

MAINE STATE LEGISLATURE

The following document is provided by the
LAW AND LEGISLATIVE DIGITAL LIBRARY
at the Maine State Law and Legislative Reference Library
<http://legislature.maine.gov/lawlib>



Reproduced from scanned originals with text recognition applied
(searchable text may contain some errors and/or omissions)

7-10-09

Date: 5/29/09

(Filing No. H- 473)

BUSINESS, RESEARCH AND ECONOMIC DEVELOPMENT

Reproduced and distributed under the direction of the Clerk of the House.

**STATE OF MAINE
HOUSE OF REPRESENTATIVES
124TH LEGISLATURE
FIRST REGULAR SESSION**

COMMITTEE AMENDMENT "A" to H.P. 843, L.D. 1223, Bill, "An Act To Allow Pharmacists To Administer Certain Immunizations"

Amend the bill by striking out everything after the enacting clause and before the summary and inserting the following:

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,

COMMITTEE AMENDMENT

R. of S.

1 lectures, conferences, extension studies, correspondence courses or such other forms of
2 continuing professional pharmaceutical education as may be approved by the board.

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

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

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

20 **SUBCHAPTER 13**

21 **ADMINISTRATION OF DRUGS AND IMMUNIZATIONS**

22 **§13831. Authority**

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

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

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

4 **§13832. Qualifications; requirements**

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

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

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

14 **3. Training.** Submit evidence acceptable to the board that the pharmacist, within the
15 3 years immediately preceding application for a certificate of administration:

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

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

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

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

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

1 **§13833. Treatment protocol**

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

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

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

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

17 **§13834. Prohibited acts**

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

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

24 **§13835. Rules**

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

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

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

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

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

35 **Sec. 4. MaineCare program.** Reimbursement under the MaineCare program for
36 services provided under the Maine Revised Statutes, Title 32, chapter 117, subchapter 13
37 is subject to the adoption of a billing mechanism by the Department of Health and Human
38 Services for the MaineCare program to implement the provisions of subchapter 13 and
39 amendment of the rules of the MaineCare benefits manual to cover the service provided
40 in subchapter 13 at a minimum of the current average wholesale price reimbursement rate

1 plus a dispensing fee of \$3.35. Prior to the adoption of a billing mechanism, a MaineCare
2 member that receives a vaccination from a pharmacist as authorized by subchapter 13
3 must be told in advance that the administration of vaccines provided by a pharmacist is
4 not covered by MaineCare and the member will be responsible for payment.

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

7 **PROFESSIONAL AND FINANCIAL REGULATION, DEPARTMENT OF**
8 **Licensing and Enforcement 0352**

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

11	OTHER SPECIAL REVENUE FUNDS	2009-10	2010-11
12	All Other	\$7,000	\$0
13			
14	OTHER SPECIAL REVENUE FUNDS TOTAL	\$7,000	\$0
15			

16 **SUMMARY**

17 This amendment allows a pharmacist to administer certain drugs and immunizations,
18 including the influenza vaccine, intranasal influenza vaccine, pneumococcal vaccine,
19 shingles or herpes zoster vaccine, tetanus-diphtheria-pertussis vaccine and tetanus-
20 diphtheria vaccine with certain restrictions. It allows a licensed pharmacist to administer
21 all forms of influenza vaccines to a person 9 years of age or older without a prescription.
22 It also allows a licensed pharmacist to administer the pneumococcal vaccine, shingles or
23 herpes zoster vaccine, tetanus-diphtheria-pertussis vaccine and tetanus-diphtheria vaccine
24 to a person with a valid prescription when the person has an existing primary care
25 physician or other existing relationship with an authorized Maine practitioner. In cases in
26 which the person does not have an existing relationship with a primary care physician or
27 other Maine practitioner the pharmacist may administer the vaccine according to a
28 treatment protocol established by an authorized practitioner or a written standing order
29 from a practitioner authorized under the laws of this State to issue an order, a prescription
30 or a protocol to a person 18 years of age or older for pneumococcal vaccine, shingles or
31 herpes zoster vaccine, tetanus-diphtheria-pertussis vaccine or booster tetanus-diphtheria
32 vaccine.

33 It also amends the continuing pharmacy education requirements for licensure renewal
34 and establishes certain training requirements in order for a licensed pharmacist to be able
35 to administer a drug or immunization. It establishes a treatment protocol for the
36 administration of the drugs and immunizations. It provides that reimbursement under the
37 MaineCare program is contingent on the adoption of a billing mechanism by the
38 Department of Health and Human Services for the MaineCare program and amendment
39 of the rules of the MaineCare benefits manual to cover the service provided at a minimum
40 of the current average wholesale price reimbursement rate plus a dispensing fee of \$3.35.
41 Prior to the adoption of a billing mechanism, a MaineCare member that receives a

1 vaccination must be told in advance that the administration of vaccines provided by a
2 pharmacist is not covered by MaineCare and the member will be responsible for payment.

3 **FISCAL NOTE REQUIRED**

4 **(See attached)**



124th MAINE LEGISLATURE

LD 1223

LR 33(02)

An Act To Allow Pharmacists To Administer Certain Immunizations

Fiscal Note for Bill as Amended by Committee Amendment "A"
Committee: Business, Research and Economic Development
Fiscal Note Required: Yes

Fiscal Note

	2009-10	2010-11	Projections 2011-12	Projections 2012-13
Appropriations/Allocations				
Other Special Revenue Funds	\$7,000	\$0	\$0	\$0

Fiscal Detail and Notes

This bill includes a one-time Other Special Revenue Funds allocation of \$7,000 in fiscal year 2009-10 for the Licensing and Enforcement program within the Department of Professional and Financial Regulation for the costs associated with rulemaking and with configuring the agency licensing system to track the qualification requirements. The Licensing and Enforcement program has sufficient cash balances within its account to support the one-time costs of this legislation.

Additional costs to the MaineCare program in the Department of Health and Human Services can be absorbed by the department utilizing existing budgeted resources.