

Rules – April 2024

4729:5-3-22 - Continuous Quality Improvement Programs in Pharmacy Services. (NEW)

(A) As used in this rule, “dispensing error” or “error in dispensing” means one or more of the following discovered after the dispensation (e.g., final verification) by the pharmacist or verification in accordance with rule 4729:5-3-17 of the Administrative Code, regardless of whether the patient received the drug:

(1) Variation from the prescriber's prescription or drug order, unless otherwise modified by the pharmacist in accordance with agency 4729 of the Administrative Code, including:

(a) Incorrect drug;

(b) Incorrect drug strength;

(c) Incorrect dosage form;

~~(d) Incorrect quantity;~~

(d) Incorrect patient; or

(e) Inadequate or incorrect packaging, labeling, or directions.

(2) Failure to exercise professional judgment in identifying and managing:

(a) Known therapeutic duplication;

(b) Known drug-disease contraindications;

(c) Known drug-drug interactions;

(d) Incorrect drug dosage or duration of drug treatment;

(e) Known drug-allergy interactions;

Commented [MC1]: Comment: Does not account for downstream systems that can identify and prevent an error.

- (f) Any product quality issue attributed to a compounded drug preparation;
 - (g) A clinically significant, avoidable delay in therapy; or
 - (h) Any other significant, actual, or potential problem with a patient's drug therapy related to the practice of pharmacy.
- (3) Sale of a drug to the incorrect patient.
- (4) Variation in bulk repackaging or filling of automated devices, including:
- (a) Incorrect drug;
 - (b) Incorrect drug strength;
 - (c) Incorrect dosage form; or
 - (d) Inadequate or incorrect packaging or labeling.

(4) A dispensing error does not include the delivery of an incorrect drug to a patient by a pharmacy delivery agent as defined in rule 4729:5-5-22 of the Administrative Code.

(B) A “dispensing error” or “error in dispensing,” as defined in paragraph (A) of this rule, may be considered a violation of division (A)(2) of section [3715.52](#) and section [3715.64](#) of the Revised Code.

(C) Each pharmacy licensed as a terminal distributor of dangerous drugs shall establish or participate in an established quality assurance program that documents and assesses dispensing errors to determine cause and an appropriate response to improve the quality of pharmacy service and prevent errors.

(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy to be made readily retrievable upon request of an agent, inspector, or employee of the board.

(2) The quality assurance program shall include necessary documentation, internal reporting, and assessment of dispensing errors to determine the cause and an appropriate response to prevent future dispensing errors.

(3) In accordance with section 4729.23 of the Revised Code, all records of the quality assurance program for each pharmacy, as established in paragraph (G) of this rule, shall be maintained for three years from the date of creation in a readily retrievable

manner. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded by the pharmacy.

Commented [MC2]: Zero report.

(4) If applicable, a quality assurance review may be conducted by a quality assurance committee established in accordance with section 2305.24 of the Revised Code.

(D) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy to be made readily retrievable upon request of an agent, inspector, or employee of the board.

(D) When a pharmacy determines or has been notified that a dispensing error has occurred, a representative of the terminal distributor of dangerous drugs shall as soon as possible:

(1) Except as provided in paragraph (D)(3) of this rule, communicate to the patient or the patient's caregiver the fact that an error in dispensing has occurred, and the steps required to avoid harm or mitigate the error.

(2) Except as provided in paragraph (D)(3) of this rule, communicate to the prescriber the fact that an error in dispensing has occurred only if the error could result in potential or actual patient harm.

(3) The communication requirement of this paragraph shall only apply when a patient receives a drug that was the result of a dispensing error **and the error poses harm to the patient. Harm includes impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.**

(4) The pharmacy shall maintain documentation that the communications requirements of this rule were completed. Such documentation shall be maintained for three years from the date of creation in a readily retrievable manner.

(E) If a pharmacy is notified of a dispensing error by the patient, the patient's caregiver, or a prescriber, a representative of the terminal distributor of dangerous drugs is not required to communicate with that individual as required in paragraph (D) of this rule.

(G) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent errors in dispensing. An investigation of each error in dispensing shall commence as soon as is reasonably possible. All errors in dispensing discovered shall be subject to a quality assurance review within thirty days of identifying an error.

(H)

~~(1) The primary purpose of the quality assurance review (e.g., root cause analysis) shall be to advance error prevention by analyzing investigative and other pertinent data collected in response to an error in dispensing and to assess the cause and any contributing factors such as system or process failures or recklessness on the part of pharmacy staff. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:~~

~~(a) The date, location, and participants in the quality assurance review;~~

~~(b) The pertinent data and other information relating to the dispensing error(s) reviewed and documentation of any patient contact required;~~

~~(c) The findings and determinations generated by the quality assurance review; and~~

~~(d) Recommend changes to pharmacy policy, procedure, systems, or processes, if any.~~

~~(2) If applicable, a quality assurance review may be conducted by a quality assurance committee established in accordance with section 2305.24 of the Revised Code.~~

~~(1) In accordance with section 4729.23 of the Revised Code, all records of the quality assurance review, as established in paragraph (G) of this rule, shall be maintained for three years from the date of creation in a readily retrievable manner.~~

(F) The terminal distributor of dangerous drugs shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program review.

(G) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this rule.

(H) The pharmacy shall comply with the reporting requirements for dispensing errors pursuant to rule 4729:5-4-02 of the Administrative Code.

Rule 4729:1-4-02 | Duty to report. (PHARMACISTS) (RESCIND ORIGINAL / NEW)

(A) As used in this rule, "error in dispensing" or "dispensing error" has the same meaning as 4729:5-3-22 of the Administrative Code.

(B) Pursuant to section [4729.10](#) of the Revised Code, a pharmacist who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the state board of pharmacy.

(C) The following shall be reported to the board no later than ten days from discovery:

(1) Except as provided in paragraphs (C)(1)(a) and (C)(1)(b) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A pharmacist shall not be required to report in accordance with this rule if the pharmacist becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The pharmacist's treatment of the individual for the condition; or

(ii) The pharmacist having access to the individual's protected health information.

(b) A pharmacist shall not be required to report in accordance with this rule if the individual voluntarily seeks treatment for a mental health condition or substance use disorder and there are no other violations of rule or law.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 4752., 3715., 3719., 3796., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual or entity licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule [4729:1-4-01](#) of the Administrative Code.

(D)

(1) Pursuant to section [4729.23](#) of the Revised Code, the identity of the pharmacist making a report in accordance with this rule shall remain confidential.

Commented [MC3]: PROPOSED CHANGE: Except as provided in paragraphs (C)(1)(a) and (C)(1)(b) of this rule, conduct indicating an individual licensed or registered by the board is practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D)(1) of this rule, a pharmacist may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing the pharmacist was the reporting individual.

(E) Reporting required in accordance with this rule shall be made by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

(1) The name of the licensee, registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;

(2) The violation which is believed to have occurred; and

(3) The date(s) of and place(s) of occurrence(s), if known.

(F) A licensed pharmacist shall notify the board of any of the following:

(1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense within ten days after the date of conviction.

(2) The pharmacist is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section [2951.041](#) of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.

(3) The pharmacist is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.

(4) Any arrest for a felony within ten days after the arrest.

(G) A pharmacist shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) A dispensing error, as defined in rule 4729:5-3-22 of the Administrative Code, shall only be reported to the board by a pharmacy in accordance with rule 4729:5-4-02 of the Administrative Code.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted

under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:2-4-02 | Duty to report. (PHARMACY INTERNS) (RESCIND ORIGINAL / NEW)

(A) As used in this rule, "error in dispensing" or "dispensing error" has the same meaning as 4729:5-3-22 of the Administrative Code.

(B) Pursuant to section [4729.10](#) of the Revised Code, a pharmacy intern who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the state board of pharmacy.

(C) The following shall be reported to the board no later than ten days from discovery:

(1) Except as provided in paragraphs (C)(1)(a) and (C)(1)(b) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A pharmacy intern shall not be required to report in accordance with this rule if the intern becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

(i) The intern's treatment of the individual for the condition; or

(ii) The intern having access to the individual's protected health information.

(b) A pharmacy intern shall not be required to report in accordance with this rule if the individual voluntarily seeks treatment for a mental health condition or substance use disorder and there are no other violations of rule or law.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 3715., 3719., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule [4729:2-4-01](#) of the Administrative Code.

(D)

(1) Pursuant to section [4729.23](#) of the Revised Code, the identity of the pharmacy intern making a report in accordance with this rule shall remain confidential.

Commented [MC4]: PROPOSED CHANGE: Except as provided in paragraphs (C)(1)(a) and (C)(1)(b) of this rule, conduct indicating an individual licensed or registered by the board is practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D) (1) of this rule, a pharmacy intern may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing the intern was the reporting individual.

(E) Reporting required in accordance this rule shall be made by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

(1) The name of the licensee, registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;

(2) The violation which is believed to have occurred; and

(3) The date(s) of and place(s) of occurrence(s), if known.

(F) A licensed pharmacy intern shall notify the board of any of the following:

(1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense within ten days after the date of conviction.

(2) The intern is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section [2951.041](#) of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.

(3) The intern is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.

(4) Any arrest for a felony within ten days after the arrest.

(G) A pharmacy intern shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) A dispensing error, as defined in rule 4729:5-3-22 of the Administrative Code, shall only be reported to the board by a pharmacy in accordance with rule 4729:5-4-02 of the Administrative Code.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted

under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:3-4-02 | Duty to report. (PHARMACY TECHNICIANS) (RESCIND ORIGINAL / NEW)

(A) As used in this rule, "error in dispensing" or "dispensing error" has the same meaning as 4729:5-3-22 of the Administrative Code.

(B) Pursuant to section [4729.10](#) of the Revised Code, a pharmacy technician trainee, registered pharmacy technician or certified pharmacy technician who has knowledge, from direct observation or objective evidence, of violations described in paragraph (C) of this rule shall report such conduct to the board.

(C) The following shall be reported to the board no later than ten days from discovery:

(1) Except as provided in paragraph (C)(1)(a) and (C)(1)(b) of this rule, conduct indicating an individual licensed or registered by the board is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(a) A registrant shall not be required to report in accordance with this rule if the registrant becomes aware of any condition described in paragraph (C)(1) of this rule as a result of either:

- (i) The registrant or licensee is involved in the treatment of the individual for the condition; or
- (ii) The registrant or licensee having access to the individual's protected health information.

(b) A registrant shall not be required to report in accordance with this rule if the individual voluntarily seeks treatment for a mental health condition or substance use disorder and there are no other violations of rule or law.

(2) Except as provided in paragraph (H) of this rule, violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 3715., 3719., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual licensed or registered by the board.

(3) Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern or pharmacist that constitutes unprofessional conduct or dishonesty as defined in rule [4729:3-4-01](#) of the Administrative Code.

(D)

(1) Pursuant to section [4729.23](#) of the Revised Code, the identity of the registrant making a report in accordance with this rule shall remain confidential.

Commented [MC5]: PROPOSED CHANGE: Except as provided in paragraphs (C)(1)(a) and (C)(1)(b) of this rule, conduct indicating an individual licensed or registered by the board is practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (D)(1) of this rule, a registrant may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (C) of this rule without disclosing the registrant was the reporting individual.

(E) Reporting required in accordance with paragraph (C) this rule shall be made by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

(1) The name of the licensee or registrant or other individual who may have committed a violation listed in paragraph (C) of this rule;

(2) The violation which is believed to have occurred; and

(3) The date(s) of and place(s) of occurrence(s), if known.

(F) An individual registered pursuant to this division shall notify the board of any of the following:

(1) Any criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense within ten days after the date of conviction.

(2) The registrant is convicted of, plead guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section [2951.041](#) of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.

(3) The registrant is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.

(4) Any arrest for a felony within ten days after the arrest.

(5) For a certified pharmacy technician, failure to maintain a current pharmacy technician certification from an organization that has been recognized by the board.

(G) An individual registered pursuant to this division shall notify the board of any disciplinary licensing or registration action taken by another state against the registrant within ten days of the notice of action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(H) A dispensing error, as defined in rule 4729:5-3-22 of the Administrative Code, shall only be reported to the board by a pharmacy in accordance with rule 4729:5-4-02 of the Administrative Code.

(I) Pursuant to section [4729.10](#) of the Revised Code, in the absence of fraud or bad faith, a person who reports in accordance with this rule or testifies in any adjudication conducted under Chapter 119. of the Revised Code is not liable to any person for damages in a civil action as a result of the report or testimony.

Rule 4729:5-4-02 | Duty to Report. (PHARMACIES) (NEW)

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

Commented [MC6]: The reference to "dishonesty" in 4729:5-4-02(A)(1) and (B)(4) is overly broad. A concern here is that the Board could allege dishonesty if further investigation of a medication error reveals facts that are simply different than were initially stated. It is not uncommon for complex investigations to reveal facts or circumstances that were unknown earlier in the process, but are not the result of dishonesty.

(2) "Dispensing error" or "error in dispensing" has the same meaning as 4729:5-3-22 of the Administrative Code.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(4) "Unprofessional conduct" means conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(B) A pharmacy licensed as a terminal distributor of dangerous drugs shall be required to report, from direct observation or objective evidence, the following to the board in accordance with paragraph (C) of this rule:

(1) Any error in dispensing when the error is the result of reckless behavior.

(2) Any error in dispensing where the error results in any of the following per the National Coordinating Council for Medication Error Reporting and Prevention Medication Error Index (Revised 2/20/2001):

(a) Category F: An error occurred that resulted in initial or prolonged hospitalization and caused temporary patient harm.

Commented [MC7]: Additionally, this has the potential for causing an unintended consequence for the Board of Pharmacy in that as the rule is written, there is the potential for the BOP to receive so many reports resulting in a daunting capacity overload. One could argue that it could be near impossible to effectively filter through so many reports and use in a meaningful manner.

(b) Category G: An error occurred that resulted in permanent patient harm.

(c) Category H: An error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest).

(d) Category I: An error occurred that resulted in patient death.

(3) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on an error or errors in dispensing.

(4) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on engaging in unprofessional conduct, dishonesty, or reckless behavior.

(5) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on the individual being addicted to or suspected of abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(C) Reporting required in accordance with this rule shall be made by mail, using the board's online complaint form (available on the board's website: www.pharmacy.ohio.gov), **or telephone** and shall include the following information:

(1) The name of the employer and the employer's terminal distributor license number;

(2) The full name and license or registration number of the licensee or registrant for which a report is being made;

(3) If applicable, an explanation of the error in dispensing that occurred, including details regarding any patient harm;

(4) If applicable, an explanation of the circumstances that resulted in the individual's termination or resignation from employment; and

(5) The date(s) of and place(s) of occurrence(s), if known.

(D) All required reporting shall be submitted to the board no later than:

(1) For an error in dispensing pursuant to paragraphs (B)(1) through (B)(3) of this rule, ten days from the date the quality assurance program review in accordance with rule 4729:5-3-22 was completed; and

(2) For the termination or resignation of an employee pursuant to paragraphs (B)(4) and (B)(5) of this rule, ten days from the date the individual is terminated or resigns from employment.

(E) Notwithstanding any provision of agency 4729 of the Administrative Code, a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy

Commented [MC8]: The OSHP is also concerned regarding the negative impact stemming from 4729:5-4-02 (B)(5), as the outlined reporting requirement may discourage individuals affected by substance use disorders from seeking treatment due to the punitive association with this requirement. The OSHP recommends against adopting this rule.

Commented [CM9R8]: Suggested Change:

The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on conduct indicating an individual licensed or registered by the board is practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

technician trainee shall not be required to make a report to the board pursuant to the applicable duty to report rules in divisions 4729:1, 4729:2, and 4729:3 of the Administrative Code if the licensee or registrant is employed by or under contract with a pharmacy licensed as a terminal distributor of dangerous drugs and the terminal distributor submits a report in accordance with paragraph (B) of this rule.

Rule 4729:1-4-01 | Disciplinary actions. (AMEND) [Pharmacists]

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant, or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" has the same meaning as defined in division (C) of section 4729.16 of the Revised Code and shall also include conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(B)

(1) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a pharmacist or applicant for a pharmacist license if the board finds the individual engaged in any of the conduct set forth in paragraph (B)(2) of this rule:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in paragraph (B)(1) of this rule if the board finds a pharmacist or applicant for a pharmacist license:

(a) Has a criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense.

- (b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy.
- (c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacist unfit to practice pharmacy.
- (d) **Except as provided for in paragraph (B)(2)(r) of this rule,** violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of Chapter 4729. of the Revised Code, sections 3715.52 to 3715.72 of the Revised Code, Chapter 2925., 3796., 3719. or 4752. of the Revised Code, or any rule adopted by the board under those provisions.
- (e) Permitted someone other than a pharmacist or pharmacy intern to practice pharmacy.
- (f) Knowingly lent the pharmacist's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy.
- (g) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home.
- (h) Violated the terms of a consult agreement entered into pursuant to section 4729.39 of the Revised Code.
- (i) Committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under this chapter or under Chapter 3796., 3715., 3719., or 4752. of the Revised Code.
- (j) Failed to comply with an order of the board or a settlement agreement.
- (k) Violated any state or federal law, regulation, or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired vehicle registration.
- (l) Has been disciplined by the state board of pharmacy pursuant to section 4729.16 of the Revised Code.
- (m) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
 - (i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration.

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug.

(n) Failed to conform to prevailing standards of care of similar pharmacists under the same or similar circumstances, whether or not actual injury to a patient is established.

(o) Has been subject to any of the following:

(i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(p) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(q) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(r) Is responsible for any of the following but only as a result of reckless behavior:

(i) An error in dispensing as defined in rule 4729:5-3-22 of the Administrative Code;

(ii) A product quality issue for any compounded drug preparation as defined in rule 4729:7-2-03 of the Administrative Code.

Rule 4729:2-4-01 | Disciplinary actions. (AMEND) [Pharmacy Interns]

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant, or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" has the same meaning as defined in division (C) of section [4729.16](#) of the Revised Code and shall also include conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(B)

(1) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a pharmacy intern or applicant for a pharmacy intern license if the board finds the individual engaged in any of the conduct set forth in paragraph (B)(2) of this rule:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in paragraph (B)(1) of this rule if the board finds a pharmacy intern or applicant for a pharmacy intern license:

(a) Has a criminal conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense.

(b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy.

(c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacy intern unfit to practice pharmacy.

(d) **Except as provided for in paragraph (B)(2)(p) of this rule,** violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of Chapter 4729. of the Revised Code, sections [3715.52](#) to [3715.72](#) of the Revised Code, Chapter 2925., 3796., 3719. or 4752. of the Revised Code, or any rule adopted by the board under those provisions.

(e) Knowingly lent the pharmacy intern's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy.

(f) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home.

(g) Committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under this chapter or under Chapter 3796., 3715., 3719. or 4752. of the Revised Code.

(h) Failed to comply with an order of the board or a settlement agreement.

(i) Violated any state or federal law, regulation, or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired vehicle registration.

(j) Has been disciplined by the state board of pharmacy pursuant to section [4729.16](#) of the Revised Code.

(k) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration.

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying, or selling a controlled substance or other dangerous drug.

(l) Failed to conform to prevailing standards of care of similar pharmacy interns under the same or similar circumstances, whether or not actual injury to a patient is established.

(m) Has been subject to any of the following:

(i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(n) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(o) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(p) Is responsible for any of the following but only as a result of reckless behavior:

(i) An error in dispensing as defined in rule 4729:5-3-22 of the Administrative Code;

(ii) A product quality issue for any compounded drug preparation as defined in rule 4729:7-2-03 of the Administrative Code.

Rule 4729:3-4-01 | Disciplinary actions. (AMEND) [Pharmacy Technicians]

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant, or applicant to include, but is not limited to, making any statement that deceives, misrepresents, or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Unprofessional conduct" means conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(B) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose one or more of the following sanctions on a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician or applicant for such registration if the board finds the individual engaged in any of the conduct set forth in paragraph (C) of this rule:

(1) Revoke, suspend, restrict, limit, or refuse to grant or renew a registration;

(2) Reprimand or place the holder of the registration on probation;

(3) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture as specified in section [4729.96](#) of the Revised Code.

(C) The board may impose the sanctions listed in paragraph (B) of this rule if the board finds a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician or applicant for such registration:

(1) **Except as provided in paragraph (C)(9) of this rule,** has engaged in any of the conduct specified in division (A)(2) of section [4729.96](#) of the Revised Code.

(2) Violated any state or federal law or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.

(3) Has been disciplined by the state board of pharmacy pursuant to section [4729.96](#) of the Revised Code.

(4) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration.

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(5) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(6) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(7) Cannot conduct authorized activities according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(8) Engaged in dishonesty or unprofessional conduct.

(9) Is responsible for any of the following but only as a result of reckless behavior:

(a) An error in dispensing as defined in rule 4729:5-3-22 of the Administrative Code;

(b) A product quality issue for any compounded drug preparation as defined in rule 4729:7-2-03 of the Administrative Code.

(D) The board may require that an individual whose registration has been suspended may not be employed by or work in a facility licensed by the state board of pharmacy to possess or distribute dangerous drugs during such period of suspension.

4729:5-5-02.3 | Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy. (AMEND)

...

(D) An outpatient pharmacy shall not retaliate or discipline ~~a pharmacist~~ pharmacy personnel who, in good faith, makes a request for additional staff or reports staffing concerns in accordance with this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

Rule 4729:5-5-18 | Dispensing customized patient medication packages by an outpatient pharmacy. (AMEND)

In lieu of dispensing two or more dangerous drugs in separate containers, a pharmacist practicing at an outpatient pharmacy may dispense a customized patient medication package. A customized patient medication package is a package for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms that complies with the following requirements:

(A) The package is designed, or each container is labeled, to indicate the day and time or period of time when the contents within each container are to be taken by the patient.

(B) The number of drugs placed in each container cannot exceed the capability of the container to prevent damage to the dosage forms.

(C) The quantity of the package dispensed may not be more than a ~~thirty-one day~~ ninety-day supply.

(D) The labels must be of sufficient size to properly and clearly label a ~~thirty-one day~~ ninety-day or less supply with all information required in accordance with this chapter of the Administrative Code, including the use of accessory labels.

(E) The package must include an expiration date or beyond-use date, which shall not exceed the expiration date on the manufacturer's container or six months from the date the drug was originally packaged, whichever date is earlier. If multiple manufacturer containers are used, the expiration date shall not exceed the expiration date on the manufacturer's container that will expire first or six months from the date the drug was originally repackaged, whichever date is earlier.

(F) Dangerous drugs which have been dispensed in a customized patient medication package may only be returned to stock or re-dispensed in accordance with all the following:

(1) The drugs have not been in the possession of the ultimate user; and

(2) The drugs have not been placed in the same container with another dangerous drug (i.e. did not come into direct contact with a different drug within the same container).

(G) The containers of a package are sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(H) Any pharmacy dispensing customized patient medication packages in accordance with this rule must implement policies and procedures that will exclude drugs having any of the following characteristics from such packaging:

- (1) The U.S.P. monograph or official labeling requires dispensing in the original container, unless there is documentation from the manufacturer stating otherwise;
- (2) The drugs or dosage forms are incompatible with packaging components or each other;
- (3) The drugs are therapeutically incompatible when administered simultaneously;
- (4) The drugs require special packaging.

Rule 4729:1-2-01 | Criteria for licensure by examination. (AMEND)

~~(A) Pursuant to sections [4729.07](#) and [4729.13](#) of the Revised Code, pharmacist licensure by examination shall consist of the "North American Pharmacist Licensure Examination" (NAPLEX) and the "Multistate Pharmacy Jurisprudence Examination" (MPJE) administered by the national association of boards of pharmacy (NABP).~~

(A) Pursuant to sections [4729.07](#) and [4729.13](#) of the Revised Code, pharmacist licensure by examination shall consist of:

(1) The "North American Pharmacist Licensure Examination" (NAPLEX) administered by the national association of boards of pharmacy (NABP); and

(2) A jurisprudence examination which shall be one of the following as determined by the board:

(a) The "Multistate Pharmacy Jurisprudence Examination" (MPJE) administered by the national association of boards of pharmacy (NABP); or

(b) A jurisprudence examination approved by the board.

~~(B)(1)~~ Unless otherwise approved by the board, the minimum passing score on each examination shall be determined by NABP.

~~(a 1)~~ Any candidate who fails to receive a passing score on the NAPLEX examination shall make application and remit the fee established by the state board of pharmacy for re-examination.

~~(b 2)~~ Any candidate who fails to receive a passing score on the ~~MPJE~~ jurisprudence examination shall make application and remit the fee established by the state board of pharmacy for re-examination.

~~(B C)~~ A candidate may use the NABP process to transfer the candidate's NAPLEX score to Ohio only after the candidate has met all of the requirements set by the board for examination and licensure in Ohio.

~~(C D)~~ Pursuant to section [4729.08](#) of the Revised Code, graduates of unapproved schools or colleges of pharmacy located outside the United States who are using an approved examination to establish equivalency of their education shall:

(1) Obtain a passing score, as determined by NABP, on the "Foreign Pharmacy Graduate Equivalency Examination (FPGEE)"; and

(2) Show oral proficiency in English by successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule [4729:1-2-04](#) of the Administrative Code.

~~(D)~~ **(E)** Any examination candidate who fails to take both of the required examinations pursuant to paragraph (A) of this rule within twelve months from the date the board receives the application materials shall submit a new application for the required examination or examinations and remit the fee established by the board, as the original application shall be deemed abandoned.

~~(E)~~ **(F)** The record of the passing score for an examination candidate who takes both of the required examinations pursuant to paragraph (A) of this rule, but successfully only completes one examination will:

(1) Be maintained up to three years if no more than twelve months has elapsed between attempts to successfully complete the remaining examination.

(2) Not be maintained if more than twelve months has elapsed between attempts to successfully complete the remaining examination. It will then be necessary for the examination candidate to repeat both examinations for Ohio licensure.

~~(F)~~ **(G)** Any candidate who has requested to transfer their NAPLEX score to Ohio must **successfully complete take** the **MPJE jurisprudence examination** within twelve months from the date the candidate completed the NAPLEX examination or the score transfer will be denied.

~~(G)~~ **(H)** Pursuant to section [4729.071](#) of the Revised Code, a candidate must submit electronic or ink fingerprint impressions for a criminal records check prior to receiving approval to take the required examinations. An examination candidate must submit fingerprint impressions no later than sixty days after the date the board receives the application materials. After sixty days, a candidate must submit a new application, the required fee, and fingerprint impressions, as the original application shall be deemed abandoned.

~~(H)~~ **(I)** Candidates shall be limited to a total of five attempts to pass the NAPLEX and the **MPJE jurisprudence examination**. The board may grant one additional attempt to pass the NAPLEX and the **MPJE jurisprudence examination** in the event of extraordinary circumstances. A candidate that exceeds the limits set forth in this paragraph is no longer eligible to obtain licensure as a pharmacist by examination pursuant to this rule.

~~(I)~~ **(J)** Pursuant to section [4729.16](#) of the Revised Code, a limited or restricted license may be issued to an applicant upon the determination of the board.

Rule 4729:1-2-02 | Criteria for licensure by reciprocity. (AMEND)

(A) An applicant seeking licensure as a pharmacist by reciprocity shall comply with all the following:

- (1) Be at least eighteen years of age.
- (2) Obtain a degree in pharmacy from a school of pharmacy approved by the state board of pharmacy.
- (3) Have met the applicable practical experience requirements by either:
 - (a) Successfully graduating after December 31, 2006 with a doctor of pharmacy degree (Pharm.D.) from a school of pharmacy approved by the state board of pharmacy; or
 - (b) Obtaining a total of at least one thousand seven hundred and forty hours of documented supervised practical experience in Ohio or any other state or jurisdiction in which the credentials are at least the equivalent of those required by this state at the time the experience was obtained. If the reciprocating state or jurisdiction requires less than the required hours, the board may grant internship credit for practice as a pharmacist.
- (4) Hold an active license or registration to practice pharmacy, which is in good standing, in a state or jurisdiction in which the credentials are at least the equivalent of those required by this state. Certification of these credentials shall be conducted by the national association of boards of pharmacy (NABP).

(B) An applicant who has met the requirements of the state or jurisdiction with which the applicant holds a certificate of good standing pursuant to a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate shall be required to establish proficiency in spoken English by providing evidence of the successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule [4729:1-2-04](#) of the Administrative Code.

(C) Except as provided in rule [4729:1-2-09](#) of the Administrative Code, candidates who qualify for licensure by reciprocity shall successfully complete a course developed by the board **or approved by the board**, that includes a scored evaluation component, on ~~Ohio's~~ **Ohio's** law and rules governing the practice of pharmacy.

(1) Candidates who do not successfully complete this course within six months following the submission of a completed application shall file a new application and required fee for licensure by reciprocity, as the original application shall be deemed abandoned.

(2) Except as provided in paragraph (C)(3) of this rule, the board may require an applicant to complete **the jurisprudence examination as defined in rule 4729:1-2-01 of the Administrative Code the "Multistate Pharmacy Jurisprudence Examination" (MPJE)** in lieu of completing the course if the applicant has never obtained a passing score on the MPJE for any state or jurisdiction.

(3) Paragraph (C)(2) of this rule does not apply to applicant who either:

(a) Received initial licensure prior to January 1, 2018; or

(b) Successfully passed a board approved state jurisprudence examination.

(D) Pursuant to section [4729.071](#) of the Revised Code, a candidate must submit electronic or ink fingerprint impressions for a criminal records check prior to receiving an initial license to practice as a pharmacist. A reciprocity candidate must submit fingerprint impressions no later than six months after the date the board receives the application materials. After six months, a candidate must submit a new application, the required fee, and fingerprint impressions.

(E) Pursuant to division (B)(2) of section [4796.03](#) of the Revised Code, the board hereby waives the requirements set forth in division (B)(1) of section [4796.03](#) of the Revised Code.

(F) Pursuant to division (F)(3) of section [4796.03](#) of the Revised Code, the required fee for reciprocity shall be three hundred thirty-seven dollars and fifty cents and any transaction fee as required by section [125.18](#) of the Revised Code.

(G) Pursuant to section [4729.16](#) of the Revised Code, a limited or restricted license may be issued to an applicant upon the determination of the board.