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Date: (Filing No. S-)

HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

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**STATE OF MAINE
SENATE
130TH LEGISLATURE
FIRST SPECIAL SESSION**

COMMITTEE AMENDMENT “ ” to S.P. 11, L.D. 4, “An Act To Amend the Maine Pharmacy Act”

Amend the bill by inserting after the title and before the enacting clause the following:

Emergency preamble. Whereas, acts and resolves of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, this legislation clarifies the definition of compounding under the Maine Pharmacy Act to include the compounding of drugs for distribution to licensed veterinarians for limited office use on behalf of their animal patients; and

Whereas, this legislation requires the Maine Board of Pharmacy to adopt rules establishing the terms and conditions for compounding for veterinarian office use; and

Whereas, this legislation prohibits compounding for veterinarian office use until rules are adopted; and

Whereas, it is important that this legislation take effect as soon as possible so that the rules can be adopted in an expedient manner; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore,'

Amend the bill by inserting before section 1 the following:

'Sec. 1. 10 MRSA §8003-H is enacted to read:

§8003-H. Licensure by endorsement

The Office of Professional and Occupational Regulation, referred to in this section as "the office," including the licensing boards and commissions within the office, shall establish a process to issue a license by endorsement to an applicant who presents proof of licensure by another jurisdiction of the United States as long as the other jurisdiction

COMMITTEE AMENDMENT

1 maintains substantially equivalent license requirements for the licensed profession or
2 occupation and as long as:

3 **1. Good standing.** The applicant is in good standing in all jurisdictions in which the
4 applicant holds or has held a license. For purposes of this subsection, "good standing"
5 means that the applicant does not have a complaint, allegation or investigation pending,
6 does not have a license that is suspended or subject to practice restrictions and has never
7 surrendered a license or had a license revoked;

8 **2. No cause for denial.** No cause for denial of a license exists under section 8003,
9 subsection 5-A, paragraph A or under any other law; and

10 **3. Fee.** The applicant pays the fee, if any, pursuant to section 8003, subsection 2-A,
11 paragraph D.

12 The office, or a licensing board or commission within the office, may require an
13 applicant to pass a jurisprudence examination if such an examination is required to be
14 passed for licensure pursuant to law or rule of the office, licensing board or commission.

15 The office, including the licensing boards and commissions within the office, shall
16 adopt rules to implement this section. Rules adopted pursuant to this paragraph are routine
17 technical rules pursuant to Title 5, chapter 375, subchapter 2-A.

18 **Sec. 2. 32 MRSA §13702-A, sub-§4,** as enacted by PL 2007, c. 402, Pt. DD, §2,
19 is amended to read:

20 **4. Compounding.** "Compounding" means the preparation, mixing, assembling,
21 packaging or labeling of a drug or device by a pharmacist for the pharmacist's patient either
22 for dispensing as the result of a practitioner's prescription drug order, or for the purpose of,
23 or as an incident to, research, teaching or chemical analysis and not for sale or dispensing.
24 "Compounding" includes the preparation of drugs or devices in anticipation of prescription
25 drug orders to be received by the pharmacist based on routine, regularly observed
26 prescribing patterns.;

27 A. For the pharmacist's patient for dispensing as the result of a practitioner's
28 prescription drug order;

29 B. For the purpose of, or as an incident to, research, teaching or chemical analysis and
30 not for sale or dispensing;

31 C. In anticipation of prescription drug orders to be received by the pharmacist based
32 on routine, regularly observed prescribing patterns for the pharmacist's patient; or

33 D. For nonpatient-specific drugs for distribution to licensed veterinarians for
34 veterinarian office use for nonfood-producing animals, as that term is defined in board
35 rule.'

36 Amend the bill by inserting after section 2 the following:

37 **'Sec. 3. 32 MRSA §13722, sub-§1, ¶B-1,** as enacted by PL 1999, c. 130, §6, is
38 amended to read:

39 B-1. Establish standards for the use, maintenance and supervision of automated
40 pharmacy systems.;

41 **Sec. 4. 32 MRSA §13722, sub-§1, ¶B-2** is enacted to read:

1 B-2. Establish the terms and conditions for compounding drugs for veterinarian office
2 use by rule, including, at a minimum:

3 (1) Requirements and specifications of minimum professional and technical
4 equipment, environments, supplies and procedures and quality assurance
5 requirements;

6 (2) Labeling requirements;

7 (3) Limits on the supply for administration to the veterinarian's patient and the
8 supply for dispensing to the veterinarian's client;

9 (4) Record-keeping requirements; and

10 (5) Procedures for notifications regarding defective drug products and adverse
11 events.

12 Compounding drugs for veterinarian office use is not permitted until rules are adopted
13 by the board pursuant to this paragraph. Rules adopted pursuant to this paragraph are
14 routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.'

15 Amend the bill by striking out all of section 5 and inserting the following:

16 '**Sec. 5. 32 MRSA §13733-A** is enacted to read:

17 **§13733-A. Licensure by endorsement**

18 In order to obtain a license as a pharmacist by endorsement, an applicant for licensure
19 must meet the requirements of Title 10, section 8003-H and any applicable rules adopted
20 pursuant to that section.'

21 Amend the bill by inserting after section 10 the following:

22 '**Sec. 11. Consultation with State Board of Veterinary Medicine.** The Maine
23 Board of Pharmacy shall consult with the State Board of Veterinary Medicine in the
24 establishment of the terms and conditions for compounding drugs for veterinarian office
25 use pursuant to the Maine Revised Statutes, Title 32, section 13722, subsection 1,
26 paragraph B-2.'

27 Amend the bill by adding before the summary the following:

28 '**Emergency clause.** In view of the emergency cited in the preamble, this legislation
29 takes effect when approved.'

30 Amend the bill by relettering or renumbering any nonconsecutive Part letter or section
31 number to read consecutively.

32 **SUMMARY**

33 This amendment clarifies the definition of compounding under the Maine Pharmacy
34 Act to include the compounding of drugs for distribution to licensed veterinarians for
35 limited office use on behalf of their animal patients. The amendment directs the Maine
36 Board of Pharmacy to adopt rules to establish the terms and conditions for the compounding
37 and distributing of animal drugs for nonpatient-specific use in veterinary offices and
38 prohibits compounding for veterinarian office use until rules are adopted. The amendment
39 requires that the Maine Board of Pharmacy consult with the State Board of Veterinary
40 Medicine.

1 The amendment removes the provision in the bill related to licensure by endorsement
2 and replaces the language with a cross-reference to a new provision authorizing all
3 licensing boards to grant licensure by endorsement.

4 The amendment also adds an emergency preamble and emergency clause.

5 **FISCAL NOTE REQUIRED**

6 **(See attached)**