



Ohio Administrative Code

Rule 4729:5-3-03 Inspections and corrective actions.

Effective: April 1, 2018

(A) Pursuant to section 3719.13 of the Revised Code, an entity licensed by the state board of pharmacy as a terminal distributor of dangerous drugs is subject to an on-site inspection by the board. An authorized board agent may, without notice, carry out an on-site inspection or investigation of an entity licensed by the board. Upon verification of the board agent's credentials, the agent shall be permitted to enter the licensed entity.

(B) Submission of an application for a license as a terminal distributor of dangerous drugs with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board agent.

(C) If an agent of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the agent may provide written notice, in a manner determined by the board, of the nature of the observed violations to the responsible person on the license or application. The licensee or applicant may also be subject to disciplinary actions pursuant to Chapter 4729. of the Revised Code and this division of the Administrative Code.

(D) Violations may include any of the following:

(1) Violating any rule of the board;

(2) Violating any provision of Chapter 4729. of the Revised Code;

(3) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301, or Chapter 3715. of the Revised Code;

(4) Violating any provision of the federal drug abuse control laws or regulations or Chapter 2925. or 3719. of the Revised Code.



(E) The licensee or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.