

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 1 DEFINITIONS

Summary: As used in the board's rules, unless the context otherwise indicates, the following words have the following meanings:

[NOTE: Additional definitions are found in 32 M.R.S.A. §13702.]

Section 8-A of this chapter is adopted to read:

- 8-A. Certified midwife.** "Certified midwife" means a midwife certified by and in good standing with the North American Registry of Midwives or the American Midwifery Certification Board, provided that "certified midwife" does not include a certified nurse midwife licensed as an advanced practice registered nurse by the State Board of Nursing.

In all other respects, this chapter is unchanged.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13722, 13723, 13811, 13812

EFFECTIVE DATE: 2/9/09

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 33 ACCESS TO CERTAIN MEDICATIONS BY CERTIFIED MIDWIVES

Summary: This chapter implements PL 2007, c. 669 by: (a) regulating the sale of certain noncontrolled drugs and substances to certified midwives, (b) regulating the purchase and administration of certain noncontrolled drugs and substances by certified midwives, and (c) requiring certified midwives to record and report their purchase and administration of certain noncontrolled drugs and substances.

1. Scope

This chapter applies solely to the acquisition and administration of certain noncontrolled drugs and substances by certified midwives.

2. Sale of Drugs to Certified Midwives

1. Limited Formulary

A pharmacist may elect to sell to a certified midwife without a prescription only the following noncontrolled drugs and substances:

- A. Oxygen, USP.;
- B. Oxytocin injection 10 units/ml 1 ml, excluding the oxytocic drug methergine, for the sole purpose of postpartum control of maternal hemorrhage;
- C. Phytonadione injection 2 mg/ml 0.5 ml (Vitamin K neonatal concentration);
- D. Erythromycin ophthalmic ointment (for eye prophylaxis); and
- E. The following local anesthetics and numbing agents for repair of lacerations:
 - (1) Lidocaine injection 1%;
 - (2) Bupivacaine injection 0.25%;
 - (3) Lidocaine topical spray 10%;
 - (4) Benzocaine topical spray 20%; and

- (5) Lidocaine 4% topical anesthetic cream

2. Verification of Certification

A pharmacist shall verify the identification and certification of a certified midwife prior to selling any of the noncontrolled drugs and substances listed in Section 2(1) of this chapter to the certified midwife. Verification consists of:

- A. Obtaining the name, address and telephone number of the certified midwife;
- B. Viewing a valid, current certification card issued to the certified midwife by the American Midwifery Certification Board or the North American Registry of Midwives; and
- C. In the discretion of the pharmacist, viewing one of the following forms of photographic identification of the certified midwife:
 - (1) A valid Maine motor vehicle operator's license;
 - (2) A valid Maine identification card issued under Title 29-A, section 1410;
 - (3) A valid United States passport; or
 - (4) A valid passport or motor vehicle operator's license of another state, territory or possession of the United States or a foreign country only if it:
 - (a) Contains a photograph of the certified midwife;
 - (b) Is encased in tamper-resistant plastic or is otherwise tamper-resistant; and
 - (c) Identifies the date of birth of the certified midwife.

3. Delivery to Certified Midwife

A pharmacist who elects to sell any of the noncontrolled drugs and substances listed in Section 2(1) of this chapter to a certified midwife must deliver the drug or substance in hand to the certified midwife personally.

4. Records of Sale

A retail pharmacy shall keep a log of oxytocin for intramuscular use and injectable vitamin K sold to certified midwives pursuant to this chapter. The log may be maintained as a separate document or may be integrated into another log of a similar nature. The log must contain the following information for each transaction:

- A. The name, quantity, dosage and lot number of the drug sold; and
- B. The name, address and telephone number of the midwife.

[NOTE: Retention and production of records of sale created pursuant to this chapter is governed by Chapter 24, Section 5 of the board's rules.]

3. Administration of Certain Noncontrolled Drugs and Substances by Certified Midwives; Further Distribution or Transfer Prohibited

A certified midwife may administer the noncontrolled drugs and substances listed in Section 2(1) of this chapter only in the course of the practice of midwifery. A certified midwife may not otherwise dispense, sell, give away or transfer the noncontrolled drugs or substances.

4. Storage of Certain Noncontrolled Drugs and Substances by Certified Midwives

A certified midwife shall store the noncontrolled drugs and substances listed in Section 2(1) of this chapter at appropriate temperatures and under appropriate conditions in accordance with manufacturers' requirements in the labeling of such drugs and substances, or with requirements in the current edition of an official compendium.

5. Records and Reporting

1. Purchase and Destruction Records

A certified midwife shall keep a log of injectable oxytocin and injectable vitamin K purchased by the midwife pursuant to this chapter. For each such purchase the log shall note:

- A. The date of purchase;
- B. The name and address of the retail pharmacy where the oxytocin or vitamin K was purchased;
- C. The name of the selling pharmacist;
- D. The quantity and dosage of oxytocin or vitamin K purchased;
- E. The expiration date of the oxytocin or vitamin K purchased; and
- F. A statement as to whether any quantity of the oxytocin or vitamin K remained unused upon the expiration date and, if any, the date and manner of destruction of the unused stock.

Purchase and destruction records must be maintained separately from the administration records required by Section 5(2) of this chapter.

2. Administration Records

A certified midwife shall keep a record of all noncontrolled drugs and substances administered by the certified midwife pursuant to this chapter. For each such administration the record shall contain:

- A. The date of administration;
- B. The route of administration;
- C. A description of the place where the drug was administered (e.g., patient's home);
- D. The name, quantity and dosage of the noncontrolled drug or substance administered;
- E. The reason for administering the noncontrolled drug or substance to the patient;
- F. A notation of any adverse reaction to the noncontrolled drug or substance administered, including a complete description of the steps taken by the certified midwife to respond to the adverse reaction and the condition of the patient afterwards; and
- G. A notation of any medical emergency experienced by a patient to whom the noncontrolled drug or substance was administered, including a complete description of the steps taken by the certified midwife to respond to the emergency and the condition of the patient afterwards.

Administration records must be maintained separately from the purchase and destruction records required by Section 5(1) of this chapter.

3. Reporting

- A. A certified midwife shall report any of the following in writing to the Department of Health and Human Services, the Maine Center for Disease Control and Prevention within 7 days of the event. The report shall be made on the form prescribed by that office:
 - (1) The administration of oxytocin for intramuscular use;
 - (2) Any time a patient experiences an adverse reaction to a noncontrolled drug or substance administered by the certified midwife, including oxytocin, with a complete description of the steps taken by the certified midwife to respond to the adverse reaction and the condition of the patient afterwards; and

- (3) Any medical emergency experienced by a patient to whom a noncontrolled drug or substance was administered by the certified midwife, including oxytocin, with a complete description of all steps taken by the certified midwife to respond to the emergency and the condition of the patient afterwards.

[NOTE: The mailing address for the reports required by this subsection is Family Health Division, Maine Center for Disease Control and Prevention, 11 State House Station, Augusta, ME 04333-0011.]

- B. A certified midwife shall provide the records of purchase, destruction and administration described in Section 5(1) and (2) to the board no later than September 1 of each year. Each annual report shall contain records of purchases, destruction and administrations that occurred during the preceding calendar year, provided that no record need be prepared for purchases, destruction or administrations that occurred prior to the effective date of this chapter.

4. Retention and Production of Records

A certified midwife shall retain the records of purchase, destruction and administration described in Section 5(1) and (2) of this chapter for a period of 5 years. A certified midwife shall produce the records to the board upon request.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13722, 13723, 13811, 13812

EFFECTIVE DATE: 2/9/09