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No. 1315

H.P. 934

House of Representatives, April 2, 2013

An Act To Ensure the Safety of Compounded Drugs

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

Millicent M. MacFarland
MILLICENT M. MacFARLAND
Clerk

Presented by Representative TREAT of Hallowell.
Cosponsored by Senator CRAVEN of Androscoggin and
Representatives: FARNSWORTH of Portland, GATTINE of Westbrook, GRAHAM of North
Yarmouth, PRINGLE of Windham, SANBORN of Gorham.

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

2 **PART A**

3 **Sec. A-1. 32 MRSA §13702-A, sub-§4-A** is enacted to read:

4 **4-A. Compounding pharmacy.** "Compounding pharmacy" means a pharmacy that
5 compounds drugs in compliance with the provisions of this chapter and the Federal Food,
6 Drug, and Cosmetic Act. "Compounding pharmacy" includes a nonsterile compounding
7 pharmacy that meets the requirements for a compounding pharmacy and the requirements
8 for a nonsterile compounding pharmacy as published in a nationally recognized
9 compendium of drug substances, dosage forms and compounded preparations and a
10 sterile compounding pharmacy that meets the requirements for a compounding pharmacy
11 and the requirements for a sterile compounding pharmacy as published in a nationally
12 recognized compendium of drug substances, dosage forms and compounded preparations.

13 **Sec. A-2. 32 MRSA §13712**, as amended by PL 2007, c. 402, Pt. DD, §3, is
14 further amended to read:

15 **§13712. Membership**

16 The board consists of 7 members, ~~two~~ 2 of whom must be public members as defined
17 in Title 5, section 12004-A and the remainder of whom must be licensed pharmacists who
18 possess the qualifications specified in section 13713. At the time of the appointment, at
19 least one of the licensed pharmacists must be a hospital pharmacist, at least one must be a
20 chain pharmacist and at least one must be an independent pharmacist. This paragraph is
21 repealed January 1, 2014.

22 Beginning with appointments made on or after January 1, 2014, the board consists of
23 7 members, 2 of whom must be public members as defined in Title 5, section 12004-A,
24 one of whom must be a physician licensed to practice under Title 32, chapter 36 or 48
25 who has experience in public health, one of whom must be an advanced practice
26 registered nurse approved to practice under Title 32, section 2205-B and the remainder of
27 whom must be licensed pharmacists who possess the qualifications specified in section
28 13713. At the time of the appointment, at least one of the licensed pharmacists must be a
29 hospital pharmacist, at least one must be a chain pharmacist and at least one must be an
30 independent pharmacist.

31 **Sec. A-3. 32 MRSA §13713, sub-§1**, as enacted by PL 1987, c. 710, §5, is
32 amended to read:

33 **1. Public members.** The public members of the board must be residents of this State
34 who are at least 21 years of age and ~~shall~~ may not be, nor ever have been, members of the
35 profession of pharmacy, the spouse of a member of the profession of pharmacy, a person
36 who has ever had any material financial interest in providing pharmacy services or a
37 person who has engaged in any activity directly related to the practice of pharmacy.
38 Beginning with appointments made on or after January 1, 2014, one of the public
39 members must be a person who has education and professional experience in the field of
40 health care safety and quality assurance.

1 **Sec. A-4. 32 MRSA §13715-B** is enacted to read:

2 **§13715-B. Annual disclosure statement**

3 Each member of the board shall file a disclosure statement by December 31st each
4 year that discloses any conflicts of interest of the member. The board shall make
5 available to the public on the board's website copies of the disclosure statements filed by
6 board members. The board shall adopt rules to implement this section. Rules adopted
7 pursuant to this section are routine technical rules as defined in Title 5, chapter 375,
8 subchapter 2-A.

9 **Sec. A-5. 32 MRSA §13721, sub-§1**, as amended by PL 2011, c. 496, §2, is
10 further amended to read:

11 **1. Responsibility.** The board's responsibility for the control and regulation of the
12 practice of pharmacy in this State includes, but is not limited to, the following actions:

13 A. The licensing by examination or by reciprocity of applicants who are qualified to
14 engage in the practice of pharmacy under this Act;

15 B. The renewal of licenses to engage in the practice of pharmacy;

16 C. The determination and issuance of standards for recognition and approval of
17 degree programs of schools and colleges of pharmacy whose graduates shall be
18 eligible for licensure in this State and the specification and enforcement of
19 requirements for practical training, including internship;

20 D. The inspection during business hours of all pharmacies, dispensaries, stores,
21 hospital pharmacies, extended care facilities, boarding homes, nursing homes, drug
22 abuse treatment centers, penal institutions, family planning centers or other drug
23 outlets in which drugs or medicines are manufactured, stored, distributed,
24 compounded, dispensed or retailed in this State;

25 E. The licensing of any pharmacy as set out in section 13751 ~~and~~, any manufacturer
26 or wholesaler whose products are distributed in this State and any pharmacy that
27 compounds drugs that is licensed in another state and that compounds drugs that are
28 delivered or dispensed in the State;

29 F. The enforcement of those provisions of this Act relating to the conduct or
30 competence of pharmacists practicing in this State and the processing of complaints
31 which could lead to the suspension, revocation or restriction of licenses to engage in
32 the practice of pharmacy;

33 G. The licensing of pharmacy interns and adoption of rules governing the training,
34 qualification and employment of pharmacy interns and pharmacy students; ~~and~~

35 H. The licensing of pharmacy technicians, including the fee as set under section
36 13724, and adoption of rules governing the training, qualification and employment of
37 pharmacy technicians, including separate licensing categories for pharmacy
38 technicians licensed for employment in sterile compounding pharmacies and in
39 nonsterile compounding pharmacies;

1 I. Participation in a national data reporting system that provides information on
2 individual pharmacies, pharmacists and pharmacy technicians;

3 J. The imposition of a fine for a violation of this chapter as provided in section
4 13754, subsection 1;

5 K. Consultation with the Board of Licensure in Medicine on rules adopted pursuant
6 to section 3269, subsection 18 for the compounding of drugs by physicians and
7 consultation with the Board of Osteopathic Licensure on rules adopted pursuant to
8 section 2581 for the compounding of drugs by osteopathic physicians;

9 L. The publication of a list, developed in cooperation with the Commissioner of
10 Health and Human Services pursuant to Title 22, section 1834, of medications that
11 may not be compounded by compounding pharmacies without prior approval of the
12 board and a list of medications that may not be compounded by physicians without
13 the approval of the Board of Licensure in Medicine or the Board of Osteopathic
14 Licensure, as applicable to the physician. In developing the lists of medications, the
15 board and the Commissioner of Health and Human Services shall consider market
16 availability of the medications, shortage of the medications, risk to patients and
17 patient rights and cost;

18 M. Appointing and convening advisory committees to make recommendations to the
19 board on licensure requirements under this chapter and qualifications for pharmacy
20 personnel, compounding specifications and standards and continuing education
21 standards; and

22 N. Making available to the public on the board's website information regarding all
23 enforcement and disciplinary actions taken by the board related to pharmacies,
24 pharmacists and pharmacy technicians in the State and information regarding
25 pharmacy inspection results. Information made available to the public under this
26 paragraph must be in a format that enables members of the public to search the
27 information by name of pharmacy, pharmacist and pharmacy technician.

28 **Sec. A-6. 32 MRSA §13721, sub-§2,** as amended by PL 1997, c. 245, §8, is
29 further amended to read:

30 **2. Reciprocal inspections.** The board may enter into reciprocal inspection
31 agreements with any state in which a mail order prescription facility selling drugs to
32 Maine citizens is located and any state in which a pharmacy is located that compounds
33 drugs that are delivered or dispensed in the State.

34 **Sec. A-7. 32 MRSA §13722, sub-§1, ¶¶B and C,** as enacted by PL 1987, c.
35 710, §5, are amended to read:

36 B. Establish the specifications of minimum professional and technical equipment,
37 environment, supplies and procedure for the compounding or dispensing of
38 medications, drugs, devices and other materials within the practice of pharmacy.
39 Specifications established under this paragraph must include specifications for sterile
40 and nonsterile compounding pharmacies licensed in the State and for pharmacies that
41 compound drugs that are delivered or dispensed in the State and that are licensed in
42 another state;

1 C. ~~Assure~~ Ensure that standards for purity and quality of medications, drugs, devices
2 and other materials within the practice of pharmacy are met. Standards for purity and
3 quality pursuant to this paragraph must include standards for sterile and nonsterile
4 compounding pharmacies licensed in the State and for pharmacies that compound
5 drugs that are delivered or dispensed in the State and that are licensed in another
6 state;

7 **Sec. A-8. 32 MRSA §13722, sub-§1, ¶D**, as amended by PL 2007, c. 402, Pt.
8 DD, §9, is further amended to read:

9 D. Issue and renew licenses for purposes of ascertaining those persons engaged in
10 the manufacture and distribution of drugs and for purposes of ascertaining those
11 pharmacies that compound drugs that are delivered or dispensed in the State and that
12 are licensed in another state;

13 **Sec. A-9. 32 MRSA §13723, sub-§7**, as amended by PL 2009, c. 415, Pt. A, §19,
14 is further amended to read:

15 **7. Investigatory powers.** The board shall notify the Department of the Attorney
16 General upon receipt of a complaint. Upon receipt of the notifications, the Attorney
17 General shall notify the department within a timely period if the alleged violation requires
18 criminal investigation. If a case does not require criminal investigation, the board or its
19 authorized representatives may investigate and gather evidence concerning alleged
20 violations of this Act or of the rules of the board. The board or an authorized
21 representative pursuant to paragraph A may remove from any premises authorized for
22 inspection pursuant to section 13721, subsection 1, paragraph D certain original records
23 relating to scheduled drugs or controlled substances, including, but not limited to,
24 prescription records, shipping and delivery records, patient profiles, inventories, all
25 documentation related to the compounding of drugs and the delivery, distribution and
26 dispensing of compounded drugs and other drug records for the purposes of analysis,
27 duplication and furthering the investigation. A signed inventory receipt of any records
28 being removed must be furnished to the premises by the board or an authorized
29 representative. When a means of producing legible photocopies is readily available at the
30 site of the records being removed, an authorized representative removing the records shall
31 leave photocopies of the records as part of an inventory receipt in accordance with this
32 subsection. Except when photocopies are left as part of an inventory receipt, the board or
33 an authorized representative removing records from the premises shall, within 48 hours
34 from the time of removal, provide to a representative of the premises photocopies of any
35 removed records, together with a certificate identifying the agency in possession of the
36 records, or return the original records. Inventory receipts and photocopies of any
37 removed records provided by the board or an authorized representative are admissible as
38 evidence if offered by any representative of the premises to prove compliance with any
39 rule of the board or requirement of law.

40 A. Prescriptions, orders and records required by this chapter and stocks of
41 prescription and legend drugs are open only to the board, the board's authorized
42 representatives, federal and state law enforcement officers whose duty it is to enforce
43 the laws of this State or of the United States relating to scheduled drugs or controlled
44 substances or to enforce conditions of probation or other supervision imposed by a

1 court relating to scheduled drugs or controlled substances and other law enforcement
2 officers authorized by the board, the Attorney General or the district attorney for the
3 purposes of inspecting, investigating and gathering evidence of violations of law or
4 any rule of the board. A person having knowledge by virtue of the person's office of
5 any such prescription, order or record may not divulge that knowledge, except before
6 a licensing board or representative or in connection with a prosecution or proceeding
7 in court.

8 B. The ~~Bureau of Health~~ Department of Health and Human Services, Maine Center
9 for Disease Control and Prevention, the board, their officers, agents, inspectors and
10 representatives, all peace officers within the State and all prosecuting attorneys shall
11 enforce all provisions of this chapter, except those specifically delegated, and shall
12 cooperate with all agencies charged with the enforcement of the laws of the United
13 States, of this State and of all other states relating to prescription or legend drugs or
14 their equivalent and to sterile and nonsterile compounding pharmacies licensed in the
15 State and to sterile and nonsterile pharmacies that compound drugs that are delivered
16 or dispensed in the State and that are licensed in another state.

17 **Sec. A-10. 32 MRSA §13724**, as amended by PL 2007, c. 402, Pt. DD, §11 and
18 PL 2011, c. 286, Pt. B, §5, is further amended to read:

19 **§13724. Fees**

20 The Director of the Office of Professional and Occupational Regulation may establish
21 by rule fees for purposes authorized under this chapter in amounts that are reasonable and
22 necessary for their respective purposes, except that the fee for any one purpose may not
23 exceed \$325. The fee schedule established under this section must establish different fees
24 for pharmacies that do not compound drugs, pharmacies that are sterile compounding
25 pharmacies and pharmacies that are nonsterile compounding pharmacies. Rules adopted
26 pursuant to this section are routine technical rules as defined in Title 5, chapter 375,
27 subchapter 2-A.

28 **Sec. A-11. 32 MRSA §13735, 2nd ¶**, as amended by PL 2009, c. 308, §2, is
29 further amended to read:

30 These courses consist of subject matter pertinent to the following general areas of
31 professional pharmaceutical education: the socioeconomic and legal aspects of health
32 care; the properties and actions of drugs and dosage forms; and the ideology,
33 characteristics and therapeutics of the disease state. The specific subject matter of the
34 courses may include, but is not limited to, pharmacology, biochemistry, physiology,
35 pharmaceutical chemistry, sterile and nonsterile compounding of drugs, pharmacy
36 administration, drug administration as it relates to the area of permitted practice,
37 pharmacy jurisprudence, public health and communicable diseases, pharmaceutical
38 marketing, professional practice management, anatomy, histology and such other subject
39 matter as represented in curricula of accredited colleges of pharmacy. The content of each
40 course offered for credit under this continuing professional educational program must be
41 approved in advance of the course by the board or its representative. The board may make
42 exceptions to this section in emergency or hardship cases.

1 **Sec. A-12. 32 MRSA §13751, sub-§2-A** is enacted to read:

2 **2-A. Compounding pharmacies.** In addition to a license in one of the
3 classifications in subsection 2, a pharmacy that compounds drugs shall apply for a license
4 as a compounding pharmacy and shall specify whether the pharmacy is a sterile
5 compounding pharmacy or a nonsterile compounding pharmacy.

6 **Sec. A-13. 32 MRSA §13751, sub-§3**, as amended by PL 2007, c. 402, Pt. DD,
7 §23, is further amended to read:

8 **3. Rules.** The board shall establish by rule the criteria that each pharmacy must meet
9 to qualify for licensure in each classification designated in subsection 2 and pursuant to
10 subsection 2-A. The board may issue various types of licenses with varying restrictions to
11 the pharmacies referred to in subsection 2, paragraph A when the board determines it
12 necessary by reason of the type of pharmacy requesting a license.

13 **Sec. A-14. 32 MRSA §13751, sub-§5** is enacted to read:

14 **5. Out-of-state pharmacies that compound drugs for delivery or dispensing in**
15 **the State.** A pharmacy that is licensed in another state and that compounds drugs that are
16 delivered or dispensed in this State shall annually obtain a license from the board under
17 subsection 1 and shall comply with subsections 2 and 2-A and all other applicable
18 provisions of this chapter.

19 **Sec. A-15. 32 MRSA §13752, sub-§2**, as amended by PL 2007, c. 402, Pt. DD,
20 §24, is further amended to read:

21 **2. Required information.** Applications for licenses must include the fee as set under
22 section 13724 and the following information about the proposed pharmacy and
23 pharmacist in charge:

24 A. Ownership of the pharmacy;

25 B. Location of the pharmacy;

26 C. Identity of the pharmacist licensed to practice in the State who will be the
27 pharmacist in charge of the pharmacy, when one is required by this chapter, and such
28 further information as the board may determine necessary. A pharmacist may be the
29 pharmacist in charge for only one pharmacy, except upon the pharmacist applying for
30 and receiving written authorization from the board. The position of pharmacist in
31 charge may not be held by a qualified assistant pharmacist; ~~and~~

32 D. A certification by the pharmacist identified as the pharmacist in charge that the
33 pharmacist has read and understands the requirements and duties of a pharmacist in
34 charge set forth in board rules; and

35 E. Whether the pharmacy will operate as a sterile compounding pharmacy or a
36 nonsterile compounding pharmacy or will not operate as a compounding pharmacy.

37 **Sec. A-16. 32 MRSA §13754, sub-§3** is enacted to read:

1 **3. Out-of-state pharmacies.** A compounding pharmacy or a pharmacy that is
2 licensed in another state that compounds drugs that are delivered or dispensed in the State
3 shall comply with the requirements of this chapter. A pharmacy that violates this chapter
4 commits a Class C crime for which a fine of not more than \$25,000 may be adjudged.

5 **PART B**

6 **Sec. B-1. 22 MRSA §§1833 to 1835** are enacted to read:

7 **§1833. Compounding pharmacies in hospitals and nursing facilities**

8 The department, after consultation with the Maine Board of Pharmacy, shall adopt
9 rules regarding compounding pharmacies in hospitals that compound drugs for use by
10 patients of the hospital and compounding pharmacies in nursing facilities that compound
11 drugs for use by patients of the nursing facility. Rules adopted pursuant to this section
12 apply in addition to any provisions of Title 32, chapter 117, subchapter 5 and are routine
13 technical rules as defined in Title 5, chapter 375, subchapter 2-A.

14 **§1834. Limitation on authority to compound drugs**

15 The commissioner shall publish a list, developed in cooperation with the Maine
16 Board of Pharmacy pursuant to Title 32, section 13721, subsection 1, paragraph L, of
17 medications that may not be compounded by compounding pharmacies without prior
18 approval of the board and a list of medications that may not be compounded by
19 physicians without the approval of the Board of Licensure in Medicine or the Board of
20 Osteopathic Licensure, as applicable to the physician. In developing the lists of
21 medications, the commissioner and the Maine Board of Pharmacy shall consider market
22 availability of the medications, shortage of the medications, risk to patients, patient rights
23 and cost.

24 **§1835. Prohibited drug purchases**

25 A hospital, nursing facility or ambulatory surgical facility licensed under this chapter
26 may not purchase drugs compounded by a pharmacy or other entity that is not licensed in
27 the State. A violation of this section is a violation of the terms of licensure of the
28 hospital, nursing facility or ambulatory surgical center. The department shall adopt rules
29 to implement this section. Rules adopted pursuant to this section are routine technical
30 rules as defined in Title 5, chapter 375, subchapter 2-A.

31 **Sec. B-2. 22 MRSA §2149-B** is enacted to read:

32 **§2149-B. Prohibited drug purchases**

33 A home health care provider licensed under this chapter may not purchase drugs
34 compounded by a pharmacy or other entity that is not licensed in the State. A violation of
35 this section is a violation of the terms of licensure of the home health care provider. The
36 department shall adopt rules to implement this section. Rules adopted pursuant to this
37 section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

38 **Sec. B-3. 22 MRSA §7808** is enacted to read:

1 **§7808. Prohibited drug purchases**

2 A residential care facility, assisted housing program, drug treatment center or
3 children's home licensed under this chapter may not purchase drugs compounded by a
4 pharmacy or other entity that is not licensed in the State. A violation of this section is a
5 violation of the terms of licensure of the residential care facility, assisted housing
6 program, drug treatment center or children's home. The department shall adopt rules to
7 implement this section. Rules adopted pursuant to this section are routine technical rules
8 as defined in Title 5, chapter 375, subchapter 2-A.

9 **Sec. B-4. 22 MRSA §8624** is enacted to read:

10 **§8624. Prohibited drug purchases**

11 A hospice program licensed under this chapter may not purchase drugs compounded
12 by a pharmacy or other entity that is not licensed in the State. A violation of this section
13 is a violation of the terms of licensure of the hospice program. The department shall
14 adopt rules to implement this section. Rules adopted pursuant to this section are routine
15 technical rules as defined in Title 5, chapter 375, subchapter 2-A.

16 **Sec. B-5. 22-A MRSA §206, sub-§9** is enacted to read:

17 **9. Consultation services to the Maine Board of Pharmacy.** The commissioner,
18 through the Director of the Maine Center for Disease Control and Prevention, shall
19 provide consultation services to the Maine Board of Pharmacy on issues pertaining to
20 epidemiology and public health.

21 **Sec. B-6. 32 MRSA §2108-B** is enacted to read:

22 **§2108-B. Prohibited drug purchases**

23 An individual licensed under this chapter may not purchase drugs compounded by a
24 pharmacy or other entity that is not licensed in the State. A violation of this section is a
25 violation of the terms of licensure under this chapter. The board shall adopt rules to
26 implement this section. Rules adopted pursuant to this section are routine technical rules
27 as defined in Title 5, chapter 375, subchapter 2-A.

28 **Sec. B-7. 32 MRSA §2581**, as amended by PL 2001, c. 492, §6, is further
29 amended by adding at the end a new paragraph to read:

30 An osteopathic physician licensed under this section may compound drugs in the
31 physician's professional office for use by patients of the physician in accordance with
32 rules adopted by the board under this section after consultation with the Maine Board of
33 Pharmacy as provided in Title 32, section 13721, subsection 1, paragraph K.

34 **Sec. B-8. 32 MRSA §2600-C** is enacted to read:

1 **§2600-C. Prohibited drug purchases**

2 An osteopathic physician licensed under this chapter may not purchase drugs
3 compounded by a pharmacy or other entity that is not licensed in the State. A violation of
4 this section is a violation of the terms of licensure of the osteopathic physician. The
5 board shall adopt rules to implement this section. Rules adopted pursuant to this section
6 are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

7 **Sec. B-9. 32 MRSA §3269, sub-§16**, as amended by PL 2001, c. 260, Pt. H, §2,
8 is further amended to read:

9 **16. Executive director.** The power to appoint an executive director who serves at
10 the pleasure of the board and who shall assist the board in carrying out its administrative
11 duties and responsibilities under this chapter. The salary range for the executive director
12 must be set by the board within the range established by Title 2, section 6-C; ~~and~~

13 **Sec. B-10. 32 MRSA §3269, sub-§17**, as enacted by PL 2001, c. 260, Pt. H, §3,
14 is amended to read:

15 **17. Approval of licenses.** The power to direct staff to review and approve
16 applications for licensure or renewal in accordance with criteria established in law or in
17 rules adopted by the board. Licensing decisions made by staff may be appealed to the
18 full board; and

19 **Sec. B-11. 32 MRSA §3269, sub-§18** is enacted to read:

20 **18. Compounding of drugs.** The power to adopt rules that grant to a physician or
21 surgeon licensed under this chapter authorization to compound drugs in the physician's or
22 surgeon's professional office for use by patients of the physician or surgeon after
23 consultation with the Maine Board of Pharmacy as provided in Title 32, section 13721,
24 subsection 1, paragraph K. Rules adopted pursuant to this subsection are routine
25 technical rules as defined in Title 5, chapter 375, subchapter 2-A.

26 **Sec. B-12. 32 MRSA §3300-D** is enacted to read:

27 **§3300-D. Prohibited drug purchases**

28 A physician licensed under this chapter may not purchase drugs compounded by a
29 pharmacy or other entity that is not licensed in the State. A violation of this section is a
30 violation of the terms of licensure of the physician. The board shall adopt rules to
31 implement this section. Rules adopted pursuant to this section are routine technical rules
32 as defined in Title 5, chapter 375, subchapter 2-A.

33 **SUMMARY**

34 This bill strengthens Maine's laws on compounding pharmacies. The bill contains the
35 following provisions.

1 1. The bill provides a definition for "compounding pharmacy" and describes sterile
2 compounding pharmacies and nonsterile compounding pharmacies.

3 2. Beginning with appointments made on or after January 1, 2014, the bill adds a
4 physician and an advanced practice registered nurse to the Maine Board of Pharmacy,
5 decreases the number of pharmacist members from 5 to 3 and requires that one public
6 member be a person who has education and professional experience in the field of health
7 care safety and quality assurance. The bill requires members of the Maine Board of
8 Pharmacy to file by December 31st an annual statement disclosing any conflicts of
9 interest and requires the Maine Board of Pharmacy to post the statements on the board's
10 publicly accessible website.

11 3. The bill requires licensed pharmacies that are compounding pharmacies to obtain
12 a license as a compounding pharmacy and to specify whether the pharmacy is a nonsterile
13 compounding pharmacy or a sterile compounding pharmacy. The bill requires the Maine
14 Board of Pharmacy to adopt rules to establish the criteria for licensure as a compounding
15 pharmacy.

16 4. The bill extends the responsibility of the Maine Board of Pharmacy to include
17 licensing out-of-state compounding pharmacies that are licensed in another state and that
18 deliver or dispense drugs in the State. The bill grants to the Maine Board of Pharmacy
19 the authority to appoint and convene advisory committees and the responsibility to
20 impose a fine on a compounding pharmacy that violates the Maine Pharmacy Act. The
21 bill requires the Maine Board of Pharmacy to participate in a national data reporting
22 system on pharmacies, pharmacists and pharmacy technicians. The bill requires the
23 Maine Board of Pharmacy to license pharmacy technicians in 2 categories: those that are
24 licensed for employment in sterile compounding pharmacies and those that are licensed
25 for employment in nonsterile compounding pharmacies. The bill requires the Maine
26 Board of Pharmacy to make available to the public on its website, in a searchable format,
27 information regarding disciplinary and enforcement actions taken by the board and the
28 results of pharmacy inspections.

29 5. The bill further extends the responsibility of the Maine Board of Pharmacy to
30 allow consultation with the Board of Licensure in Medicine, the Board of Osteopathic
31 Licensure and the Commissioner of Health and Human Services regarding the
32 compounding of drugs.

33 6. The bill requires the Maine Board of Pharmacy to ensure standards for purity and
34 quality are met by compounding pharmacies.

35 7. With regard to the investigatory powers of the Maine Board of Pharmacy, the bill
36 adds documentation regarding compounding to the list of items that the board may
37 remove from a premises being inspected.

38 8. The bill requires the Department of Health and Human Services, Maine Center for
39 Disease Control and Prevention and the Maine Board of Pharmacy and law enforcement
40 to cooperate with other law enforcement agencies concerned with compounding
41 pharmacies.

1 9. The bill requires that licensing fees for pharmacies distinguish those that are not
2 compounding pharmacies from those that are compounding pharmacies and, among
3 compounding pharmacies, distinguish nonsterile compounding pharmacies from sterile
4 compounding pharmacies.

5 10. The bill adds sterile and nonsterile compounding of drugs to the specific subject
6 matter of course work for continuing education for pharmacists.

7 11. The bill makes a violation of the Maine Pharmacy Act by a compounding
8 pharmacy a Class C crime and authorizes a fine of up to \$25,000.

9 12. The bill requires the Department of Health and Human Services to adopt rules
10 regarding compounding pharmacies in hospitals and nursing facilities.

11 13. The bill requires the Commissioner of Health and Human Services, through the
12 Director of the Maine Center for Disease Control and Prevention, to provide consultation
13 services to the Maine Board of Pharmacy on issues related to epidemiology and public
14 health.

15 14. The bill prohibits licensed health care facilities and practitioners from purchasing
16 drugs compounded by a pharmacy or other entity that is not licensed in Maine, designates
17 such purchases a violation of the licensure statutes and directs the licensing authorities to
18 adopt rules to enforce the prohibition.