Public Law

124th Legislature

First Regular Session

Chapter 308

H.P. 843 - L.D. 1223

An Act To Allow Pharmacists To Administer Certain Immunizations

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

Sec. 1. 32 MRSA §13702-A, sub-§28, as enacted by PL 2007, c. 402, Pt. DD, §2, is amended to read:

28. Practice of pharmacy. "Practice of pharmacy" means the interpretation and evaluation of prescription drug orders; the compounding, dispensing, labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices; the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records for these drugs and devices; the administration of influenza vaccine, intranasal influenza vaccine, pneumococcal vaccine, shingles or herpes zoster vaccine, tetanus-diphtheria-pertussis vaccine and tetanus-diphtheria vaccine; the responsibility for advising, when necessary or regulated, of therapeutic values, content, hazards and use of drugs and devices; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy.

Sec. 2. 32 MRSA §13735, as amended by PL 2007, c. 402, Pt. DD, §16, is further amended to read:

§ 13735. Continuing pharmacy education

An annual renewal license may not be issued by the board until the applicant certifies 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. Of the 15 hours to be completed, at least 2 hours must be in board-approved courses on drug administration as described in section 13702-A, subsection 28. The continuing professional pharmaceutical educational courses 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.

These courses consist of subject matter pertinent to the following general areas of professional pharmaceutical education: ~~The~~ 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, 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.

Each application for approval of a continuing education program or course must be submitted according to the guidelines prescribed by rule by the board, together with a fee as set under section 13724.

Sec. 3. 32 MRSA c. 117, sub-c. 13 is enacted to read:

SUBCHAPTER 13

Administration of Drugs and Immunizations

§ 13831. Authority

1. Administration of influenza vaccines. A pharmacist licensed in this State who meets the qualifications and requirements of section 13832 and rules adopted by the board may administer topically or by injection or by inhalation all forms of influenza vaccines, including intranasal influenza vaccines, to a person 9 years of age or older without a prescription.

2. Administration of other vaccines. A pharmacist licensed in this State who meets the qualifications and requirements of section 13832 and rules adopted by the board, in addition to influenza vaccines under subsection 1, may administer pneumococcal vaccine, shingles or herpes zoster vaccine, tetanus-diphtheria-pertussis vaccine, tetanus-diphtheria vaccine and booster tetanus-diphtheria vaccine to a person according to a valid prescription when the person has an existing primary care physician or other existing relationship with an authorized practitioner in this State. When the person does not have an existing relationship with a primary care physician or other practitioner in this State the pharmacist may proceed to administer according to a treatment protocol established by an authorized practitioner or a written standing order from a practitioner authorized under the laws of this State to issue an order, a prescription or a protocol to a person 18 years of age or older for pneumococcal vaccine, shingles or herpes zoster vaccine, tetanus-diphtheria-pertussis vaccine, tetanus-diphtheria vaccine or booster tetanus-diphtheria vaccine.

3. Emergency administration of certain drugs. A pharmacist may administer epinephrine or diphenhydramine, or both, to a person in an emergency situation resulting from an adverse reaction to an immunization administered by the pharmacist.

§ 13832. Qualifications; requirements

In order to administer a drug or immunization under this subchapter, a pharmacist must:

1. Certificate; application and fee. Possess a current certificate of administration issued by the board pursuant to this subchapter. The pharmacist must submit an application in the form prescribed by the board together with the requirements set forth under this subchapter and certificate fee as set forth under section 13724. The certificate of administration expires and is subject to the conditions in the same manner as stated in section 13734;

2. License. Hold a valid unrestricted pharmacist license in this State;

3. Training. Submit evidence acceptable to the board that the pharmacist, within the 3 years immediately preceding application for a certificate of administration:

A. Has completed a 20-hour course of study in the areas of drug administration authorized under this subchapter and as described in subsection 4;

B. Has graduated with a Doctor of Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education that includes completion of training in the areas of drug administration authorized under this subchapter satisfactory to the board, including instruction in the areas identified in subsection 4 received as part of the pharmacist's pharmacy degree program; or

C. Possesses a current certificate of administration issued by another jurisdiction that authorizes the pharmacist to administer drugs comparable to those authorized under this chapter and that is based on the pharmacist's completion of training or course work as described in subsection 4, or its equivalent as determined by the board, and has continuous administration practice since the pharmacist received such training or since completion of a retraining program as required in this subchapter, as long as such retraining incorporates the areas identified in subsection 4;

4. Didactic; practical course. Satisfactorily complete a didactic and practical course approved by the board that includes the current guidelines and recommendations of the federal Department of Health and Human Services, Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body, and that includes, but is not limited to, disease epidemiology, indications for use of vaccines, vaccine characteristics, injection techniques, adverse reactions to vaccines, emergency response to adverse events, immunization screening, informed consent, record keeping, registries, including the immunization information system established under Title 22, section 1064, registry training and reporting mechanisms, including reporting adverse events, life support training, biohazard waste disposal and sterile techniques and related topics; and

5. Life support training. Submit evidence of completing cardiovascular life support training accepted by the American Heart Association, the American Red Cross or other similar training organization.

§ 13833. Treatment protocol

The pharmacist shall administer drugs and immunizations in compliance with a treatment protocol established by a practitioner authorized under the laws of this State to order administration of those drugs and immunizations approved by the board. A copy of the treatment protocol must be submitted to the board. At a minimum the treatment protocol must include:

1. Standards. Standards for observation of the person receiving the drug or immunization to determine whether the person has an adverse reaction, as adopted in rules by the board;

2. Procedures. Procedures to be followed by the pharmacist when administering epinephrine, diphenhydramine, or both, to a person who has an adverse reaction to an immunization administered by the pharmacist; and

3. Notification. Notification to the authorized practitioner who issued the prescription, standing order or protocol under section 13831, subsection 2 of the administration by the pharmacist of the drug or immunization, or both, within 3 business days.

§ 13834. Prohibited acts

1. Delegate authority. A pharmacist may not delegate the pharmacist's authority to administer drugs or immunizations.

2. Administer drugs. A pharmacist may not engage in the administration of drugs or immunizations unless the pharmacist meets the qualifications and requirements of section 13832 and the pharmacist has obtained a board-issued certificate of administration.

§ 13835. Rules

The board, after consultation with the Maine Center for Disease Control and Prevention and the Board of Licensure in Medicine, shall adopt rules to implement this subchapter. The rules must include, at a minimum:

1. Criteria. Criteria for the operation of a drug administration clinic within or outside a retail pharmacy, rural health clinic or free clinic licensed under section 13751;

2. Record keeping. Record keeping and documentation procedures and reporting requirements, giving preference to electronic means when available; and

3. Recipient assessment. Recipient assessment, consent and rights.

Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 4. MaineCare program. Reimbursement under the MaineCare program for services provided under the Maine Revised Statutes, Title 32, chapter 117, subchapter 13 is subject to the adoption of a billing mechanism by the Department of Health and Human Services for the MaineCare program to implement the provisions of subchapter 13 and amendment of the rules of the MaineCare benefits manual to cover the service provided in subchapter 13 at a minimum of the current average wholesale price reimbursement rate plus a dispensing fee of $3.35. Prior to the adoption of a billing mechanism, a MaineCare member that receives a vaccination from a pharmacist as authorized by subchapter 13 must be told in advance that the administration of vaccines provided by a pharmacist is not covered by MaineCare and the member will be responsible for payment.

Sec. 5. Appropriations and allocations. The following appropriations and allocations are made.

PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF

Licensing and Enforcement 0352

Initiative: Allocates one-time funds to configure the agency licensing system and for the costs of rulemaking.

OTHER SPECIAL REVENUE FUNDS	**2009-10**	**2010-11**
All Other	$7,000	$0
OTHER SPECIAL REVENUE FUNDS TOTAL	$7,000	$0

Effective September 12, 2009