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Legislative Document **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.

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

PART A

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

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

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

§13712. Membership

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 This paragraph is repealed January 1, 2014.

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

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

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

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

§13715-B. Annual disclosure statement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§13724. Fees

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

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

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

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

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

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

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

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

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

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

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

A. Ownership of the pharmacy;

B. Location of the pharmacy;

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

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

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

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

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

PART B

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

§1833. Compounding pharmacies in hospitals and nursing facilities

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

§1834. Limitation on authority to compound drugs

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

§1835. Prohibited drug purchases

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

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

§2149-B. Prohibited drug purchases

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

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

§7808. Prohibited drug purchases

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

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

§8624. Prohibited drug purchases

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

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

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

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

§2108-B. Prohibited drug purchases

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

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

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

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

§2600-C. Prohibited drug purchases

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

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

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

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

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

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

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

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

§3300-D. Prohibited drug purchases

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

SUMMARY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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