THE SENATE
TWENTY-SEVENTH LEGISLATURE, 2014
STATE OF HAWAII

S.B. NO. 3005

JAN 23 2014

A BILL FOR AN ACT

RELATING TO COMPOUNDING PHARMACIES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 461, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"PART . STERILE COMPOUNDING PERMITS

§461-A Definitions. For the purposes of this part:

"Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug only:

(1) As the result of a practitioner's prescription drug order or initiative based upon the practitioner and patient relationship in the course of professional practice;

(2) For the purpose of, or incidental to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device; or

(3) In anticipation of a prescription drug order based upon routine, regularly observed prescribing patterns.

"Designee" means a public agency or private entity approved by the board to conduct inspections of pharmacies that prepare sterile drug products.

"Sterile compounding" means the compounding of biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals through the use of aseptic techniques.

"Sterile compounding permit holder" means a pharmacy licensed under this chapter that obtains or holds a permit issued under this part.

"Sterile drug product" means a drug product that:

(1) Is prepared using aseptic techniques; and

(2) Is not required to be prepared in response to a patient specific prescription.

§461-B Distribution of sterile drug products. No person may distribute sterile drug products in the State unless the sterile drug products are produced in a facility that holds a manufacturer's permit or other permit designated by the United States Food and Drug Administration to ensure the safety of sterile drug products.

§461-C Sterile compounding; permit required. (a) No person may perform sterile compounding in the State or dispense

sterile compounded preparations in the State that were compounded outside of the State, unless:

(1) The person holds a license as a pharmacist issued by the board under part I;

(2) The person obtains a sterile compounding permit issued by the board under this part; and

(3) The sterile compounding conforms to the standards set forth in the United States Pharmacopeia, General Chapter 797, "Pharmaceutical Compounding - Sterile Preparations".

(b) A separate sterile compounding permit shall be required for each site at which sterile compounding is performed or at which sterile compounded preparations are dispensed.

(c) A sterile compounding permit shall not be transferable and shall be required in addition to and does not replace any other permit or license that the pharmacy holds.

§461-D Application for a permit. (a) To apply for a sterile compounding permit, an applicant shall:

(1) Pay to the board an application fee charged by the board through its rules; and

(2) Submit an application to the board on the form prescribed by the board.

(b) The board shall not issue a sterile compounding permit to an applicant unless the board:

(1) Conducts an inspection of the pharmacy applying for the permit; and

(2) Finds that the pharmacy meets the board's requirements.

(c) The board shall issue a sterile compounding permit to any applicant that meets the requirements of this section.

§461-E Permit expiration; renewal. (a) A sterile compounding permit shall expire on December 31 of each odd-numbered year.

(b) Not sooner than ninety days before a sterile compounding permit expires, a sterile compounding permit holder may apply to renew its sterile compounding permit for an additional two-year term if the pharmacy:

(1) Otherwise meets the requirements for the permit;

(2) Pays to the board the renewal fee established by the board through its rules; and

(3) Submits the renewal application to the board on a form prescribed by the board.

(c) The board shall renew a permit if a sterile compounding permit holder meets the requirements of this section.

§461-F Rulemaking powers. (a) The board shall adopt rules to carry out this part.

(b) The rules shall:

(1) Establish requirements for sterile compounding permit holders based upon risk;

(2) Require compliance with the United States Pharmacopeia, General Chapter 797, "Pharmaceutical Compounding - Sterile Preparations";

(3) Require each sterile compounded preparation to be dispensed or administered in accordance with a prescription from a practitioner;

(4) Require:

(A) Inspections;

(B) Reporting of adverse events and evidence of environmental contamination; and

(C) Reporting of deficiencies, disciplinary action, or changes in accreditation status; and

(5) Require a sterile compounding permit holder to ensure that personnel engaging in sterile compounding are

trained and demonstrate competence in the safe handling and compounding of sterile preparations.

§461-G Inspections. (a) Subject to subsection (b), the board:

(1) Shall inspect a sterile compounding permit holder with a frequency based upon risk, as set forth in rules adopted by the board;

(2) Shall include, in all inspections under paragraph (1), a review in accordance with rules adopted by the board, of:

(A) Quality assurance testing reports; and

(B) Microbial testing of a sampling of the compounded preparations of the sterile compounding permit holder; and

(3) May inspect a sterile compounding permit holder at any time:

(A) To verify compliance with permit requirements; or

(B) To investigate a complaint.

(b) If a pharmacy or permit holder is performing sterile compounding outside the State, the board may rely upon an inspection conducted by a designee to conduct inspections under this part.

The board shall not approve a designee to conduct inspections of pharmacies or permit holders outside the State unless the inspections are conducted in accordance with this part and the rules adopted thereunder.

A pharmacy or permit holder outside the State shall be responsible for obtaining an inspection from a designee to meet the requirements of this part.

§461-H Reports by sterile compounding permit holders. (a) The board shall:

(1) Determine the adverse events and evidence of environmental contamination that a sterile compounding permit holder shall report to the board; and

(2) Require a sterile compounding permit holder to report to the board the adverse events or evidence of environmental contamination within five calendar days after the sterile compounding permit holder becomes aware of the adverse events or evidence of environmental contamination.

(b) The board shall:

(1) Determine the deficiencies, disciplinary actions, and changes in accreditation status described in

subsection (c) that a sterile compounding permit holder shall report to the board; and

(2) Require a sterile compounding permit holder to report to the board the deficiencies, disciplinary actions, and changes in accreditation status within five calendar days after the sterile compounding permit holder becomes aware of the deficiencies, disciplinary actions, or changes in accreditation status.

(c) The board may require a sterile compounding permit holder to report under subsection (b)(1):

(1) A deficiency noted during an inspection, during an accreditation site visit, or in official correspondence from a state or federal agency, a professional association, or an accreditation organization;

(2) Disciplinary action by a state or federal agency, including a revocation, suspension, probation, censure, reprimand, or restriction placed upon a license, a permit, or any other authorization of the sterile compounding permit holder or a health care practitioner who is an owner, operator, or employee of a sterile compounding permit holder; or

(3) A change in accreditation status issued by a professional association or an accreditation organization relating to the sterile compounding permit holder."

SECTION 2. Chapter 461, Hawaii Revised Statutes, is amended by designating sections 461-1 to 461-22 as part I, entitled "General Provisions".

SECTION 3. In codifying the new sections added by section 1 of this Act, the revisor of statutes shall substitute appropriate section numbers for the letters used in designating the new sections in this Act.

SECTION 4. This Act shall take effect on January 1, 2016.

INTRODUCED BY: _____

S.B. NO. 3005

Report Title:
Pharmacies; Compounding

Description:
Requires pharmacies to obtain a separate sterile compounding permit from the Board of Pharmacy in order to engage in sterile compounding activities.

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