the Massachusetts chapter of the American Academy of Emergency Physicians; the Massachusetts Chapter of the American Medical Directors Association; and the Massachusetts Hospital Association. The rules and regulations shall govern each collaborative practice agreement, shall be defined and limited by section 24B½ of this chapter, chapter 94C and other applicable statutes. The board of registration in medicine and the board of registration in pharmacy shall address the following issues: (a) further limitations and conditions on sites and settings where a collaborative practice may take place beyond those of section 24; (b) the qualifications of participating pharmacists and physicians; (c) the scope of conditions or diseases to be managed, the initial list of which shall not include more than 5 disease states considered appropriate for collaborative

management, providing that the 5 diseases selected for collaborative management in the retail setting must be from among those referenced in clause (5) of section (c) of section 24B½; (d) practice protocols; (e) risk management activities; (f) documentation of any initiation, modification or discontinuation of a patient's medication therapy in the patient's permanent medical record; (g) outcome measurements; and (i) informed consent procedures. The board of registration in medicine and the board of registration in pharmacy shall reconsider these regulations on a periodic basis, as considered appropriate by the commissioner of public health for the purposes of adding or removing disease states to be managed under collaborative drug therapy treatment, as well as for the purpose of updating the rules and regulations governing collaborative drug therapy management, as necessary.

H.R., DEC 3 0 2008

Passed to be engrossed, in concurrence, with an amendment striking out all after the enacting clause and inserting in place thereof the text contained in House document numbered 5188. Sent to the Senate for concurrence.

[at "A"] Steven J. Jamar, Clerk.

Senate Committee on BTR
Correctly drawn
For the Committee

SENATE, JANUARY 5, 2009

Senate concurs in the House amendment.

William F. Welch, Clerk.

Senate Committee on BTR
Correctly drawn

For the Committee

Senate Committee on BTR
Correctly drawn

For the Committee

Senate, No. 2706

BILL TO ESTABLISH COLLABORATIVE DRUG THERAPY MANAGEMENT

Senate, May 15, 2008 –

Substituted by amendment by the Senate (Moore) as a new draft of S. 420 & Engrossed.

Correctly drawn.

, for B.T.R.

DEC 30 2008 -Read 3rd. & engrossed

Senate Committee on BTR
Correctly drawn
For the Committee

Senate Committee on BTR
Correctly drawn
For the Committee

SENATE, JANUARY 5, 2009

Rules suspended - Senate concur in the House amendment

H. R., May 19, 2008

Read; and referred, under Rule 33, to the committee on Ways and Means.

, *Clerk.*

DEC 29 2008

H.R., ...,

~~*Read; and referred, under Rule 7A, to the committee on Steering, Policy and Scheduling.*~~ with an amendment H.5188 new text pending.

, *Clerk.*

DEC 29 2008, *Reported and placed in O.D. for a second reading with an amendment H.5188 new text pending.*

For the Committee.

..... Rule 7A suspended (Cabi , Rd. 2nd., **AMENDED** (W&M) (text of H. 5188); and ord. 3rd.

Text of an amendment recommended by the committee on Ways and Means to the Senate Bill to establish collaborative drug therapy management (Senate, No. 2706). December 29, 2008.

The Commonwealth of Massachusetts

IN THE YEAR TWO THOUSAND EIGHT

AN ACT TO ESTABLISH COLLABORATIVE DRUG THERAPY MANAGEMENT.

By striking out all after the enacting clause and inserting in place thereof the following:

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1.

Subsection (g) of section 7 of chapter 94C of the General Laws, as appearing in the 2006 Official Edition, is hereby amended by ~~inserting at the end thereof~~ adding the following 3 paragraphs:–

The commissioner shall issue regulations authorizing pharmacists, who have been duly registered in accordance with section 24½ of chapter 112, to engage in collaborative drug therapy management and to issue written prescriptions in accordance with the provisions of said section 24½ and guidelines mutually developed and agreed upon by the supervising physician and the pharmacist in a collaborative practice agreement, as defined in section 24½ of chapter 112, established in accordance with regulations of the board of registration in medicine and board of registration in pharmacy. Prior to issuing such regulations, the commissioner shall consult with the board of registration in medicine and the board of registration in pharmacy with regard to ~~those~~ schedules of controlled substances for which a pharmacist may be authorized to prescribe within the scope of his collaborative practice.

The commissioner may gather patient outcome and cost-savings data if available from objective sources and review community retail drug business-based collaborative drug therapy management. If the commissioner finds that sufficient data and funding sources exist to conduct a valid study, he shall conduct a study within 2 years after that finding. The study shall include representatives of the board of registration in medicine and the

NOTE. — Use ONE side of paper ONLY. DOUBLE SPACE. Insert additional leaves, if necessary.

board of registration in pharmacy. In conducting the study, the commissioner shall hold at least 1 public hearing to receive testimony from the public, including representatives of pharmacy and medicine and other concerned parties.

SECTION 2. Said chapter 94C, as so appearing, is hereby further amended by striking out section 9 and inserting in place thereof the following section:–

Section 9. (a) A physician, dentist, podiatrist, optometrist as limited by sections 66 and 66B of chapter 112 and ~~paragraph~~ (h) of section 7, nurse practitioner and psychiatric nurse mental health clinical specialist as limited by ~~paragraph~~ (g) of said section 7 and section 80E of said chapter 112, physician assistant as limited by said ~~paragraph~~ (g) of said section 7 and section 9E of said chapter 112, certified nurse-midwife as provided in section 80C of said chapter 112, pharmacist as limited by said ~~paragraph~~ (g) of said section 7 and section 24B½ of said chapter 112, or veterinarian when registered pursuant to said section 7, may, when acting in accordance with applicable federal law and any provision of this chapter which is consistent with federal law and in good faith and in the course of a professional practice for the alleviation of pain and suffering or for the treatment or alleviation of disease, possess controlled substances as may reasonably be required for the purpose of patient treatment and may administer controlled substances or may cause the same to be administered under his direction by a nurse.

A practitioner may cause controlled substances to be administered under his direction by a licensed dental hygienist, for the purposes of local anesthesia only.

(b) Notwithstanding section 17, a physician, physician assistant, dentist, podiatrist, optometrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist as limited by said ~~paragraph~~ (g) of said section 7 and section 24B½ of said chapter 112, or veterinarian registered pursuant to said section 7, may, when acting in good faith and in the practice of medicine, dentistry, podiatry, optometry, nurse-midwifery, pharmacy or veterinary medicine or as a nurse, as the case may be, and when authorized by a physician, dentist, podiatrist, optometrist, nurse practitioner, physician assistant, certified nurse-midwife, psychiatric nurse mental health clinical specialist or veterinarian in the course of such nurse's professional practice, dispense by delivering to an ultimate user a controlled substance in a single dose or in a quantity that is, in the opinion of such physician, dentist, podiatrist, optometrist, nurse practitioner, physician assistant, certified midwife, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian, essential for the treatment of the patient. The amount or quantity of any controlled substance dispensed under this subsection shall not exceed the quantity of a controlled substance necessary for the immediate and proper treatment of the patient until it is possible for the patient to have a prescription filled by a pharmacy. All controlled substances required by the patient as part of his treatment shall be dispensed by prescription to the ultimate user in accordance with this chapter.

This section shall not prohibit or limit the dispensing of any prescription medication that

is classified by the department as schedule VI and that is provided by the manufacturer as part of an indigent patient program or for use as samples if the prescription medication is: (i) dispensed to the patient by a professional authorized to dispense controlled substances pursuant to this section; (ii) dispensed in the package provided by the manufacturer; and (iii) provided at no charge to the patient. The department shall promulgate rules and regulations governing the dispensing of medication pursuant to this section. These rules and regulations shall include, but not be limited to, those concerning the types and amounts of medications that may be dispensed and the appropriate safeguards for the labeling and dispensing of such medications.

(c) A nurse who has obtained from a physician, dentist, physician assistant, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian a controlled substance for dispensing to an ultimate user pursuant to ~~paragraph~~ (b) or for administration to a patient pursuant to ~~paragraph~~ (a) during the absence of the physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian, shall return to the physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian any unused portion of the controlled substance which is no longer required by the patient.

A licensed dental hygienist who has obtained a controlled substance from a practitioner for dispensing to an ultimate user pursuant to ~~paragraph~~ (a) shall return to such practitioner any unused portion of the substance which is no longer required by the patient.

(d) Every physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian shall, in the course of a professional practice, keep and maintain records, open to inspection by the commissioner during reasonable business hours, which shall include: the names and quantities of any controlled substances in schedules I, II or III received by the practitioner; the name and address of each patient to whom such controlled substance is administered or dispensed; the name, dosage and strength per dosage unit of each such controlled substance; and the date of such administration or dispensing.

(e) Notwithstanding ~~paragraph~~ (b), a physician, nurse practitioner, physician assistant, pharmacist as limited by ~~paragraph~~ (g) of section 7 ~~of this chapter~~ and section 24B½ of said chapter 112 or certified nurse-midwife, when acting in good faith and providing care under a program funded in whole or in part by 42 U.S.C. 300, or in a clinic licensed by the department to provide comparable medical services or a registered nurse, registered pursuant to section 74 of chapter 112 and authorized by such physician, nurse practitioner, physician assistant, pharmacist as limited by said ~~paragraph~~ (g) of said section 7 and section 24B½ of said chapter 112, or certified nurse-midwife, may lawfully

dispense controlled substances pursuant to schedule VI to recipients of such services in such quantity as needed for treatment and shall be exempt from the requirement that such dispensing be in a single dosage or as necessary for immediate and proper treatment under subsection (b). A registered nurse shall dispense under this subsection only as provided in section 17. The department may establish rules and regulations controlling the dispensing of these medications, including, but not limited to, the types and amounts of medications dispensed and appropriate safeguards for dispensing.

SECTION 3. Chapter 112 of the General Laws is hereby amended by inserting after section 24B the following 2 sections:-

Section 24B½. (a) As used in this section and section 24B¾ the following ~~terms~~ words shall, unless the context clearly requires otherwise, have the following meanings: –

"Collaborative drug therapy management", the initiating, monitoring, modifying and discontinuing of a patient's drug therapy by a pharmacist in accordance with a collaborative practice agreement; provided, however, that 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 when the evaluation shall not include a diagnostic component.

"Collaborative practice agreement", a written and signed agreement between a pharmacist with training and experience relevant to the scope of the collaborative practice and a supervising physician that defines the collaborative practice in which the pharmacist and supervising physician propose to engage. The collaborative practice shall be within the scope of the supervising physician's practice. Each collaborative practice agreement shall be subject to review and renewal on a biennial basis. A collaborative practice agreement shall include individually developed guidelines for any prescriptive practice of the pharmacist.

"Commissioner", the commissioner of the department of public health.

"Department", the department of public health.

"Patient", a person who is referred to a pharmacist by his supervising physician for the purpose of receiving collaborative drug therapy management services from the pharmacist. The supervising physician shall assess the patient and include a diagnosis when referring the patient to the collaborating pharmacist. The patient shall be notified of, and shall consent to, the collaborative drug therapy management services in the retail drug business setting. Individual referral and consent shall be recorded by the pharmacist and the supervising physician in the patient's record.

(b) In order for a pharmacist to enter into a collaborative practice agreement, the pharmacist shall: (1) hold a current license to practice pharmacy in the commonwealth and currently be engaged in pharmacy practice in the commonwealth; (2) have at least $1,000,000 of professional liability insurance; (3) have earned a doctor of pharmacy degree or have completed 5 years of experience as a licensed pharmacist or the equivalent; (4) agree to devote a portion of his practice to the defined drug therapy area that the pharmacist shall co-manage; and (5) agree to complete, in each year of the agreement, at least 5 additional contact hours or 0.5 continuing education units of board-approved continuing education that addresses areas of practice generally related to collaborative practice agreements.

(c) Collaborative drug therapy management shall only be allowed in the following settings: (1) hospitals licensed pursuant to section 51 of chapter 111, subject to approval by the medical staff executive committee at a licensed hospital or designee; (2) long-term care facilities licensed pursuant to section 71 of chapter 111, subject to approval by the long-term care facilities' medical director or designee; (3) inpatient or outpatient hospice settings licensed pursuant to section 57D of chapter 111, subject to approval by the hospice's medical director or designee; (4) ambulatory care clinics licensed pursuant to section 51 of chapter 111, with on-site supervision by the attending physician and a collaborating pharmacist, subject to approval by the ambulatory care clinic's medical staff executive committee or designee, or medical director or designee; (5) a collaborating pharmacist in a retail drug business, as registered in section 38 of chapter 112 and limited by this section, with supervision by a physician according to the terms of his collaborative practice agreement and limited to the following: patients 18 years of age or older; an extension by 30 days of current drug therapy prescribed by the supervising physician; administration of vaccines or the modification of dosages of medications prescribed by the supervising physician for asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV or AIDS, osteoporosis and co-morbidities identified by the supervising physician for the individual patient along with the primary diagnosis. The collaborative practice agreement shall specifically reference each disease state being co-managed. A patient shall be referred by a supervising physician to that physician's collaborating pharmacist and shall be given notice of the collaboration and shall consent to the collaboration. No collaborative practice agreement in the retail drug business setting may permit the prescribing of schedule II through V controlled substances, as defined in section 3 of chapter 94C. A pharmacist in the retail setting, who has a collaborative practice agreement with a supervising physician which specifically allows initial prescriptions for referred patients of the supervising physician, may issue prescriptions for schedule VI controlled substances, as defined in clause 6 of section 3 of chapter 94C. Such prescriptions shall be for a patient diagnosis specified in the supervising physician's individual referral of that patient. A copy of the prescription shall be sent to the supervising physician within 24 hours.

(d) A retail drug business practicing in collaborative drug therapy management under this

section shall not be required to register as a Health Facility under 105 CMR 700.004(A)(2)(d).

(e) A physician or a physician group may hire pharmacists for the purpose of practicing collaborative drug therapy management under a collaborative practice agreement, as defined in subsection (a), for the benefit of a patient of that physician or physician group. No retail pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement with a patient. Nothing shall prohibit a retail pharmacy from hiring a physician or licensed medical practitioner for the purpose of conducting quality assurance reviews of its pharmacists that are engaged in the practice of collaborative drug therapy.

Section 24B¾. The board of registration in medicine and the board of registration in pharmacy shall issue rules and regulations to implement collaborative drug therapy management pursuant to section 24B½ and sections 7 and 9 of chapter 94C. To aid in the implementation, the board of registration in medicine and the board of registration in pharmacy shall consult with at least 1 individual from each of the following groups: the department of public health; the Massachusetts Society of Health-System Pharmacists; the Massachusetts chapter of the American Society of Consultant Pharmacists; the Massachusetts Pharmacists Association; the Massachusetts Independent Pharmacists Association; the Massachusetts Chain Pharmacy Council; the Massachusetts College of Pharmacy and Health Sciences; the Bouvé College of Health Sciences at Northeastern University; the Massachusetts Medical Society; the Massachusetts Academy of Family Physicians; the Massachusetts Chapter of the American Academy of Pediatrics; the Massachusetts Psychiatric Society; the Massachusetts chapter of the American Academy of Emergency Physicians; the Massachusetts Chapter of the American Medical Directors Association; and the Massachusetts Hospital Association. The rules and regulations shall govern each collaborative practice agreement, shall be defined and limited by section 24B½, chapter 94C and other applicable statutes. The board of registration in medicine and the board of registration in pharmacy shall address the following issues: (a) further limitations and conditions on sites and settings where a collaborative practice may take place beyond those of section 24; (b) the qualifications of participating pharmacists and physicians; (c) the scope of conditions or diseases to be managed, the initial list of which shall not include more than 5 disease states considered appropriate for collaborative management, providing that the 5 diseases selected for collaborative management in the retail setting must be from among those referenced in clause (5) of section (c) of section 24B½; (d) practice protocols; (e) risk management activities; (f) documentation of any initiation, modification or discontinuation of a patient's medication therapy in the patient's permanent medical record; (g) outcome measurements; and (h) informed consent procedures. The board of registration in medicine and the board of registration in pharmacy shall reconsider these regulations on a periodic basis, as considered appropriate by the commissioner for the purposes of adding or removing disease states to be managed under collaborative drug therapy treatment, as well as for the purpose of updating the rules and regulations governing collaborative drug therapy management, as necessary.

Mr. Moore moves to amend the bill (Senate, No. 420) by substituting a new draft with the same title (Senate, No. 2706).

House, No. 5188

BILL to establish collaborative drug therapy management

H. R., December 29 2009.
Rec. (W&M) new text for S. 2706.
Substituted as new text, see Senate, No. 2706.

The Commonwealth of Massachusetts

House of Representatives, **December 29, 2008**

The committee on **WAYS AND MEANS**, *to whom was referred the*

Bill to establish collaborative drug therapy management (Senate No. 2706),

REPORT *recommending that the same ought to pass* with an amendment by striking out all after the enacting clause and inserting in place thereof the text contained in House Document numbered 5188.

Robert A. DeLeo, *Chairman*
For the Committee

OTP
amend

REPORT — HOUSE

OUGHT TO PASS

(S) SO2706 P01 H34

Of the *Committee on*

WAYS AND MEANS

Bill to establish collaborative drug therapy management.

Senate, JUL 19 2007 Senate , .

Read and, under Rule 26, referred to the committee on Ethics and Rules.

William F. Welch, *Clerk.*

APR 28 2008 — OD
rules suspended —

— Read 2nd & ord. 3rd.

APR 29 2008 - Read 3d. -

Postponed (Moore) to the next session.

[Question on engrossment]

MAY 15 2008 - AMended (Moore) by substitution of S. 2706.

S00420

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in the General Court assembled.

The undersigned, citizen of _____, respectfully petitions for the passage of the accompanying bill and for legislation.

to establish collaborative drug therapy management

Richard T. Moore	Worcester and Norfolk
Joan M. Menard	1st Bristol
Scott P. Brown	Norfolk, Bristol and Middlesex
Jennifer M. Callahan	18th Worcester
Brian A. Joyce	Suffolk and Norfolk

SENATE DOCKET, NO. SD00579
Filed: 1/9/2007

EA

PETITION --- SENATE

Senator Richard T. Moore
of Worcester and Norfolk

presents the petition of Richard T. Moore, for legislation to establish collaborative drug therapy management (Joan M. Menard, Scott P. Brown and other members of the General Court.

[Accompanied by bill, Senate, No. 420]

Senate, January 10th, 2007
Referred to the committee on
Elder Affairs

Sent to the House for concurrence,
William F. Welch, Clerk.

House of Reps., JUN 07 2007
The House concurs.
Steven T. James, Clerk.

Senate JUN 4 2007.
Committee on Elder Affairs
asks to be discharged and
recommends reference to
Committee on Health Care Financing
Patricia Jehlen
For the Committee.

Acc: Sent to the House for concurrence.
William F. Welch, Clerk

H.R., JUN 07 2007

The House concurs,
Steven T. James, Clerk.

The Commonwealth of Massachusetts

Senate, JUL 17 2007,

The committee on Health Care Financing..., *to whom was referred the petition (accompanied by* bill, Senate, *No.* 420.) *of*

Richard T. Moore, Joan M. Menard, Scott P. Brown, Jennifer M. Callahan and other members of the General Court for legislation to establish collaborative drug therapy management.

REPORT *recommending that the bill* [redacted] *accompanying said petition ought to pass.*

(Estimated cost: less than $100,000).

Richard T. Moore,

For the Committee.

REPORT — SENATE

BILL [redacted]

REPORT of committee on

Health Care Financing

The Commonwealth of Massachusetts

Senate, APR 2 8 2008

The committee on Ethics and Rules to whom was referred the

Senate Bill to establish collaborative drug therapy management (Senate, No. 420).

REPORT *that the matter be placed in the Orders of the Day for the next session.*

For the committee.

REPORT — SENATE

REPORT of committee on

Ethics and Rules

on _____

_____

_____

_____

EA

Docket Number: **SD00579**

[SIMILAR MATTER FILED DURING PAST SESSION
SEE NO. SENATE 2691 OF 2005-2006]

The Commonwealth of Massachusetts

IN THE YEAR OF TWO THOUSAND AND SEVEN

AN ACT TO ESTABLISH COLLABORATIVE DRUG THERAPY MANAGEMENT

Be it enacted by the Senate and House of Representatives in General Court assembled,
And by the authority of the same, as follows:

SECTION 1. Chapter 112, Section 24 of the General Laws as appearing in the 2000 Official Edition, is hereby amended by adding at the end thereof, the following:

"Collaborative drug therapy management" means 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.

"Collaborative practice agreement" is a written and signed agreement, entered into voluntarily, between a pharmacist with advanced 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.

For a Pharmacist to enter into a collaborative practice agreement, the pharmacist shall:

a. Hold a current license to practice pharmacy in Massachusetts;

b. Have at least $1,000,000 of professional liability insurance;

c. Have earned a Pharm. D. degree or completed three (3) years of experience as a licensed pharmacist, or the equivalent; and

d. Complete at least five (5) additional contact hours or 0.5 continuing education units of board-approved continuing education each year. Such continuing education shall address the area(s) of practice generally related to the collaborative practice agreement(s).

Collaborative practice agreements shall only be allowed in the following settings:

a. Hospitals as licensed in section 51 of chapter one hundred eleven.

b. Long Term Care facilities as licensed in section 71 of chapter one hundred eleven.

c. Licensed inpatient or outpatient hospice settings as licensed in section 57D of chapter one hundred eleven.

d. Ambulatory care clinics, as licensed in section 51 of chapter one hundred eleven, with onsite supervision by the attending physician and with a collaborating pharmacist who has no connection to any retail pharmacy.

e. A collaborating pharmacist in a community retail drug business, as registered in section 39 of chapter one hundred twelve, with supervision by a physician limited to the following diseases: asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV/AIDS and osteoporosis, and all co-morbidities associated with the primary diagnosis. Not withstanding any special acts, rules or laws to the contrary, a participating community retail drug business is not required to register as Health Facility under 105 CMR 700.004 (A) (2) (d).

The Department of Public Health shall gather patient outcome and cost savings data and review community retail drug business based Collaborative Drug Therapy Management to amend Department of Public Health regulations and extend the number of diseases periodically, if deemed appropriate. The first review of the data shall occur not less than two years of the date of promulgation of regulations by the Department of Public Health on Collaborative Drug Therapy Management. The Department of Public Health may convene a group to study the data. Members of this group shall be comprised of, but not limited to one individual to be an employee of the Department of Public Health; one individual from the Board of Registration in Medicine and one individual from the Board of Registration in Pharmacy; one or more individuals from Massachusetts Society of Health System Pharmacists, the Massachusetts Chapter of the American Society of Consultant Pharmacists, the Massachusetts Pharmacists Association, the Massachusetts Independent Pharmacists Association, the Massachusetts Chain Pharmacy Council, the Massachusetts College of Pharmacy and Health Sciences and the Bouve College of Health Sciences at Northeastern University; and, one or more individuals from Massachusetts Medical Society, the Massachusetts Chapter of the American Medical Directors Association and the Massachusetts Hospital Association.

SECTION 2. Chapter 94C, Section 7 (g) of the General Laws as appearing in the Official Edition, is hereby amended by adding at the end thereof, the following:–

The commissioner shall promulgate regulations that provide for the registration of pharmacists, who have been duly registered in accordance with section twenty four of chapter one hundred and twelve, to issue written prescriptions in accordance with guidelines mutually developed and agreed upon by the supervising physician and the pharmacist in a collaborative practice agreement, as defined in section 24 of chapter one hundred and twelve, established in accordance with regulations of the Board of Registration in Medicine and Board of Registration in Pharmacy. Prior to promulgating such regulations, the commissioner shall consult with the Board of Registration in Medicine and Board of Registration in Pharmacy with regard to those schedules of controlled substances for which pharmacists may be registered.

SECTION 3. Chapter 112, Section 24B and Chapter 112, Section 2 of the General Laws as appearing in the 2000 Official Edition, is hereby amended by adding at the end thereof, the following:–

The Board of Registration in Medicine and the Board of Registration in Pharmacy shall promulgate rules and regulations to implement the provisions of this act. To aid in the implementation, the Board of Registration in Medicine and the Board of Registration in Pharmacy will consult with at least one individual from each of the following groups: one individual to be an employee of the Department of Public Health; one individual from the Board of Registration in Medicine and one individual from the Board of Registration in Pharmacy; one or more individuals from Massachusetts Society of Health System Pharmacists, the Massachusetts Chapter of the American Society of Consultant Pharmacists, the Massachusetts Pharmacists Association, the Massachusetts Independent Pharmacists Association, the Massachusetts Chain Pharmacy Council,

the Massachusetts College of Pharmacy and Health Sciences and the Bouve College of Health Sciences at Northeastern University; and, one or more individuals from Massachusetts Medical Society, the Massachusetts Chapter of the American Medical Directors Association and the Massachusetts Hospital Association. Said rules and regulations governing each collaborative practice agreement shall include, but shall not be limited to: (1) site and setting where the collaborative practice is to take place; (2) qualifications of pharmacists and physicians participating; (3) the role of any employed health care professional with prescriptive privileges participating in the collaborative practice; (4) scope of conditions or diseases to be managed, the initial list of which shall not include more than 5 disease states deemed appropriate for collaborative management; (5) practice protocols; (6) risk management activities; (7) documentation of any initiation, modification and/or discontinuation of a patient's medication therapy in the patient's permanent medical record; (8) outcome measurements; and (9) informed consent procedures. The Board of Registration in Medicine and the Board of Registration in Pharmacy shall reconsider these regulations on a periodic basis as deemed appropriate by the commissioner of the department of public health for the purposes of adding or removing disease states to be managed under collaborative drug therapy treatment, as well as for the purpose of updating the rules and regulations governing collaborative drug therapy treatment as necessary.

SECTION 4. Section 9 of said chapter 94C is hereby amended by striking out paragraph (a), (b), (c), (d) and (e) as so appearing, and inserting in place thereof the following: –

(a) A physician, dentist, podiatrist, optometrist as limited by sections 66 and 66B of chapter 112 and paragraph (h) of section 7, nurse practitioner and psychiatric nurse mental health clinical specialist as limited by paragraph (g) of said section 7 and section 80E of said chapter 112, physician assistant as limited by said paragraph (g) of said section 7 and section 9E of said chapter 112, a certified

nurse-midwife as provided in section 80C of said chapter 112, pharmacist as limited by said paragraph (g) of said section 7 and section 24 of said chapter 112, or a veterinarian when registered pursuant to the provisions of said section 7 and acting in accordance with the provisions of applicable federal law and any provision of this chapter which is consistent with federal law, in good faith and in the course of a professional practice for the alleviation of pain and suffering or for the treatment or alleviation of disease, may possess such controlled substances as may reasonably be required for the purpose of patient treatment and may administer controlled substances or may cause the same to be administered under his direction by a nurse.

(b) Notwithstanding the provisions of section 17, a physician, physician assistant, dentist, podiatrist, optometrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist as limited by said paragraph (g) of said section 7 and section 24 of said chapter 112, or veterinarian who is registered pursuant to the provisions of section 7, when acting in good faith and in the practice of medicine, dentistry, podiatry, optometry, nurse-midwifery, pharmacy, or veterinary medicine or a nurse, when authorized by a physician, dentist, podiatrist, optometrist, nurse practitioner, physician assistant, certified nurse-midwife, psychiatric nurse mental health clinical specialist or veterinarian in the course of such nurse's professional practice, may dispense by delivering to an ultimate user, a controlled substance in a single dose or in such quantity as is, in the opinion of such physician, dentist, podiatrist, optometrist, nurse practitioner, physician assistant, certified midwife, psychiatric nurse mental health clinical specialist or veterinarian, essential for the treatment of the patient; provided, however, that such amount or quantity of such controlled substance shall not exceed the amount needed for the immediate treatment of the patient and that all such controlled substances required by the patient as part of such treatment shall be dispensed by prescription to such ultimate user in accordance with the

provisions of this chapter. For the purposes of this section, the words "amount needed for the immediate treatment of the patient" shall mean the quantity of a controlled substance which is necessary for the proper treatment of the patient until it is possible for such patient to have a prescription filled by a pharmacy.

This section shall not be construed to prohibit or limit the dispensing of any prescription medication that is classified by the department of public health as schedule VI and that is provided free of charge by the manufacturer as part of an indigent patient program or for use as samples if such prescription medications are: (1) dispensed to the patient by a professional authorized to dispense controlled substances pursuant to this section; (2) dispensed in the package provided by the manufacturer; and (3) provided at no charge to the patient. The department shall promulgate rules and regulations governing the dispensing of medication pursuant to this section. Said rules and regulations shall include, but not be limited to, the types and amounts of medications that may be dispensed and the appropriate safeguards for the labeling and dispensing of such medications.

(c) A nurse who has obtained from a physician, dentist, physician assistant, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian, a controlled substance for dispensing to an ultimate user, pursuant to the provisions of paragraph (b) or for administration to a patient pursuant to the provisions of paragraph (a), during the absence of such physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian shall return to such physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner, psychiatric nurse mental health clinical specialist, pharmacist or veterinarian any unused portion of such substance which is no longer required by the patient.

(d) Every physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse practitioner or psychiatric nurse mental health clinical specialist, pharmacist or veterinarian shall, in the course of a professional practice, keep and maintain records open to inspection by the commissioner during reasonable business hours, which shall contain the names and quantities of any controlled substances in Schedule I, II or III received by such practitioner; the name and address of the patient to whom such controlled substance is administered or dispensed; the name, dosage and strength per dosage unit of such controlled substance and the date of such administration or dispensing.

(e) Notwithstanding the provisions of paragraph (b), a physician, nurse practitioner, physician assistant, pharmacist as limited by said paragraph (g) of said section 7 and section 24 of said chapter 112, or certified nurse-midwife, when acting in good faith and providing care under a program funded in whole or in part by 42 USC 300, or in a clinic licensed by the department to provide comparable medical services or a registered nurse, registered pursuant to the provisions of section seventy-four of chapter one hundred and twelve and authorized by such physician, nurse practitioner, physician assistant, pharmacist as limited by said paragraph (g) of said section 7 and section 24 of said chapter 112, or certified nurse-midwife may lawfully dispense controlled substances pursuant to Schedule VI to recipients of such services in such quantity as needed for treatment, and shall be exempt from the requirement that such dispensing be in a single dosage or as necessary for immediate treatment; provided, however, that such registered nurse shall not so dispense except as provided in section seventeen. The department may establish rules and regulations controlling the dispensing of said medications including, but not limited to, the types and amounts of medications dispensed and appropriate safeguards for dispensing.

S 2706, amended

AN ACT ESTABLISHING COLLABORATIVE DRUG THERAPY MANAGEMENT.

House of Representatives, January 6, 2009.

Rightly and Truly Prepared for Final Passage.

Steven T. James, House Clerk.

In Senate, January 6, 2009.

Rightly and Truly Prepared for Final Passage.

William T. Welch, Senate Clerk.

This Act originated in the Senate William T. Welch, Clerk.

2009 JAN 15 PM 4:02

SECRETARY OF STATE