7/17/19

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

**Rescind:**

- 4729-5-17 – Specifies requirements for prescribers who personally furnish dangerous drugs.
- 4729-9-01 – The rule outlines the definitions section for OAC 4729-9.

Comments on the proposed rules will be accepted until close of business on July 31, 2019. Please send all comments to the following email address: Ali.Simon@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov
The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.
Regulatory Intent

1. Please describe in plain language the regulation that is being rescinded.
   - 4729-5-17 – Specifies requirements for prescribers who personally furnish dangerous drugs.
   - 4729-9-01 – The rule outlines the definitions section for OAC 4729-9.

2. Why is the regulation being rescinded?
   *Please be specific (ORC change, request of stakeholders, etc.)*

   The Board is in the process of implementing new rule divisions specific to each Board license type. The content of these rules can be found in the newly implemented rules. The newly created divisions will provide clarity for each license type and eliminate confusion.

3. Please describe in general terms the adverse impacts to business, including currently impacted industries, in the existing rule(s).

   4729-5-17 - Prescribers licensed as terminal distributors of dangerous drugs are impacted by the rule. There are administrative costs associated with compliance (including recordkeeping). The prescriber is required to conduct a final check of any drug prior to it being personally furnished.

   4729-9-01 – This rule applies to the following license types: pharmacist, intern, technician, terminal distributor and drug distributor. The rule does outline that an applicant whose applications fall under the category of an abandoned application will forfeit all fees associated with said application.

4. Are there other regulations (either existing or to be created) which will replace the regulation being rescinded or which will now apply because this regulation is being rescinded? This can include rules, statute, federal regulations, agency policies, or industry standards etc.

   The content of the rules can be found in new divisions specific to each prescriber license type. For 4729-5-17, the rule content will be found in OAC 4729:5-19-02, 4729:5-20-02, 4729:5-21-02.

   For 4729-9-01, the rule content can be (or will be found) found in OAC 4729:1-1-01, 4729:2-1-01, 4729:3-1-01, 4729:5-1-01 and 4729:6-1-01.

5. Does the rescission of this regulation eliminate flexibility or create more adverse impacts for stakeholders? If yes, please describe stakeholder outreach and justify the impacts.
The content of these rules can be found in new divisions/chapters specific to each license type. There is not a change in flexibility or the creation of additional adverse impact.
4729-5-17 Personally furnishing dangerous drugs. (RESCIND)

(A) Whenever a prescriber personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, the prescriber shall affix to the container a label showing:

(1) The name and address of the prescriber.

(2) The name of the patient for whom the drug is intended. If the patient is an animal, the name of the owner and identification of the animal.

(3) Name and strength of the dangerous drug.

(4) Directions for use.

(5) Date furnished.

(6) If a compounded drug product, the statement "Compounded Drug Product" or other similar statement shall also be displayed prominently on the label.

(B) Whenever a prescriber personally furnishes a dangerous drug, labeled as a sample pursuant to section 3719.81 of the Revised Code and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide, in written format, the following:

(1) Name of the prescriber.

(2) Name of the patient. If the patient is an animal, the name of the owner and identification of the animal.

(3) Directions for use.

(C) For controlled substances, personally furnishing quantities are limited to a seventy-two hour supply and in any thirty day period the personally furnishing quantities supplied to all patients shall not exceed two thousand five hundred dosage units pursuant to section 4729.291 of the Revised Code.

(D) None of the following shall be counted in determining whether the amounts specified in paragraph (C) of this rule have been exceeded:

(1) Methadone personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07 (9/1/2015);

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program that possesses a terminal distributor of dangerous drugs license issued under section 4729.54 of the Revised Code, is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11 (9/1/2015), and meets either of the following criteria:

(a) Buprenorphine and methadone are personally furnished by physicians treating patients participating in the program.
(b) Buprenorphine, but not methadone, is personally furnished by physicians treating patients participating in the program, the program is accredited by a national accrediting organization approved by the substance abuse and mental health services administration, the service of personally furnishing buprenorphine has, notwithstanding section 5119.371 of the Revised Code, been certified by the department of mental health and addiction services under section 5119.36 of the Revised Code, and the program maintains in the record of a patient to whom buprenorphine has been administered or personally furnished a copy of the physician's signed and dated written order for that act.

(c) Controlled substances personally furnished to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(E) Paragraph (C) of this rule does not apply to a prescriber who is a veterinarian.

(F) A prescriber may designate a health care professional acting within the scope of the professional's practice and, under the supervision of the prescriber, to prepare and package a dangerous drug that will be personally furnished by the prescriber.

(G) A prescriber shall perform the final check of the dangerous drug prior to personally furnishing. The final check shall be documented using positive identification pursuant to rule 4729-5-01 of the Administrative Code.

(H) Counseling.

(1) A prescriber or the prescriber's designee shall personally offer to provide the service of counseling pursuant to paragraph (H)(2) of this rule to the patient or caregiver whenever any dangerous drug is personally furnished. A prescriber shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. In this situation, when counseling is refused, the prescriber or the prescriber's designee shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver, unless the prescriber is a veterinarian.

(2) Prescriber counseling may include, but is not limited to, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) The intended use of the drug and the expected action;

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;
(g) Proper storage;

(h) Action to be taken in the event of a missed dose; and

(i) The prescriber's comments relevant to the individual's drug therapy, including other necessary information unique to the specific patient or drug.

(I) Distribution of dangerous drugs.

(1) A prescriber may delegate an individual or individuals to distribute dangerous drugs personally furnished by a prescriber if all of the following apply:

(a) A prescriber authorized to personally furnish dangerous drugs provides on-site supervision;

(b) The designated individual offers counseling to the patient or caregiver to be provided by the on-site prescriber in accordance with paragraph (H) of this rule; and

(c) This task may be delegated in accordance with applicable state laws and rules.

(2) Paragraphs (I)(1)(a) and (I)(b) of this rule do not apply in any of the following:

(a) The drug is provided to the patient by a health care professional, acting within the scope of the professional's practice, and the drug provided is either:

(i) Methadone for the purpose of treating drug dependence or addiction; or

(ii) Buprenorphine for the purpose of treating drug dependence or addiction as part of an opioid treatment program that is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11 (9/1/2015).

(b) The dangerous drug is being provided to a patient by a licensed Ohio pharmacist.

(c) The dangerous drug is being provided in accordance with paragraph (K) of this rule.

(d) A non-controlled dangerous drug is provided to the patient by a health care professional, acting within the scope of the professional's practice, and a prescriber authorized to personally furnish dangerous drugs is available for counseling by means of electronic communication during normal hours of operation.

(J) No prescriber may personally furnish to a patient to whom there is no valid prescriber patient relationship, pursuant to applicable state and federal laws, regulations, and rules. This may include a requirement for a documented patient encounter.

(K) Personally furnishing naloxone.
(1) Except as provided in paragraph (K)(3) of this rule, an authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with section 4731.941 of the Revised Code, shall do all of the following:

(a) Prepare, package and appropriately label the naloxone.

(b) Conduct the final check of the naloxone prior to personally furnishing on behalf of the prescriber.

(c) Keep and maintain all records in accordance with rule 4729-9-22 of the Administrative Code.

(d) Conduct patient counseling, including training on the use of naloxone, as specified in the physician protocol.

(2) An authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with section 4731.941 of the Revised Code may personally furnish the drug to themselves in order to assist an individual who there is reason to believe is experiencing an opioid-related overdose if all of the following conditions are met:

(a) The authorized individual complies with the protocol established by the authorizing physician, including having completed the training required by the protocol.

(b) The authorized individual has received training instructing them to summon emergency services as soon as practicable either before or after administering naloxone.

(c) Such practice is authorized in the physician approved protocol.

(3) An authorized individual personally furnishing naloxone pursuant to paragraph (K)(2) of this rule shall not be required to comply with the paragraph (K)(1)(a), (K)(1)(b) or (K)(1)(d) of this rule.

(L) Records of drugs personally furnished shall be kept in accordance with rules 4729-9-22 and 4729-9-14 of the Administrative Code.

(M) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729-5-10 of the Administrative Code is the property of that patient and is not considered personal furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729-5-10 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(N) Paragraph (M) of this rule does not prohibit a prescriber from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber.
4729-9-01 Definitions. (RESCIND)

(A) "Dangerous drug", as defined in section 4729.01 of the Revised Code, means any drug or drug product whose commercial package bears a label containing the symbol "Rx only", the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian," or any similar restrictive statement.

(B) "Adulterated drug" includes a dangerous drug to which any of the following applies:

(1) A compounded dangerous drug if it exceeds the beyond use date as indicated in United States pharmacopeia chapters 795 and 797, USP 38 - NF 33, or any official supplement thereto (10/16/2016).

(2) Meets any of the requirements described in section 3715.63 of the Revised Code.

(3) Is beyond the expiration date as stated by the manufacturer, packer, or distributor in its labeling or it is not stored, dispensed or personally furnished according to the requirement of the federal act as indicated in the product labeling. This does not apply to expired drugs that are donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.

(C) "Psychiatric outpatient facility" means a facility where psychiatric evaluation and treatment is provided on an outpatient basis.

(D) As used in Chapters 3719. and 4729. of the Revised Code, "registered" and "licensed" mean that an individual or facility has met the initial qualifications for registration or licensure with the state board of pharmacy and have complied with renewal procedures, including payment of applicable fees.

(E) "Revoke", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license or registration rendering such license or registration void and such license or registration may not be reissued. "Revoke" is an action that is permanent against the license/registration and licensee/registrant.

(F) "Suspend", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license or registration rendering such license or registration without force and effect for a period of time as determined by the state board of pharmacy. The board may require that an individual whose license or 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.

(G) "Summary suspension", as used in Chapters 3719. and 4729. of the Revised Code, means to take immediate action against a license or registration without a prior hearing rendering such license or registration without force and effect for a period of time as indicated in section 3719.031, 3719.121, 4729.561 or 4729.571 of the Revised Code. The board may suspend a license or registration issued pursuant to Chapters 3719. and 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(H) "Place on probation", as used in Chapter 4729. of the Revised Code, means to take action against a license or registration suspending some or all of the sanctions imposed by the board against that license or registration. The terms of the probation shall state the period of time covered by the probation and may include other conditions as determined by the state board of pharmacy.
"Refuse to grant or renew", as used in Chapter 4729. of the Revised Code, means to deny original or continued licensure or registration for a period of at least twelve months. After twelve months, or such period of time as the individual board order may require, an individual or facility licensed or registered by the board or an individual or facility seeking to attain such status by licensure or registration, and whose license or registration the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A pharmacist, or an individual or facility that seeks to attain such status by licensure or registration, whose license the state board of pharmacy has refused to grant or renew must meet any requirements established by the board or must pass any examination required by the board.

"Campus", as used to describe a type of terminal distributor of dangerous drugs license issued pursuant to section 4729.51 of the Revised Code, means an establishment or place consisting of multiple buildings where dangerous drugs are stored that are located on a contiguous plot of land. All such buildings and stocks of dangerous drugs shall be under common ownership and control.

"Certified diabetes educator", as used in Chapters 3719. and 4729. of the Revised Code, means a person who has been certified to conduct diabetes education by the "National Certification Board for Diabetes Educators (NCBDE)."

"Abandoned application" means an application submitted for licensure or registration that meets the requirements in paragraphs (L)(1) and (L)(2) of this rule. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If the application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the requirements in effect at the time of reapplication.

(1) An application shall be deemed abandoned if any of the following apply:

(a) An applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board.

(b) An applicant for a terminal distributor of dangerous drugs that fails to demonstrate compliance with rules 4729-5-11, 4729-9-11 and 4729-9-05 of the Administrative Code within ninety days of receipt of a completed application. The applicant may submit a request to the director of licensing for a one-time ninety-day extension.

(c) An applicant for a wholesale distributor of dangerous drugs that fails to demonstrate compliance with rule 4729-5-11 and the applicable licensing rules pursuant to Chapter 4729-9 of the Administrative Code within ninety days of receipt of a completed application. The applicant may submit a request to the director of licensing for a one-time ninety-day extension.

(d) An applicant for a wholesale distributor of dangerous drugs with an outsourcing facility classification that fails to demonstrate compliance with rules 4729-5-11 and 4729-16-02 of the Administrative Code.

(e) An applicant for licensure as a pharmacist pursuant to rules 4729:1-2-01 and 4729:1-2-02 of the Administrative Code.

(2) An application shall not be deemed abandoned if the application is subject to any of the following:
(a) An administrative proceeding; or

(b) If there is discipline pending against the applicant.