# MAINE STATE LEGISLATURE

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## 125th MAINE LEGISLATURE

### **SECOND REGULAR SESSION-2012**

**Legislative Document** 

No. 1715

H.P. 1267

House of Representatives, December 23, 2011

An Act To Allow for Timely Access to and Enhanced Administration of All Vaccines

Approved for introduction by a majority of the Legislative Council pursuant to Joint Rule 203.

Received by the Clerk of the House on December 21, 2011. Referred to the Committee on Labor, Commerce, Research and Economic Development pursuant to Joint Rule 308.2 and ordered printed pursuant to Joint Rule 401.

HEATHER J.R. PRIEST Clerk

Heath & Buit

Presented by Representative STRANG BURGESS of Cumberland.

Cosponsored by Senator RECTOR of Knox and

Representatives: CUSHING of Hampden, FOSSEL of Alna, MOULTON of York, Speaker NUTTING of Oakland, VOLK of Scarborough, WALLACE of Dexter, Senators: DIAMOND of Cumberland, MARTIN of Kennebec.

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

- **Sec. 1. 32 MRSA §13702-A, sub-§28,** as amended by PL 2009, c. 308, §1, is further amended to read:
- 28. Practice of pharmacy. "Practice of pharmacy" means the interpretation and evaluation of prescription drug orders; the compounding, dispensing, and 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 all vaccines licensed by the United States Food and Drug Administration; 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 §13755 is enacted to read:

#### §13755. Vaccine clinics

A pharmacy may operate a drug and vaccine administration clinic inside, outside or off the pharmacy's premises.

- **Sec. 3. 32 MRSA §13831, sub-§§2 and 3,** as enacted by PL 2009, c. 308, §3, are amended to read:
- **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 all vaccines licensed by the United States Food and Drug Administration to a person 18 years of age or older 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 tetanusdiphtheria vaccine any vaccine licensed by the United States Food and Drug Administration.
- **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 a vaccine administered by the pharmacist.

1	<b>Sec. 4. 32 MRSA §13831, sub-§4</b> is enacted to read:
2 3 4 5	4. Vaccine clinics. A pharmacist or pharmacy licensed under this chapter may operate a drug and vaccine administration clinic inside, outside or off the pharmacy's premises if the pharmacist or pharmacy obtains approval from the board for the plan of operation of such clinics pursuant to rules adopted under section 13835, subsection 1.
6 7	<b>Sec. 5. 32 MRSA §13832, first</b> ¶, as enacted by PL 2009, c. 308, §3, is amended to read:
8 9	In order to administer a drug or immunization vaccine under this subchapter, a pharmacist must:
10	<b>Sec. 6. 32 MRSA §13833,</b> as enacted by PL 2009, c. 308, §3, is amended to read:
11	§13833. Treatment protocol
12 13 14 15 16	The pharmacist shall administer drugs and <u>immunizations</u> <u>vaccines</u> in compliance with a treatment protocol established by a practitioner authorized under the laws of this State to order administration of those drugs and <u>immunizations</u> <u>vaccines</u> approved by the board. A copy of the treatment protocol must be submitted to the board. At a minimum the treatment protocol must include:
17 18 19	1. Standards. Standards for observation of the person receiving the drug or immunization vaccine to determine whether the person has an adverse reaction, as adopted in rules by the board;
20 21 22	<b>2. Procedures.</b> Procedures to be followed by the pharmacist when administering epinephrine, or diphenhydramine, or both, to a person who has an adverse reaction to an immunization a vaccine administered by the pharmacist; and
23 24 25 26	<b>3. Notification.</b> 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 vaccine, or both, within 3 business days.

- **Sec. 7. 32 MRSA §13834,** as enacted by PL 2009, c. 308, §3, is amended to read:
- **§13834.** Prohibited acts

- **1. Delegate authority.** A pharmacist may not delegate the pharmacist's authority to administer drugs or immunizations vaccines.
  - **2. Administer drugs.** A pharmacist may not engage in the administration of drugs or immunizations vaccines unless the pharmacist meets the qualifications and requirements of section 13832 and the pharmacist has obtained a board-issued certificate of administration.
  - **Sec. 8. 32 MRSA §13835, sub-§1,** as enacted by PL 2009, c. 308, §3, is amended to read:

- 1. Criteria. Criteria for the operation of a drug <u>and vaccine</u> administration clinic <u>within or inside</u>, outside a <u>or off the premises of a</u> retail pharmacy, rural health clinic or free clinic licensed under section 13751. The rules must require one-time board approval <u>of the plan of operation for any drug and vaccine administration clinics to be operated by a pharmacist or pharmacy and may not require board approval of each individual clinic;</u>
- **Sec. 9.** Maine Revised Statutes headnote amended; revision clause. In the Maine Revised Statutes, Title 32, chapter 117, subchapter 13, in the subchapter headnote, the words "administration of drugs and immunizations" are amended to read "administration of drugs and vaccines" and the Revisor of Statutes shall implement this revision when updating, publishing or republishing the statutes.

11 SUMMARY

 This bill makes the following changes to the laws governing the administration of vaccines by licensed pharmacists:

- 1. It broadens the scope of vaccines that a licensed pharmacist may administer to a person 18 years of age or older to allow for the administration of any vaccines licensed by the United States Department of Health and Human Services, Food and Drug Administration; and
- 2. It requires one-time approval from the Maine Board of Pharmacy of a pharmacist's or pharmacy's plan of operation for vaccine administration clinics and requires the board to adopt by rule criteria for the approval of such clinics.