OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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Rule Changes Effective August 22, 2014

The following rule changes will take effect on August 22, 2014:

- **4729-3-01:** Authorizes the Board of Pharmacy to waive the 2:1 ratio for the operation of immunization clinics or other specific circumstances.

- **4729-5-17:** Clarifies that prescriber dispensing limits to not apply in the following instances, as indicated in law: (a) methadone provided to patients for the purpose of treating drug addiction, (b) buprenorphine provided to patients for the purpose of treating drug addiction, (c) controlled substances provided to research subjects by a facility conducting clinical research, (d) and a prescriber who is a veterinarian.

- **4729-5-35:** Removes the 100% accuracy requirement for automated drug delivery systems and also provides an appeal process by which a terminal distributor of dangerous drugs can appeal a decision by a Board of Pharmacy inspector.

- **4729-5-38:** Authorizes a licensed pharmacist to administer the measles, mumps, and rubella (MMR) vaccine to individuals 18 years and older.

- **4729-6-01:** Changes references from the Ohio Department of Alcohol and Drug Addiction Services to the Ohio Department of Mental Health and Addiction Services.

- **4729-6-03:** Changes references from the Ohio Department of Alcohol and Drug Addiction Services to the Ohio Department of Mental Health and Addiction Services.

- **4729-7-06:** Changes the requirement that in-state continuing education providers submit their participant lists to the Board. Instead, providers will be required to maintain those records. In addition, in-state providers will no longer have to send notification to the Board before or within fourteen days after a program has been presented. However, providers of law CE are still required to send notice or a sample of the program or experience certificate to the board no later than 14 days after a program is presented.

- **4729-9-26:** Corrects a typo in the criminal records check for pain management clinics section of the OAC.

- **4729-33-01:** Updates definitions section to reflect change in EMS terminology and to reference the correct cross references to sections of the OAC and ORC.

- **4729-33-02:** Updates the EMS licensure section to reference to the official name of the state board of emergency medical, fire and transportation services and clarifies that volunteer personnel should also be listed on the terminal distributor of dangerous drugs license application.

- **4729-33-05:** Defines "posting up" as a temporary, short-term location of the EMS unit for less than twenty-four hours where the EMS unit is under constant supervision of the EMS personnel on duty. Exempts emergency situations from this requirement.

For any questions regarding these changes or any additional administrative rules, please contact the Ohio State Board of Pharmacy at 614-466-4143.

4729-3-01 **Definitions.**

As used in Chapter 4729-3 of the Administrative Code:

(A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.

(B) "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of an internship program.

(1) A "preceptor" is a pharmacist who holds a current identification card which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship pursuant to paragraph (C) of rule 4729-3-05 of the Administrative Code.

(2) A person may serve as the preceptor for more than one intern. The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty unless otherwise approved by the board.

(3) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship.

(C) "Director of internship" has the same meaning as provided in section 4729.11 of the Revised Code.

(D) "In good standing" means that the preceptor has not been denied the privilege of supervising interns by the board.

(E) "Statement of Preceptor" is a form provided by the state board of pharmacy that identifies the preceptor and internship site for a pharmacy intern.

(F) "Practical Experience Affidavit" is a form provided by the state board of pharmacy used to submit evidence of practical experience for internship credit pursuant to rule 4729-3-06 of the Administrative Code.

(G) "School of pharmacy" has the same meaning as a college of pharmacy or a department of pharmacy of a university, which has been recognized and approved by the state board of pharmacy.

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4729-5-17 **Labeling by prescribers who personally furnish dangerous drugs to their patients.**

(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.

(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 division (C) of this rule have been exceeded:

(1) Methadone provided to patients for the purpose of treating drug addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07 (6/23/2005);

(2) Buprenorphine provided to patients for the purpose of treating drug addiction, if the prescriber is exempt from separate registration with the United States

drug enforcement administration pursuant to 21 C.F.R. 1301.28 (5/22/2008);

(3) Controlled substances provided 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) Division (C) of this rule does not apply to a prescriber who is a veterinarian.

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Prior Effective Dates: 06/01/1999, 03/31/2000, 05/22/2014

4729-5-35 **Automated drug delivery systems.**

~~All~~

(A) All automated drug delivery systems intended for use by a terminal distributor of dangerous drugs to assist in the dispensing of a drug pursuant to rules 4729-5-01 and 4729-17-01 of the Administrative Code must meet the following requirements:

~~(A)~~(1) Each automated drug delivery system must be approved via the procedure established in division (B) of this rule by the board of pharmacy prior to its implementation by the terminal distributor of dangerous drugs;

~~(B)~~(2) The automated drug delivery system shall have a documented and ongoing quality assurance program that monitors total system performance and includes security measures to ensure the safe and effective distribution of drugs ~~includes the requirement for one hundred per cent accuracy in drug and strength delivered~~;

~~(C)~~(3) The automated drug delivery system shall have adequate security to prevent unauthorized individuals from accessing or obtaining dangerous drugs and includes safegaurds to detect diversion of dangerous drugs;

~~(D)~~(4) The records kept by the automated drug delivery system shall comply with all board requirements.

(B) Prior to the approval of an automated drug delivery system, the board shall receive a request from the responsible person on the terminal distributor of dangerous drugs license. Upon notification, the board shall conduct an inspection of the system to determine if it meets the requirements in division (A) of this section.

(C) If an inspection does not result in the approval of an automated drug delivery system, the responsible person named on the terminal distributor of dangerous drugs may request an in-person meeting with the board to appeal the denial.

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4729-5-38 **Immunization administration.**

~~In~~

(A) In addition to the immunizations and medications listed in section 4729.41 of the Revised Code and pursuant to the requirements noted in section 4729.41 of the Revised Code and rules 4729-5-36 and 4729-5-37 of the Administrative Code, a pharmacist may administer ~~the zoster vaccine according to~~ the following vaccinations~~requirements~~:

~~(A)~~(1) The zoster vaccine according to~~patient must meet~~ the age criteria specified in the F.D.A. approved labeling; and

(2) the measles, mumps, and rubella (MMR) vaccine.

(B) The pharmacist must be able to document meeting the training criteria required by rule 4729-5-36 of the Administrative Code.

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4729-6-01 **Definitions; impaired pharmacists.**

As used in Chapter 4729-6 of the Administrative Code:

(A) "Substance abuse/chemical dependency" means a condition involving the use of alcohol or other drugs to a degree that it interferes in the functional life of the licensee, as manifested by physical health, family, job, legal, financial, or emotional/psychiatric problems.

(B) "Impaired pharmacist" means a pharmacist who, because of his/her use of psychoactive substances, is unable to practice pharmacy with requisite judgment, skill, competence, or safety to the public.

(C) "Approved treatment provider" means a designated treatment program pursuant to section 4729.18 of the Revised Code and rule 4729-6-03 of the Administrative Code.

(D) "Limited approved treatment provider" means a board approved and designated treatment program pursuant to section 4729.18 of the Revised Code and rule 4729-6-05 of the Administrative Code.

(E) "Intervenor" means a person who participates in a process whereby a pharmacist alleged to be impaired is confronted to evaluate the presence of impairment and, if indicated, who refers the pharmacist for assessment and treatment of the problem.

(F) "Referral for assessment" means a process whereby an intervenor who has reason to believe that a pharmacist is impaired directs that individual to be examined for diagnosis and treatment.

(G) "Treatment assessor" means an individual who is licensed under Chapter 4731. of the Revised Code as a doctor of medicine or a doctor of osteopathic medicine and surgery and who is a certified addictionist or an individual who is certified by the Ohio department of ~~alcohol and drug~~mental health and addiction services ~~(ODADAS)~~ as a certified chemical dependency counselor 3 or 2 pursuant to ~~section 3793.07 of the Revised Code and~~ division 3793:2 of the Administrative Code and who by training and experience can make an assessment of a pharmacist's impairment.

(H) "Individualized treatment plan" is a written document which shall provide for inpatient treatment, outpatient treatment, family therapy, psychotherapy, professional support groups, twelve-step programs, aftercare including support and self-help groups, monitoring programs consisting of random, chain of evidence drug screens, and work site review. The above services and other services may be determined by an approved treatment provider.

(I) "Treatment contract" means the document which outlines the individualized treatment plan, the requirement to cease practice, the requirement for compliance by the impaired pharmacist, and the requirement for notification of the board for non-compliance or relapse pursuant to section 4729.18 of the Revised Code.

(J) "Inpatient treatment" shall consist of placing the pharmacist in an approved treatment provider facility that will provide lodging and food, as well as care and treatment for detoxification and rehabilitation as indicated by the treatment contract.

(K) "Outpatient treatment" shall consist of the pharmacist not residing in an inpatient treatment facility but who is participating in aftercare, twelve-step programs, professional support group (if available), and monitoring programs consisting of random, chain of evidence drug screens and work site review, to establish compliance.

(L) "Responsible person" for an approved treatment provider or limited approved treatment provider is an individual who shall be in full and actual charge of the treatment program; including but not limited to, assuring the provider has the necessary facilities and personnel to provide services, maintaining records, and notification of the board when required.

(M) "Twelve-step program" is a self-help program such as Alcoholics Anonymous or Narcotics Anonymous which the individual shall be required to personally attend. The minimum attendance required shall not be less than three documented meetings each week.

(N) "Aftercare" is a counselor-facilitated group meeting which directly responds to problems relating to the ongoing treatment and monitoring of the pharmacist's sobriety, and should extend for a minimum of six months.

(O) "Professional support group" is a group of peers meeting to discuss the problems specific to recovery and re-entry to practice of the licensed professional.

(P) "Relapse" means a positive drug screen or a return to a pattern of impairment activities which affects the pharmacist's ability to practice.

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4729-6-03 **Requirements for approved treatment providers.**

(A) An approved treatment provider, as defined in rule 4729-6-01 of the Administrative Code, shall meet or exceed the following requirements:

(1) Certification by the Ohio department of mental health ~~alcohol~~ and ~~drug~~ addiction services ~~(ODADAS)~~ pursuant to Chapter ~~3793~~5119. of the Revised Code;

(2) Accreditation by the appropriate accrediting agency(s); and

(3) Have certified personnel including but not limited to intervenor, treatment assessor, and responsible person as defined in rule 4729-6-01 of the Administrative Code.

(B) An intervenor associated with an approved treatment provider shall:

(1) Respond to information from concerned individuals;

(2) Ascertain validity of the information received;

(3) Assess the situation and, if the pharmacist is showing evidence of impairment, the intervenor shall refer the individual for evaluation;

(4) If the pharmacist fails to comply within one week to a referral for evaluation, the intervenor must report the name of the pharmacist to the board of pharmacy within one working day.

(C) A treatment assessor associated with an approved treatment provider shall evaluate a pharmacist referred to the approved treatment provider to determine if the pharmacist has a substance abuse/chemical dependency related impairment.

(D) If such an impairment exists, the approved treatment program shall formulate the pharmacist's individualized treatment plan as defined in rule 4729-6-01 of the Administrative Code. The specific requirements shall be determined by an assessment of psychological, physical, developmental, family, social, environmental, recreational, and professional needs. The individualized treatment plan shall be part of a treatment contract which the impaired pharmacist must sign. If the impaired pharmacist fails to sign the treatment contract and enter treatment within forty-eight hours of the determination that the pharmacist needs treatment, the approved treatment provider must report the name of the pharmacist to the board of pharmacy within one working day.

(E) The responsible person for the approved treatment provider shall:

(1) Establish a system of records that will provide for complete information about an impaired pharmacist from intervention through the rehabilitation stage;

(2) Establish treatment contracts meeting the requirements of this chapter and a system of follow up to determine compliance by the impaired pharmacist with the treatment contract;

(3) Assure confidentiality of the impaired pharmacist, except:

(a) If the pharmacist fails to comply within one week to a referral for evaluation;

(b) If the impaired pharmacist fails to sign the contract and enter treatment within forty-eight hours of the determination that the pharmacist needs treatment;

(c) If the impaired pharmacist does not suspend practice on entering treatment;

(d) If the impaired pharmacist does not comply with the terms of the treatment contract;

(e) If the impaired pharmacist resumes practice before the approved treatment provider has made a clear determination that the pharmacist is capable of practicing;

(f) If the impaired pharmacist suffers a relapse at any time during or following rehabilitation.

(4) Notify the state board of pharmacy within one working day if the pharmacist violates any portion of this rule.

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4729-7-06 **Criteria for in-state approved providers of continuing pharmacy education.**

In-state providers who desire to become approved by the state board of pharmacy must demonstrate ability and willingness to offer quality continuing pharmacy education in a responsible manner and shall submit evidence of this on applications supplied by the board. The minimal criteria include:

(A) There shall be a responsible person charged with the administration of the continuing pharmacy education program and liaison with the board. Unless otherwise approved by the board, the responsible person shall be a pharmacist licensed to practice pharmacy in Ohio.

(B) Providers shall award continuing pharmacy education credit to successful participants in terms of C.E.U.s.

(C) Providers shall maintain ~~send~~ a list of successful program or experience participants and their Ohio registration numbers ~~to the board within fourteen days of the experience or maintain such records~~ for a five-year period to be made available to the board on request.

(D) Providers shall award a certificate to each successful participant containing at least the following information:

(1) The name of the provider;

(2) The completion date of the experience;

(3) The name of the participant;

(4) The title of the experience;

(5) The number of C.E.U.s the experience has been assigned;

(6) The program or experience identification number according to the numbering system designated by the board; and

(7) The positive identification of the responsible person.

(E) Ohio jurisprudence program providers shall submit a provider program notice or a sample of the program or experience certificate to the board no later than 14 days after a program is presented.

~~(E)~~(F) Providers shall develop and employ evaluation techniques that will assess the effectiveness of the continuing pharmacy education experiences with the goal of continual improvement.

~~(F)~~(G) Providers should utilize an evaluation mechanism for the purpose of allowing each participant to assess the achievement of personal objectives.

~~(G) Providers shall send notification to the board before or within fourteen days after a program has been presented. The notification shall include the name of the presenter(s) and the items noted in paragraphs (D)(1), (D)(2), (D(4), (D)(5), and (D)(6) of this rule.~~

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4729-9-26 **Criminal records check for pain management clinics.**

Pursuant to division (B) of section 4729.552 of the Revised Code, a new 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 the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. Additionally, a criminal records check is required every time there is a change in ownership for each new owner(s) or officer(s). The criminal records check shall consist of both a BCI&I criminal records check and a federal bureau of investigations (FBI) records check. The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The physician owner(s) or physician officers must submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code. 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 ~~of~~ or a felony drug abuse offense as defined in section 2925.01 of the Revised Code. Employees must submit electronic fingerprint impressions to the physician owner(s) or physician officers pursuant to rule 4729-4-04 of the Administrative Code.

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4729-33-01 **Definitions.**

As used in Chapter 4729-33 of the Administrative Code:

(A) "Certificate to practice" means the level to which an individual is trained and licensed as defined in sections 4765.01, 4765.011 and 4765.30 of the Revised Code and rule 4765-1-01 of the Administrative Code.

(B) "Controlled substance" has the same meaning as in section 4729.01 of the Revised Code.

(C) "Dangerous Drug" has the same meaning as in section 4729.01 of the Revised Code and in rule 4729-9-01 of the Administrative Code.

(D) "Emergency medical service (EMS) organization" has the same meaning as in section 4765.01 of the Revised Code.

(E) "Medical director" has the same meaning as in rule 4765-10-06 of the Administrative Code.

(F) "Mutual aid" means a formal written agreement between two or more EMS organizations to assist in emergency medical coverage in the other's usual area of coverage including having access to dangerous drugs during the emergency situation.

(G) "Posting up" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy.

(H) "Posting up at a special event" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy pursuant to a formal agreement with the sponsors of the special event.

(I) "Readily retrievable" means all records which are required to be maintained must be provided upon request to the inspector or agent of the board of pharmacy within three working days.

(J) "Responsible person" has the same meaning as in rule 4729-13-01 of the Administrative Code.

(K) "Satellite" means an address licensed by the board as a terminal distributor of dangerous drugs that is separate from the licensed headquarters address of the EMS organization.

(L) "Scope of practice shall be defined as in section 4765.35 of the Revised Code and rule 4765-12-~~03~~04 of the Administrative Code for a ~~first~~ emergency medical responder, section 4765.37 of the Revised Code and rule 4765-15-04 of the Administrative Code for an emergency medical technician~~-basic~~, section 4765.38 of the Revised Code and rule 4765-16-04 of the Administrative Code for an advanced emergency medical technician~~-intermediate~~, and section 4765.39 of the Revised Code and rule 4765-17-03 of the Administrative Code for a~~an emergency medical technician-~~paramedic, and sections 4765-6-01, 4765-6-03, 4765-6-04 and 4765-6-05 of the Administrative Code.

(M) "Special event" means an event requiring EMS coverage for more than twenty-four hours including, but not limited to, the following:

(1) A county fair.

(2) A weekend festival.

(N) "Standing order" and "protocol" have the same meanings as in rule 4729-5-01 of the Administrative Code.

(O) "Tamper-evident" means the package is sealed 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.

(P) "Terminal distributor of dangerous drugs" has the same meaning as in section 4729.01 of the Revised Code.

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4729-33-02 **Licensure.**

(A) Any emergency medical service (EMS) organization that desires to stock dangerous drugs shall apply for and maintain a license as a terminal distributor of dangerous drugs. The one location that serves as the main station will be deemed the headquarters location. Any other locations associated with this headquarters where dangerous drugs will be stored will be licensed as "satellites". Only the headquarters location will be charged a license fee or renewal license fee.

(B) Each location, headquarters and satellites, must be licensed as a limited terminal distributor of dangerous drugs and must maintain a current terminal distributor of dangerous drugs license and drug addendum.

(C) An application for licensure must include all of the following:

(1) A completed application;

(2) A compilation of all protocols involving dangerous drugs that have been signed by the medical director and notarized;

(3) A list of drugs referenced in the protocols to be stocked by the EMS organization, signed by the medical director and notarized;

(4) A list of personnel employed, including volunteers, by the EMS organization who may access and administer dangerous drugs, which includes the name of the individual, level of certification, their certification number, and expiration date;

(5) A list of any and all formal written mutual aid agreements with other EMS organizations;

(6) The fee for the appropriate category of licensure.

(D) Each location, headquarters and satellite, may only possess those dangerous drugs that are listed on the drug addendum and only at locations licensed by the board of pharmacy.

(1) A medical director may add dangerous drugs to the drug list by submitting revised, signed and notarized protocols and list of medications, and the addendum update fee.

(2) A medical director may delete dangerous drugs from the drug list by submitting

a letter listing the drugs to be deleted.

(E) A new application and fee is required prior to any change of location, addition of a satellite location, change of category, name change, or change of ownership. These changes may be made during the annual renewal period with no additional fee other than the renewal fee.

(F) The responsible person shall provide supervision and control of all locations where dangerous drugs are stored. The responsible person must be a physician licensed pursuant to Chapter 4731. of the Revised Code or a pharmacist licensed pursuant to Chapter 4729. of the Revised Code.

(1) To change the responsible person, the new responsible person must complete and return a notification of change of responsible person form within thirty days by regular mail or verified facsimile transmission.

(2) To change the medical director, the new medical director must submit a signed and notarized letter stating that he/she is accepting responsibility for the EMS organization.

(a) If the new medical director approves of the current protocol and drug list, a signed and notarized letter must be submitted stating the current protocols and drug list on file have been reviewed and are approved by the medical director for use by this EMS organization, or

(b) If the new medical director desires to change the protocols or drug list, the medical director must submit the revised, signed, and notarized protocols and drug list, and the addendum update fee.

(G) Any changes in protocols that involve dangerous drugs must be submitted to the state board of pharmacy prior to the implementation of the protocols involved. The state board of pharmacy may discuss such protocols with the state board of emergency medical, fire and transportation services, state medical board, or other governmental agencies as needed to assure their validity.

(H) Any change of personnel requires a letter from the organization within thirty days of the change listing the type of change (addition, update, or deletion), names of the personnel involved, level of certification, their certification number, and expiration date.

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4729-33-05 **Posting up.**

(A) Except when "posting up at a special event", "posting up" must be a temporary, short-term location of the EMS unit for less than twenty-four hours where the EMS unit is under constant supervision of the EMS personnel on duty, including but not limited to:

(1) Local school sports event;

(2) Coverage of a station pursuant to a written mutual aid agreement.

(B) "Posting up at a special event" requires prior written notification to, and approval from, the state board of pharmacy office. This notification must include the name and location of the event, dates of the event, and name and telephone number of the contact person of the EMS unit.

(C) The requirements of this rule do not apply in the event of an emergency management assistance compact or an emergency declared by the governor.

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