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Legislative Document

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S.P. 395

In Senate, March 21, 2013

**An Act To Allow Collaborative Practice Agreements between
Authorized Practitioners and Pharmacists**

Reference to the Committee on Labor, Commerce, Research and Economic Development suggested and ordered printed.

A handwritten signature in black ink, appearing to read 'D M Grant'.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator CUSHING of Penobscot.
Cosponsored by Representative MALABY of Hancock and
Senators: COLLINS of York, HAMPER of Oxford, KATZ of Kennebec, THIBODEAU of
Waldo, Representatives: HARVELL of Farmington, NUTTING of Oakland, PARRY of
Arundel, SIROCKI of Scarborough.

1 **Be it enacted by the People of the State of Maine as follows:**

2 **Sec. 1. 32 MRSA §13702-A, sub-§§2-A and 2-B** are enacted to read:

3 **2-A. Collaborative drug therapy management.** "Collaborative drug therapy
4 management" means the initiating, monitoring, modifying and discontinuing of a patient's
5 drug therapy by a pharmacist in accordance with a collaborative practice agreement.
6 "Collaborative drug therapy management" includes collecting and reviewing patient
7 histories; obtaining and checking vital signs, including pulse, temperature, blood pressure
8 and respiration; and, under the supervision of, or in direct consultation with, a
9 practitioner, ordering and evaluating the results of laboratory tests directly related to drug
10 therapy when performed in accordance with approved protocols applicable to the practice
11 setting and when the evaluation does not include a diagnostic component.

12 **2-B. Collaborative practice agreement.** "Collaborative practice agreement" means
13 a written and signed agreement between one or more pharmacists with training and
14 experience relevant to the scope of the collaborative practice and a practitioner that
15 supervises or provides direct consultation to the pharmacist or pharmacists engaging in
16 collaborative drug therapy management that:

17 A. Defines the collaborative practice, which must be within the scope of the
18 supervising practitioner's practice, in which the pharmacist or pharmacists may
19 engage;

20 B. States the beginning and ending dates of the period of time during which the
21 agreement is in effect; and

22 C. Includes individually developed guidelines for the prescriptive practice of the
23 participating pharmacist or pharmacists.

24 **Sec. 2. 32 MRSA §13702-A, sub-§28**, as amended by PL 2011, c. 577, §1, is
25 further amended to read:

26 **28. Practice of pharmacy.** "Practice of pharmacy" means the interpretation and
27 evaluation of prescription drug orders; the compounding, dispensing and labeling of
28 drugs and devices, except labeling by a manufacturer, packer or distributor of
29 nonprescription drugs and commercially packaged legend drugs and devices; the
30 participation in drug selection and drug utilization reviews; the proper and safe storage of
31 drugs and devices and the maintenance of proper records for these drugs and devices; the
32 administration of vaccines licensed by the United States Food and Drug Administration
33 that are recommended by the United States Centers for Disease Control and Prevention
34 Advisory Committee on Immunization Practices, or successor organization, for
35 administration to adults; the performance of collaborative drug therapy management; the
36 responsibility for advising, when necessary or regulated, of therapeutic values, content,
37 hazards and use of drugs and devices; and the offering or performing of those acts,
38 services, operations or transactions necessary in the conduct, operation, management and
39 control of a pharmacy.

40 **Sec. 3. 32 MRSA §13735, first ¶**, as amended by PL 2009, c. 308, §2, is further
41 amended to read:

1 An annual renewal license may not be issued by the board until the applicant certifies
2 to the board that, during the calendar year preceding an application for renewal, the
3 applicant has participated in not less than 15 hours of approved courses of continuing
4 professional pharmaceutical education as set out in this section. Of the 15 hours to be
5 completed, at least 2 hours must be in board-approved courses on drug administration as
6 described in section 13702-A, subsection 28. A pharmacist who enters into a
7 collaborative practice agreement must agree to complete, in each year of the agreement, 5
8 of the 15 hours required in this section in the areas of practice covered by the agreement.
9 The continuing professional pharmaceutical educational courses consist of postgraduate
10 studies, institutes, seminars, workshops, lectures, conferences, extension studies,
11 correspondence courses or such other forms of continuing professional pharmaceutical
12 education as may be approved by the board.

13 **Sec. 4. 32 MRSA c. 117, sub-c. 14** is enacted to read:

14 **SUBCHAPTER 14**

15 **COLLABORATIVE DRUG THERAPY MANAGEMENT**

16 **§13841. Authority**

17 **1. Engage in collaborative drug therapy management.** A pharmacist licensed in
18 this State who meets the qualifications and requirements of section 13842 and rules
19 adopted by the board may engage in collaborative drug therapy management pursuant to
20 a collaborative practice agreement with a practitioner.

21 **2. Scope of authority.** A pharmacist engaging in collaborative drug therapy
22 management pursuant to subsection 1 is entitled to adequate access to a patient's history,
23 disease status, drug therapy and laboratory and procedure results and may:

24 A. Collect and review a patient's history;

25 B. Obtain and check vital signs;

26 C. Order and evaluate the results of laboratory tests directly related to drug therapy
27 under the supervision of, or in direct consultation with, a practitioner and in
28 accordance with approved protocols applicable to the practice setting and when the
29 evaluation does not include a diagnostic component; and

30 D. Initiate, monitor, modify and discontinue drug therapy for a particular patient
31 pursuant to the collaborative practice agreement with the practitioner.

32 **§13842. Qualifications**

33 In order to enter into a collaborative practice agreement with a practitioner under this
34 subchapter, a pharmacist must:

35 **1. License.** Hold a valid unrestricted pharmacist license in this State;

36 **2. Training.** Submit evidence acceptable to the board that the pharmacist:

1 A. Possesses certification from the Board of Pharmacy Specialties or successor
2 organization or has completed an accredited residency program. If the residency
3 program is not in the area of practice covered by the agreement, the pharmacist must
4 complete a continuing education certificate program or at least 15 hours of continuing
5 education in the area of practice covered by the agreement;

6 B. Has graduated with a Doctor of Pharmacy degree from a college of pharmacy
7 accredited by the American Council on Pharmaceutical Education, has 2 years of
8 professional experience and has completed a continuing education certificate program
9 or at least 15 hours of continuing education in the area of practice covered by the
10 agreement; or

11 C. Has graduated with a Bachelor of Science in Pharmacy degree from a college of
12 pharmacy accredited by the American Council on Pharmaceutical Education, has 3
13 years of professional experience and has completed a continuing education certificate
14 program or at least 15 hours of continuing education in the area of practice covered
15 by the agreement.

16 **§13843. Collaborative practice agreement**

17 A pharmacist may engage in collaborative drug therapy management pursuant to a
18 collaborative practice agreement in accordance with this section.

19 **1. Submit to board.** The pharmacist shall submit a copy of the collaborative
20 practice agreement to the board prior to the commencement of the collaborative practice.

21 **2. Review and revision.** The signatories to a collaborative practice agreement shall
22 establish a procedure for reviewing and, if necessary, revising the procedures and
23 protocols of the collaborative practice agreement.

24 **3. Health information privacy.** Services provided pursuant to a collaborative
25 practice agreement must be performed in compliance with the federal Health Insurance
26 Portability and Accountability Act of 1996, 42 United States Code, Section 1320d et seq.
27 and its regulations, 45 Code of Federal Regulations, Parts 160-164.

28 **4. Amendments to agreement.** Amendments to a collaborative practice agreement
29 must be documented, signed and dated.

30 **5. Assessment; risk management.** A collaborative practice agreement must include
31 a plan for measuring and assessing patient outcomes and must include proof that liability
32 insurance is maintained by all parties to the agreement.

33 **6. Contents of agreement.** A practitioner and a pharmacist desiring to engage in
34 collaborative practice in accordance with this subchapter shall execute a collaborative
35 practice agreement that must contain, but is not limited to:

36 A. Identification and signatures of the parties to the collaborative practice agreement,
37 the dates the agreement is signed and the beginning and ending dates of the period of
38 time during which the agreement is in effect;

- 1 B. A provision that allows either party to cancel the collaborative practice agreement
- 2 by written notification;
- 3 C. Specification of the site and setting at which the collaborative practice will occur;
- 4 D. Specification of the qualifications of the participants in the collaborative practice
- 5 agreement; and
- 6 E. A detailed description of the types of diseases, drugs or drug categories involved
- 7 and collaborative drug therapy management allowed in each patient's case.

8 **§13844. Conditions or diseases managed; scope of practice**

9 **1. Generally accepted standards of care.** A pharmacist may engage in

10 collaborative drug therapy management pursuant to a collaborative practice agreement

11 only for conditions or diseases with generally accepted standards of care.

12 **2. Prohibition.** A pharmacist who is engaged in collaborative drug therapy

13 management pursuant to a collaborative practice agreement may not, as part of the

14 collaborative practice, participate in research or clinical or investigational trials.

15 **3. Limitation.** A collaborative practice agreement may include only the conditions

16 or diseases to be managed that meet the qualifications and scope of practice for each

17 party to the agreement.

18 **§13845. Practice protocols**

19 A pharmacist may engage in collaborative drug therapy management in compliance

20 with a treatment protocol established by the practitioner with whom the pharmacist has a

21 collaborative practice agreement. A copy of the treatment protocol must be submitted to

22 the board. At a minimum, the treatment protocol must include a statement by the

23 practitioner that describes the activities in which the pharmacist is authorized to engage

24 and a provision that allows the practitioner, when appropriate, to override a collaborative

25 practice decision made by the pharmacist.

26 **§13846. Rules**

27 The board, after consultation with the Department of Health and Human Services and

28 the Board of Licensure in Medicine, shall adopt rules to implement this subchapter. The

29 rules must include rules establishing record-keeping and documentation procedures and

30 reporting requirements and must allow for electronic filing when possible. Rules adopted

31 pursuant to this section are routine technical rules as defined in Title 5, chapter 375,

32 subchapter 2-A.

33 **SUMMARY**

34 This bill authorizes licensed, qualified pharmacists in the State to engage in

35 collaborative drug therapy management pursuant to a collaborative practice agreement

36 with an authorized practitioner.