PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17748b Compounding nonsterile or sterile pharmaceuticals for prescriber or health facility or agency to administer to patients without prescription; authorization; report of adverse event; list of authorized pharmacies and pharmacists; selling or redispensing to prescriber or health facility or agency.

Sec. 17748b. (1) Except as otherwise provided in this subsection, a pharmacist or pharmacy shall not compound nonsterile or sterile pharmaceuticals for a prescriber or health facility or agency licensed under article 17 to administer to the prescriber's, facility's, or agency's patients without a prescription, unless the pharmaceutical compounded by the pharmacist or pharmacy complies with the most recent guidance on pharmacy compounding of human drug products under 21 USC 353a. Upon application by a pharmacist or compounding pharmacy, the department may authorize the pharmacist or compounding pharmacy to compound nonsterile or sterile pharmaceuticals for a prescriber or health facility or agency licensed under article 17 to administer to the prescriber's, facility's, or agency's patients in limited quantities without a prescription. This subsection does not apply to the compounding of topical nonsterile pharmaceuticals. The department shall prescribe the form of the application for use under this subsection, which application must include at least all of the following information:

(a) The name and license number of the pharmacist or pharmacy requesting authorization to compound under this subsection.

(b) The name of the specific prescriber or health facility or agency that is requesting compounded pharmaceuticals and an affidavit from the prescriber or designated agent of the health facility or agency attesting to the need and that the compounded pharmaceuticals are only for patients located in this state or in states immediately adjacent to this state.

(c) The pharmaceuticals to be compounded and the reason for the need to compound the pharmaceuticals.

(d) The anticipated quantities of pharmaceuticals to be compounded each month and the frequency of the need to compound before receipt of a prescription or documentation supporting the anticipated quantities.

(e) The conditions of operation including practices consistent with USP standards and requirements for sterility testing.

(2) A pharmacist or compounding pharmacy that is authorized to compound nonsterile or sterile pharmaceuticals for a prescriber or health facility or agency under subsection (1) shall do all of the following:

(a) Maintain complete and accurate records on a monthly basis of requests from and pharmaceuticals compounded for each prescriber or health facility or agency.

(b) Provide the information described in subdivision (a) to the department as specified in rules or upon request.

(3) The authorization granted under subsection (1) is for a 2-year period consistent with the 2-year license cycle of the pharmacy. The department may, without prior notice to the pharmacist or pharmacy, physically inspect the facility where the compounding of nonsterile or sterile pharmaceuticals occurs.

(4) The department shall not authorize a pharmacist or compounding pharmacy to compound nonsterile or sterile pharmaceuticals without a prescription if the pharmacist or pharmacy is under investigation, is in the process of being disciplined, or is in a disciplinary status.

(5) Except as otherwise provided in this subsection, the department may immediately revoke the authorization granted under subsection (1) if there is a confirmed deviation or violation of the compounding process or if an adverse event directly related to sterility or integrity of the product and associated with a compounded nonsterile or sterile pharmaceutical is detected. If the health, safety, and welfare of the public are not in immediate jeopardy, the department shall provide at least 30 days' notice of the revocation of authorization under this subsection.

(6) A pharmacy or pharmacist authorized to compound pharmaceuticals under this section that becomes aware of an adverse event attributed to the integrity of the product of a compounded pharmaceutical shall report the adverse event to the department not later than 10 calendar days after becoming aware of the adverse event. For purposes of this subsection, an adverse event does not include an isolated allergic reaction to a substance included in the compound if the allergic reaction is treated and relieved with standard protocol.

(7) The department shall post and maintain a list of pharmacies and pharmacists who are authorized to compound pharmaceuticals under this section on its internet website. The department shall update the list required under this subsection at least quarterly.

(8) A prescriber or health facility or agency that obtains compounded pharmaceuticals under this section shall not redispense or sell the compounded pharmaceutical to a patient, a prescriber, or health facility or agency.

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