Steven W. Schierholt, Esq.
Executive Director

John R. Kasich
Governor

STATE OF OHIO BOARD OF PHARMACY

Prescriber Office or Clinic Rules – Comments Requested

Date Issued: February 26, 2018

In accordance with sections 4729.26 and 3719.28 of the Ohio Revised Code, the State of Ohio Board of Pharmacy is proposing the adoption of new rules governing the operation of prescriber offices or clinics (non-veterinary).

At this time, public comment is being sought on this rule package prior to the rules being filed with the Common-Sense Initiative.

Comments on the proposed rules will be accepted until 5:00 pm (EST) on **March 26, 2018**.

Please send all comments to the following email address:
Ali.Simon@pharmacy.ohio.gov

4729:5-19 – Clinics and Prescriber Offices

4729:5-19-01 – Clinics and Prescriber Offices – Definitions.

As used in Chapter 4729:5-19 of the Administrative Code:

(A) “Clinic” or “Prescriber Office” means a facility licensed as a terminal distributor of dangerous drugs in accordance with 4729.51 of the Revised Code where a licensed prescriber serves as the responsible person on the license and drugs are possessed on-site for administration or personally furnishing. The facility shall comply with all requirements set forth in this chapter.

(B) "Direct supervision" or "personal supervision" means licensed prescriber shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

(C) “Dosage unit” means any of the following:

(1) A single pill, capsule, ampule, tablet;

(2) In the case of a liquid solution, one (1) milliliter;

(3) In the case of a cream, lotion or gel, one (1) gram; or

(4) Any other form of administration available as a single unit.

(D) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(E) "Personally furnish" or “personally furnishing” means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting.

(F)

(1) "Positive identification" means a method of identifying a person that does not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

(G) “Readily retrievable” means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(H) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(I) “Sample” means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

(K) "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to the drugs or hypodermics stored within is not possible without leaving visible proof that such access has been attempted or made.

4729:5-19-02 – Personally furnishing dangerous drugs.

(A) A prescriber who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, 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.

(3) Name and strength of the dangerous drug.

(4) Directions for use.

(5) Date furnished.

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

(B) A prescriber who personally furnishes a dangerous drug labeled as a sample and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide written documentation accompanying the sample including the following:

(1) Name of the prescriber.

(2) Name of the patient.

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

(F) A prescriber shall perform the final check of the dangerous drug (i.e. the final association of a drug with a patient) prior to personally furnishing. The final check shall be documented using positive identification.

(G) Counseling.

(1) A prescriber or the prescriber's designee shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (G)(2) of this rule to the owner or caregiver whenever any dangerous drug is personally furnished. A prescriber shall not be required to counsel an owner or caregiver when the owner or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.

(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 patient’s drug therapy, including other necessary information unique to the specific patient or drug.

(H) Distribution of dangerous drugs.

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

(a) A prescriber authorized to personally furnish dangerous drugs provides direct supervision;

(b) Counseling is offered in accordance with paragraph (G) of this rule;

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

(d) The drugs are sealed in a tamper-evident manner.

(2) Paragraph (H)(1)(a) of this rule does not apply if a non-controlled dangerous is provided to the patient by a licensed 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.

(I) 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.

(J) Personally furnishing naloxone.

(1) Except as provided in paragraph (J)(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 this chapter.

(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 (J)(2) of this rule shall not be required to comply with the paragraph (J)(1)(a), (J)(1)(b) or (J)(1)(d) of this rule.

(L) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 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 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(M) Paragraph (L) 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.

(N) A prescriber personally furnishing controlled substances and dangerous drugs containing gabapentin shall comply with all drug database reporting requirements pursuant to Chapter 4729. of the Revised Code and all rules adopted thereunder.

4729:5-19-03 – Security and control of dangerous drugs.

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license.

(B) Controlled substance dangerous drugs, dangerous drugs containing propofol, uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms, and poisons must be stored in an area or areas secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, to deter and detect unauthorized access.

(1) Only a prescriber shall have possession of the keys or access codes to the secure area or areas specified in paragraph (B) of this rule. Any additional keys shall be maintained in a secure place that is inaccessible to unauthorized persons.

(2) A licensed health care professional, acting within the scope of the professional's practice may have access to controlled substances, dangerous drugs containing propofol, and poisons only under the direct supervision of a prescriber.

(3) Only a prescriber shall have access to uncompleted prescription blank(s) used for writing a prescription.

(4) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the direct supervision of a prescriber.

(5) Only prescribers may have unsupervised access to controlled substance dangerous drugs.

(C) Non-controlled dangerous drugs and hypodermics shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All records relating to the administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access.

(E) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board.

(F) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code.

(G) Disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.

(H) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

4729:5-19-04 – Record Keeping.

(A) A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed or transferred.

(B) The acts of prescribing, administering, and disposal of controlled substance dangerous drugs shall be documented with positive identification.

(C) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the persons from whom received and the date of receipt.

(D) Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drug were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver.

(E) Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the identification of the licensed health care professional administering the drug, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered and the date of administration.

(1) Records of non-controlled substance dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(2) Records of controlled substance dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph if documented using positive identification.

(F) Records of dangerous drug disposal, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, the identification of the licensed health care professional that performed the disposal.

(G) Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(H) Records of transfer conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, and quantity of the dangerous drug transferred, the address of the location where the drugs were transferred and the date of transfer.

(I) All records maintained in accordance with this rule shall be readily retrievable and shall be kept for a period of three years at the place where the dangerous drugs are located.

(1) A terminal distributor intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

(J) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;

(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(3) Contains security features to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.