

# SENATE NO. 420

## **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:*

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

3 "Collaborative drug therapy management" means the initiating, monitoring, modifying and  
4 discontinuing of a patient's drug therapy by a pharmacist in accordance with a collaborative practice  
5 agreement. Collaborative drug therapy management may include: collecting and reviewing patient  
6 histories, obtaining and checking vital signs, including pulse, temperature, blood pressure and  
7 respiration; and under the supervision of, or in direct consultation with a physician, ordering and  
8 evaluating the results of laboratory tests directly related to drug therapy when performed in  
9 accordance with approved protocols applicable to the practice setting and providing such evaluation  
10 does not include any diagnostic component.

11 "Collaborative practice agreement" is a written and signed agreement, entered into voluntarily,  
12 between a pharmacist with advanced training and experience relevant to the scope of collaborative  
13 practice and one or more supervising physicians that defines the collaborative pharmacy practice in

14 which the pharmacist and supervising physician(s) propose to engage. The collaborative practice  
15 must be within the scope of practice of the supervising physician(s). Each collaborative practice  
16 agreement shall be subject to review and renewal on a biennial basis.

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

- 18 a. Hold a current license to practice pharmacy in Massachusetts;
- 19 b. Have at least \$1,000,000 of professional liability insurance;
- 20 c. Have earned a Pharm. D. degree or completed three (3) years of experience as a  
21 licensed pharmacist, or the equivalent; and
- 22 d. Complete at least five (5) additional contact hours or 0.5 continuing education units of  
23 board-approved continuing education each year. Such continuing education shall  
24 address the area(s) of practice generally related to the collaborative practice  
25 agreement(s).

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

- 27 a. Hospitals as licensed in section 51 of chapter one hundred eleven.
- 28 b. Long Term Care facilities as licensed in section 71 of chapter one hundred eleven.
- 29 c. Licensed inpatient or outpatient hospice settings as licensed in section 57D of chapter  
30 one hundred eleven.
- 31 d. Ambulatory care clinics, as licensed in section 51 of chapter one hundred eleven, with  
32 onsite supervision by the attending physician and with a collaborating pharmacist who  
33 has no connection to any retail pharmacy.
- 34 e. A collaborating pharmacist in a community retail drug business, as registered in section  
35 39 of chapter one hundred twelve, with supervision by a physician limited to the  
36 following diseases: asthma, chronic obstructive pulmonary disease, diabetes,

37 hypertension, hyperlipidemia, congestive heart failure, HIV/AIDS and osteoporosis, and  
38 all co-morbidities associated with the primary diagnosis. Notwithstanding any special  
39 acts, rules or laws to the contrary, a participating community retail drug business is not  
40 required to register as Health Facility under 105 CMR 700.004 (A) (2) (d).

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

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

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

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

71       The Board of Registration in Medicine and the Board of Registration in Pharmacy shall  
72 promulgate rules and regulations to implement the provisions of this act. To aid in the  
73 implementation, the Board of Registration in Medicine and the Board of Registration in Pharmacy  
74 will consult with at least one individual from each of the following groups: one individual to be an  
75 employee of the Department of Public Health; one individual from the Board of Registration in  
76 Medicine and one individual from the Board of Registration in Pharmacy; one or more individuals  
77 from Massachusetts Society of Health System Pharmacists, the Massachusetts Chapter of the  
78 American Society of Consultant Pharmacists, the Massachusetts Pharmacists Association, the  
79 Massachusetts Independent Pharmacists Association, the Massachusetts Chain Pharmacy Council,  
80 the Massachusetts College of Pharmacy and Health Sciences and the Bouve College of Health  
81 Sciences at Northeastern University; and, one or more individuals from Massachusetts Medical

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

97 SECTION 4. Section 9 of said chapter 94C is hereby amended by striking out paragraph (a),  
98 (b), (c), (d) and (e) as so appearing, and inserting in place thereof the following: –  
99 (a) A physician, dentist, podiatrist, optometrist as limited by sections 66 and 66B of chapter 112 and  
100 paragraph (h) of section 7, nurse practitioner and psychiatric nurse mental health clinical specialist  
101 as limited by paragraph (g) of said section 7 and section 80E of said chapter 112, physician assistant  
102 as limited by said paragraph (g) of said section 7 and section 9E of said chapter 112, a certified  
103 nurse-midwife as provided in section 80C of said chapter 112, pharmacist as limited by said  
104 paragraph (g) of said section 7 and section 24 of said chapter 112, or a veterinarian when registered

105 pursuant to the provisions of said section 7 and acting in accordance with the provisions of  
106 applicable federal law and any provision of this chapter which is consistent with federal law, in  
107 good faith and in the course of a professional practice for the alleviation of pain and suffering or for  
108 the treatment or alleviation of disease, may possess such controlled substances as may reasonably  
109 be required for the purpose of patient treatment and may administer controlled substances or may  
110 cause the same to be administered under his direction by a nurse.

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

128 necessary for the proper treatment of the patient until it is possible for such patient to have a  
129 prescription filled by a pharmacy.

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

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

148 (d) Every physician, physician assistant, dentist, podiatrist, certified nurse-midwife, nurse  
149 practitioner or psychiatric nurse mental health clinical specialist, pharmacist or veterinarian shall, in  
150 the course of a professional practice, keep and maintain records open to inspection by the

151 commissioner during reasonable business hours, which shall contain the names and quantities of  
152 any controlled substances in Schedule I, II or III received by such practitioner; the name and  
153 address of the patient to whom such controlled substance is administered or dispensed; the name,  
154 dosage and strength per dosage unit of such controlled substance and the date of such  
155 administration or dispensing.

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