



**STATE OF
OHIO**
BOARD OF PHARMACY

Internal Management Rule on Accountability and Administrative Discipline for Licensees and Responsible Individuals - Public Comments Requested

Acting under the authority of Ohio Revised Code Chapter 4729, the State of Ohio Board of Pharmacy proposes the adoption of an internal management rule regarding responsible individuals. As used in this rule, a "Responsible Individual" means any of the following:

- (1) A responsible person for any license issued under Chapter 4729. of the Revised Code in accordance with rules 4729:5-2-01 and 4729:6-2-01 of the Administrative Code;*
- (2) A designated representative for any dispensary provisional license or dispensary holding a certificate of operation in accordance with rule 3796:6-3-05 of the Administrative Code;
and*
- (3) A designated representative for a licensed or registered home medical equipment services provider pursuant to rule 4729:11-2-01 of the Administrative Code.*

The Board is seeking to implement general guidance to determine when a responsible individual should also be held accountable for a violation occurring at a Board of Pharmacy licensed location. This internal management rule was drafted using similar standards adopted by the California Board of Pharmacy: https://www.pharmacy.ca.gov/laws_regs/1760_fdgc.pdf

Please be advised that this rule still permits the Board to consider other factors and is intended to provide general guidance when reviewing cases for citation. The goal of the rule is to ensure consistency across the Board's administrative citation process.

Comments on the proposed rule will be accepted until close of business on **September 25, 2020**. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov.



4729-2-05 - Accountability and Administrative Discipline for Licensees and Responsible Individuals

(A) As used in this rule:

(1) "Licensee" shall include any facility licensed or registered by the board under Chapters 4729., 4752., and 3796. of the Revised Code.

(2) "Responsible individual" means any of the following:

(a) A responsible person for any license issued under Chapter 4729. of the Revised Code in accordance with rules 4729:5-2-01 and 4729:6-2-01 of the Administrative Code;

(b) A designated representative for any dispensary provisional license or dispensary holding a certificate of operation in accordance with rule 3796:6-3-05 of the Administrative Code; and

(c) A designated representative for a licensed or registered home medical equipment services provider pursuant to rule 4729:11-2-01 of the Administrative Code.

(B) Except as provided in this rule or as otherwise determined by the board, the board of pharmacy shall hold a licensee and the licensee's responsible individual accountable for violations of state and federal laws, rules, and regulations of personnel working for the licensee.

(1) The board shall consider the following mitigating factors in determining whether to issue a citation to a licensee's responsible individual:

(a) The responsible individual did not engage, either directly or indirectly, in conduct that violated any state and federal laws, rules, and regulations pertaining to the operation of the licensee.

(b) The responsible individual did not permit, encourage, approve of, either tacitly or implicitly or through willful ignorance, any conduct committed by another person that violated state and federal laws, rules, and regulations pertaining to the operation of the licensee.

(c) The responsible individual reported the violation, or suspected violation, of any state and federal laws, rules, and regulations pertaining to the operation of the licensee to the board in accordance with the reporting requirements of agency 4729, 4752, and 3796 of the Administrative Code.

(d) The responsible individual took all actions reasonably necessary to stop and remedy the violation, or suspected violation, of any state and federal laws, rules, and regulations pertaining to the operation of the licensee as soon as reasonably possible following the discovery of the violation.

(e) The violation is the result of a failure on the part of the licensee that, based upon the facts and circumstances of the violation, is deemed beyond the control of the licensee's responsible individual.

(f) The extent to which the responsible individual cooperated with the board's investigation of the alleged violations.

(2) The board shall consider the following aggravating factors in determining whether to issue a citation to a licensee's responsible individual:

- (a) The extent and gravity of personal, economic, or public damage or harm;
- (b) The vulnerability of the patient(s);
- (c) Commission of fraud, misrepresentation, or deception in applying for or securing a license issued by the board;
- (d) Commission of fraud, misrepresentation, or deception during an inspection or investigation;
- (e) Willful or reckless conduct or knowingly making a professional omission;
- (f) Pattern of misconduct that serves as a basis of discipline;
- (g) Prior disciplinary action(s);
- (h) Attempted concealment of the conduct which serves as a basis for disciplinary action; and
- (i) Violation of a board order or settlement agreement.