

4729-9-09

Inspections and Corrective Actions.

(A) Pursuant to section 3719.13, an entity licensed or registered by the state board of pharmacy 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 or registered by the board. Upon verification of the board agent's credentials, the agent shall be permitted to enter the licensed or registered entity.

(B) Submission of an application for a license or registration 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 prescribed by the board, of the nature of the observed violations to the responsible person on the license, registration or application. The licensee, registrant or applicant may also be subject to disciplinary actions pursuant to sections 4729.16, 4729.56 and 4729.57 of the Revised 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.A. 301, or Chapter 3715. of the Revised Code;

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

(E) The licensee, registrant or applicant shall submit to the board within thirty days, in a manner prescribed by the board, either of the following:

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

(2) An explanation disputing the observed violations.

Effective: 02/17/2017

Five Year Review (FYR) Dates: 02/17/2022

CERTIFIED ELECTRONICALLY

Certification

02/07/2017

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28
Rule Amplifies: 4729.25, 3719.18, 3719.13