



PUBLIC CHAPTER NO. 149

SENATE BILL NO. 1269

By Reeves

Substituted for: House Bill No. 877

By Terry, Hazlewood

AN ACT to amend Tennessee Code Annotated, Section 63-10-216, relative to pharmacies.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 63-10-216, is amended by deleting the section and substituting the following:

(a)(1) Prior to initial licensure in this state as a compounding pharmacy, a pharmacy located outside of this state must have an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Out-of-state pharmacy practice sites must provide to the board a copy of the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, or an equivalent inspection accepted by the board, that must have been within the previous twelve (12) months.

(2) Prior to renewal of its license in this state, an out-of-state pharmacy practice site must provide to the board the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, or an equivalent inspection accepted by the board, that must have been within the previous twelve (12) months.

(3) The board may require additional information before issuing or renewing a pharmacy license to ensure compliance with applicable laws of this state and rules of the board.

(b) A compounding pharmacy that has an active license issued by the board shall notify the board within fourteen (14) business days of receipt of an order or decision by a regulatory or licensing agency, other than the board, imposing a disciplinary action, including a warning, on the pharmacy.

(c) A pharmacy engaged in compounding must comply with relevant United States Pharmacopeia (USP) guidelines as adopted by the board by rule.

(d) A pharmacy that engages in sterile compounding, except hospital pharmacies compounding for inpatients of a hospital, shall, upon request, make available to the board the quantity of sterile compounded products dispensed in a defined time period in accordance with rules promulgated by the board. However, the executive director of the board may request this information from a hospital pharmacy for cause and the hospital pharmacy shall respond in a timely manner as defined by the executive director of the board.

SECTION 2. This act takes effect upon becoming a law, the public welfare requiring it.

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PASSED:

March 29, 2021

WA e RANDY MCNALLY SPEAKER OF THE SENATE

CAMERON SEXTON, SPEAKER HOUSE OF REPRESENTATIVES

APPROVED this 13th day of 4pril 2021

Bri Les BILL LEE EE. GOVERNOR