

AN ACT TO ESTABLISH COLLABORATIVE DRUG THERAPY MANAGEMENT
TO IMPROVE PHARMACEUTICAL CARE FOR PATIENTS IN MASSACHUSETTS.

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. Notwithstanding any special acts, rules or laws to the contrary, aA 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.