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H.P. 434 House of Representatives, January 19, 1999

An Act to Update and Amend the Maine Pharmacy Act.

Submitted by the Department of Professional and Financial Regulation pursuant to Joint Rule 204.

Reference to the Committee on Business and Economic Development suggested and ordered printed.

JOSEPH W. MAYO, Clerk

Presented by Representative CAMERON of Rumford.
Cosponsored by Representatives: BRUNO of Raymond, NUTTING of Oakland, WESTON of Montville.

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

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

1-A. Automated pharmacy systems. "Automated pharmacy systems" means mechanical systems that perform operations or activities, other than compounding, relative to the storage, packaging, labeling, dispensing or distribution of medications, and systems that collect, control and maintain all transactional information.

Sec. 2. 32 MRSA §13702, sub-§2-A, is enacted to read:

2-A. Compounding. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device either for dispensing as the result of a practitioner's prescription drug order, or for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing. "Compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

Sec. 3. 32 MRSA §13702, sub-§10-A, is enacted to read:

10-A. Electronic transmission. "Electronic transmission" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

Sec. 4. 32 MRSA §13702, sub-§23, as enacted by PL 1987, c. 710, §5, is amended to read:

23. Practitioner. "Practitioner" means a ~~physician, dentist, podiatrist, veterinarian, scientific investigator or other person, other than pharmacists, licensed in the United States and Canada to dispense, conduct research with respect to or administer drugs in the course of professional practice or research~~ an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

Sec. 5. 32 MRSA §13702, sub-§25, as enacted by PL 1987, c. 710, §5, is amended to read:

25. Prescription drug order. "Prescription drug order" means a lawful written or oral order of a practitioner for a drug or device. Written orders may be issued on a prescription form or by electronic transmission.

Sec. 6. 32 MRSA §13722, sub-§1, ¶B-1 is enacted to read:

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

Sec. 7. 32 MRSA §13733, sub-§1, ¶G, as enacted by PL 1987, c. 710, §5, is amended to read:

G. Have presented to the board proof of initial licensure by examination and proof that the license and any other license or licenses granted to the applicant by any other state or states have not been suspended, revoked, canceled or otherwise restricted for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed, but not engaged in the practice of pharmacy. If an otherwise qualified applicant for licensure by reciprocity has had a license suspended, revoked, cancelled or otherwise restricted for any reason, the board may assess the prior disciplinary event and in its discretion issue the license; and

Sec. 8. 32 MRSA §13735, first ¶, as enacted by PL 1987, c. 710, §5, is amended to read:

~~No~~ An annual renewal certificate may not be issued by the board until the applicant submits proof satisfactory to the board that, during the calendar year preceding an application for renewal, the applicant has participated in not less than 15 hours of approved courses of continuing professional pharmaceutical education as set out in this section. The continuing professional pharmaceutical educational courses ~~shall~~ consist of postgraduate studies, institutes, seminars, workshops, lectures, conferences, extension studies, correspondence courses or such other forms of continuing professional pharmaceutical education as may be approved by the board.

Sec. 9. 32 MRSA §13741, third ¶, as amended by PL 1993, c. 600, Pt. A, §271, is further amended to read:

If, in the opinion of the board, the factual basis of the complaint is or may be true and the complaint is of sufficient gravity to warrant further action, the board may request an informal conference with the licensee. The board shall provide the licensee with adequate notice of the conference and of the issues to be discussed. The conference ~~must~~ may be conducted in executive session of the board, pursuant to Title 1, section 405, ~~unless otherwise requested by the licensee~~. Statements made at the conference may not be introduced at a subsequent formal hearing unless all parties consent.

Sec. 10. 32 MRSA §13742, sub-§2, as amended by PL 1993, c. 600, Pt. A, §272, is further amended to read:

2. Grounds for action. The following ~~shall be~~ are grounds for discipline, for an action to refuse to issue a modification

of the license or for refusal to renew the license of a person licensed under this chapter:

A. The practice of fraud or deceit in obtaining a license under this chapter or in connection with service rendered within the scope of the license issued;

B. Habitual substance abuse that has resulted or is forseeably likely to result in the licensee performing duties in a manner that endangers the health or safety of patients;

C. A professional diagnosis of a mental or physical condition ~~which~~ that has resulted or may result in the licensee performing duties in a manner ~~which~~ that endangers the health or safety of the patients;

D. Aiding or abetting the practice of pharmacy by a person not duly licensed under this chapter and who was represented as duly licensed;

E. Incompetence in the practice for which the licensee is licensed. A licensee ~~shall be deemed~~ is incompetent in the practice if the licensee has:

(1) Engaged in conduct ~~which~~ that evidences a lack of ability or fitness to discharge the duty owed by the licensee to a client, patient or the general public; or

(2) Engaged in conduct ~~which~~ that evidences a lack of knowledge or inability to apply principles or skills to carry out the practice for which the licensee is licensed;

F. Engaging in unprofessional conduct by violating any standard of professional behavior, including but not limited to a breach of confidentiality of health care information pursuant to Title 22, section 1711-C, ~~which~~ that has been established in the practice for which the licensee is licensed;

G. Subject to the limitations of Title 5, chapter 341, conviction of a crime ~~which~~ that involves dishonesty or false statement or ~~which~~ that relates directly to the practice for which the licensee is licensed or conviction of any crime for which incarceration for one year or more may be imposed;

H. Engaging in false, misleading or deceptive advertising; or

I. Any violation of this Act or of any rule adopted by the board.

Sec. 11. 32 MRSA §13752, sub-§2, ¶C, as enacted by PL 1987, c. 710, §5, is amended to read:

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

Sec. 12. 32 MRSA §13752-A is enacted to read:

§13752-A. Site inspection required

1. Opening facility. Successful applicants for registration of a drug outlet pursuant to this subchapter may open and operate the approved facility only:

A. Upon the completion of a site inspection of the facility by a member of the board or an inspector for the board; or

B. Upon the pharmacist in charge certifying to the board, on forms prescribed by the board, that the facility is secure, suitable for operation as a drug outlet and in compliance with applicable federal and state laws, rules and regulations governing the practice of pharmacy.

2. Facility inspection. Registered drug outlets that open and operate pursuant to subsection 1, paragraph B must be inspected by a member of the board or an inspector for the board within 30 days of opening. Facilities that are found to be insecure, not suitable for operation as a drug outlet or not in compliance with applicable federal and state laws, rules and regulations governing the practice of pharmacy are subject to a board-ordered emergency revocation of registration. The outlet may not operate after revocation. The emergency revocation is a final agency action and is not subject to judicial review, but a new application for registration may be submitted pursuant to section 13752, and if approved, a site inspection must be performed pursuant to subsection 1, paragraph A.

Sec. 13. 32 MRSA §13785, last ¶, as enacted by PL 1987, c. 710, §5, is amended to read:

A patient profile record must be maintained for a period of not less than ~~5 years~~ the amount of time required under federal Medicare laws, beginning from the date of the last entry in the

profile record. As used in this section, "Medicare" means the Health Insurance for the Aged Act, Title XVIII of the Social Security Amendments of 1965, as amended.

Sec. 14. 32 MRSA §13794, as enacted by PL 1987, c. 710, §5, is amended to read:

§13794. Labeling of prescriptions

Every drug dispensed pursuant to prescription, whether for a legend drug or not, ~~shall~~ must carry on the label the following information: ~~The~~ the prescription number; the date of filling; the patient's name; directions for use; the name and strength of the drug and the amount dispensed, including either the brand name of the drug or, if a generic and therapeutically equivalent drug is dispensed, it ~~shall~~ must be in accordance with section 13781; the beyond use date of the drug; the name of the practitioner prescribing the drug; and the name, address and telephone number of the pharmacy where the prescription was compounded and dispensed. For purposes of this section, "beyond use date" means a date beyond which the contents of the prescription are not recommended to be used.

Sec. 15. Statutory Review Committee

1. Establishment. The Commissioner of Professional and Financial Regulation shall establish a statutory review committee within 30 days of the effective date of this Act. The size and composition of the committee is determined by the commissioner, except that, membership must include a licensed pharmacist in independent practice, a representative of a corporate pharmacy chain, a licensed pharmacist working in an institutional setting, a consumer representative and a representative of prescribing practitioners. At least one pharmacist member must be a member of the Board of Pharmacy.

2. Charge. The committee is charged with the following duties:

A. To review the current scope of practice for pharmacists, as set forth in the Maine Revised Statutes, Title 32, section 13702, subsection 22 and to recommend whether changes should be made to reflect current professional practices or prospective professional practices that would be advantageous to the public. The discussion regarding scope of practice must include, but is not limited to, drug or device administration and collaborative practice.

B. To review the adequacy of the current regulatory relationship between the Maine Board of Pharmacy and institutional pharmacies and propose changes if necessary.

3. Report. No later than January 1, 2000, the statutory review committee shall submit a written report together with recommended legislation, if any, to the Governor and the joint standing committee of the Legislature having jurisdiction over business and economic development matters with a copy to the Executive Director of the Legislative Council and the Law and Legislative Reference Library. The statutory review committee shall make an oral report to the joint standing committee of the Legislature having jurisdiction over business and economic development matters no later than February 1, 2000. The joint standing committee of the Legislature having jurisdiction over business and economic development matters may submit legislation based on the recommendations of the statutory review committee.

SUMMARY

This bill implements the recommendations of the Pharmacy Act Review Group, which was established by the Department of Professional and Financial Regulation to update the Maine Pharmacy Act.

The bill defines automated pharmacy systems and authorizes the Maine Board of Pharmacy to establish standards for their use. The bill redefines practitioner, reflecting the increased number of professions that are authorized to prescribe. It allows the board to use discretion in issuing a license by reciprocity, and aligns the board's license and continuing education cycles with the calendar year. The bill removes the automatic provision of executive session for informal conferences and adds breach of confidentiality to the area of unprofessional conduct. The bill allows a pharmacist to be in charge of more than one outlet with written permission from the board and allows drug outlets to open prior to state site inspection. The bill ties record retention requirements to those of federal Medicare laws and requires dispensed drug labels to include the beyond use date of the drug.

Finally, the bill establishes a statutory review committee to review the current scope of practice for pharmacists and to make recommendations for change if necessary. The review must address the issues of drug administration and collaborative practice and the current regulatory relationship between the Board of Pharmacy and institutional pharmacies. The review committee is charged with making recommendations back to the Governor and Legislature.