

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17748a Compounding services for sterile pharmaceuticals; accreditation; notification of complaint; maintenance and retention of records; resale of excess compounded pharmaceuticals prohibited; distribution of samples or complimentary starter doses; advertisement or promotion of compounding services; compounding pharmaceutical that is unavailable in marketplace; compounding and manufacturing at same location; rules.

Sec. 17748a. (1) Beginning September 30, 2014, an applicant for a new pharmacy license for a pharmacy that will provide compounding services for sterile pharmaceuticals shall submit verification of current accreditation through a national accrediting organization approved by the board or verify the pharmacy is in the accreditation process. The department shall not issue a license to a pharmacy described in this subsection that is not accredited unless the applicant demonstrates compliance with USP standards in a manner determined by the board.

(2) By September 30, 2016, a pharmacy that is licensed on September 30, 2014 and that provides compounding services for sterile pharmaceuticals must be accredited by a national accrediting organization approved by the board, be verified by the board as being in the accreditation process, or be in compliance with USP standards in a manner determined by the board.

(3) Notwithstanding any provision of part 161 to the contrary, a pharmacy that provides compounding services for sterile pharmaceuticals shall submit with a license renewal application verification of current accreditation or compliance with USP standards, as applicable.

(4) A person that provides services consistent with an outsourcing facility shall comply with requirements of the FDA applicable to compounding services for sterile pharmaceuticals.

(5) A pharmacy shall notify the department of a complaint filed by another state in which the pharmacy is licensed for violations of that state's pharmacy laws, an investigation by federal authorities regarding violations of federal law, or an investigation by any agency into violations of accreditation standards regarding compounding activities within 30 days of knowledge of the complaint or investigation.

(6) Except for distribution within a hospital or another health care entity under common control when regulated by federal law, a pharmacist shall maintain a record of a compounded sterile pharmaceutical in the same manner and for the same retention period as prescribed in rules for other prescription records. The pharmacist shall include, but is not limited to including, all of the following information in the record required under this subsection:

(a) The name, strength, quantity, and dosage form of the compounded pharmaceutical.

(b) The formula to compound that includes mixing instructions, all ingredients and their quantities, and any additional information needed to prepare the compounded pharmaceutical.

(c) The prescription number or assigned internal identification number.

(d) The date of preparation.

(e) The manufacturer and lot number of each ingredient.

(f) The expiration or beyond-use date.

(g) The name of the person who prepared the compounded pharmaceutical.

(h) The name of the pharmacist who approved the compounded pharmaceutical.

(7) A pharmacist shall not offer excess compounded pharmaceuticals to other pharmacies for resale. A compounding pharmacy shall not distribute samples or complimentary starter doses of a compounded pharmaceutical to a health professional.

(8) A compounding pharmacy may advertise or otherwise promote the fact that they provide compounding services.

(9) Based on the existence of a health professional/patient relationship and the presentation of a valid prescription, or in anticipation of the receipt of a prescription based on routine, regularly observed prescription patterns, a pharmacist may compound for a patient a nonsterile or sterile pharmaceutical that is not commercially available in the marketplace.

(10) Notwithstanding any provision of this act to the contrary, a person shall not compound and manufacture drug products or allow the compounding and manufacturing of drug products at the same location.

(11) The department, in consultation with the board, may promulgate rules regarding conditions and facilities for the compounding of nonsterile and sterile pharmaceuticals.

History: Add. 2014, Act 280, Eff. Sept. 30, 2014;—Am. 2015, Act 133, Imd. Eff. Sept. 30, 2015.

Popular name: Act 368