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STATE OF OHIO BOARD OF PHARMACY

Pain Management 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 pain management clinics.

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

4729:5-11 – Pain Management Clinics

4729:5-11-01 – Pain Management Clinics – Definitions.

As used in Chapter 4729:5-11 of the Administrative Code:

(A) “Pain management clinic” means a facility licensed as a terminal distributor of dangerous drugs in accordance with 4729.552 of the Revised Code. 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) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(D) "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. A prescriber at a pain management clinic who personally furnishes a dangerous drug shall comply with the requirements of rule 4729:5-19-02 of the Administrative Code.

(E)

(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.

(F) “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.

(G) "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.

(H) “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.

(I) "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.

4729:5-11-02 – Criminal records checks for pain management clinics.

(A) As used in this rule, “physician” means a person authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(B) All criminal records checks conducted in accordance with this rule shall consist of both an Ohio bureau of criminal identification and investigation (BCI&I) records check and a federal bureau of investigations (FBI) records check.

(C) Pursuant to section 4729.552 of the Revised Code, a terminal distributor of dangerous drug license with a pain management clinic classification will not be issued until the physician owner(s), or, if incorporated, the physician officers, of the pain management clinic submit fingerprints to BCI&I for a criminal records check. The results of the criminal records check must be sent directly to the state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months.

(D) If there is a change in any of the persons listed in paragraph (B) of this rule, only the new persons shall submit to a criminal records check as part of the change of ownership requirements pursuant to rule 4729:5-2-03 of the Administrative Code.

(E) Physician owner(s) or physician officers are required to have all employees submit to a BCI&I and FBI criminal records check to ensure that no person has been previously convicted of, or pleaded guilty to a theft offense that would constitute a felony as described in division (K)(3) of section 2913.01 of the Revised Code or a felony drug abuse offense as defined in section 2925.01 of the Revised Code.

(1) BCI&I shall send the results of the BCI&I criminal records check directly to the employer or potential employer. BCI&I shall provide a letter regarding the FBI criminal records check to the employer or potential employer stating that there is either no record of any conviction or a letter stating that the request may not meet the criteria.

(2) When an employer or potential employer receives a letter stating that the request may not meet the criteria, they may share this information with the employee or potential employee.

(3) In order to complete the criminal records check, the employee or potential employee must then complete a "Request for Release-FBI Rapsheet" and send it to BCI&I to request a copy of the FBI criminal record results be sent directly to the employee or potential employee. The employee or potential employee must provide the results to the employer or potential employer in the original sealed envelope received from BCI&I.

(4) The criminal records check shall be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "WebCheck" provider agency located in Ohio. The employer may accept the results of a criminal records check based on ink impressions from a "WebCheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

4729:5-11-03 – 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.

(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.

4729:5-11-04 – 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 who personally furnished 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 person 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 disposed, 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 chapter 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.