

The following rules are being circulated for comments from interested parties. The proposed changes are highlighted below.

Limited Branch of Medicine:

- 4731-1-02 Application of Rules Governing Limited Branches of Medicine or Surgery-No Change
- 4731-1-05 Scope of Practice: Massage Therapy-No Change
- 4731-1-06 Scope of Practice: Naprapathy-No Change

Consult Agreements:

- 4731-35-01 Consult Agreements-No Change
- 4731-35-02 Standards for Managing Drug Therapy-No Change

Military Provisions:

- 4731-36-01 Military Provisions Related to Education and Experience Requirements for Licensure-Proposed to amend to add information regarding dietetics educational programs.
- 4731-36-02 Military Provisions Related to Renewal of License and Continuing Education-Proposed to amend to clarify the continuing education reporting period.
- 4731-36-03 Processing Applications from Service Members, Veterans, or Spouses of Service Members or Veterans-No Change
- 4731-36-04 Temporary Licensure for Members of the Military and Spouses Who are Licensed in Another Jurisdiction-No Change

Controlled Substance Prescribing:

- 4731-11-01 Definitions-Proposed No Change
- 4731-11-13 Prescribing of Opiate Analgesics for Acute Pain-Proposed No Change
- 4731-11-14 Prescribing for Subacute and Chronic Pain-Proposed to amend to update rule references
- 4731-29-01 Standards and Procedures for the Operation of a Pain Management Clinic-Proposed to amend to update rule references.

4731-1-02

Application of rules governing limited branches of medicine or surgery.

- (A) Rules adopted by the board governing the practice of limited branches of medicine apply to practitioners of those limited branches listed in sections 4731.15 and 4731.151 of the Revised Code.
- (B) Any person holding a valid license to practice one or more of the limited branches of medicine is subject to disciplinary action by the board, and may additionally be subject to criminal prosecution, if such person performs acts beyond the scope of the limited branch for which the person holds a license or which otherwise violates the rules governing practitioners of limited branches of medicine.
- (C) For purposes of division (B)(18) of section 4731.22 of the Revised Code, the code of ethics and standards of practice of the "American Massage Therapy Association" applies to all persons holding a license to practice massage therapy. The code of ethics may be obtained from the medical board's website at med.ohio.gov/.

4731-1-05

Scope of practice: massage therapy.

- (A) Massage therapy is the treatment of disorders of the human body by the manipulation of soft tissue through the systematic external application of massage techniques including touch, stroking, friction, vibration, percussion, kneading, stretching, compression, and joint movements within the normal physiologic range of motion; and adjunctive thereto, the external application of water, heat, cold, topical preparations, and mechanical devices.
- (B) A massage therapist shall not diagnose a patient's condition. A massage therapist shall evaluate whether the application of massage therapy is advisable. A massage therapist may provide information or education consistent with that evaluation, including referral to an appropriate licensed health care professional, provided that any form of treatment advised by a massage therapist falls within the scope of practice of, and relates directly to a condition that is amenable to treatment by, a massage therapist. In determining whether the application of massage therapy is advisable, a massage therapist shall be limited to taking a written or verbal inquiry, visual inspection including observation of range of motion, touch, and the taking of a pulse, temperature and blood pressure.
- (C) No person shall use the words or letters "massage therapist," "licensed massage therapist," "L.M.T." or any other letters, words, abbreviations, or insignia, indicating or implying that the person is a licensed massage therapist without a valid license under Chapter 4731. of the Revised Code.
- (D) A massage therapist may perform the following services in compliance with the following:
- (1) A massage therapist may treat temporomandibular joint dysfunction provided that the patient has been directly referred in writing for such treatment to the massage therapist by a physician currently licensed pursuant to Chapter 4731. of the Revised Code, by a chiropractor currently licensed pursuant to Chapter 4734. of the Revised Code, or a dentist currently licensed pursuant to Chapter 4715. of the Revised Code.
 - (2) A massage therapist may apply ultrasound, diathermy, electrical neuromuscular stimulation, or substantially similar modalities provided that the patient has been directly referred in writing for such treatment to the massage therapist by a physician or podiatric physician licensed under Chapter 4731. of the Revised Code, physician assistant licensed under Chapter 4730. of the Revised Code, chiropractor licensed under Chapter 4734. of the Revised Code, advanced practice registered nurse licensed under Chapter 4723. of the Revised Code, or physical therapist licensed under Chapter 4755. of the Revised Code, who is acting within the scope of their professional license.

- (a) The massage therapist must perform the modality within the minimal standards of care.
 - (b) If the food and drug administration classifies the device as a prescription device, as that term is defined in 21 CFR 801.109 amended as of June 15, 2016, or a restricted device that can only be sold, distributed, or used upon the order of an authorized healthcare provider, the massage therapist's application of the device must be done under the on-site supervision of the referring practitioner.
 - (c) If the food and drug administration classifies the device as an over-the-counter device, the massage therapist may apply the device without the on-site supervision of the referring practitioner.
- (E) All persons who hold a license to practice massage therapy issued pursuant to section 4731.17 of the Revised Code shall prominently display that license in the office or place where a major portion of the license holder's practice is conducted. If a license holder does not have a primary practice location, the license holder shall at all times when practicing keep either the wall certificate on the holder's person or provide verification of licensure status from the board's internet web site upon request.
- (F) Massage therapy does not include:
- (1) Colonic irrigation;
 - (2) The practice of chiropractic, including the application of a high velocity-low amplitude thrusting force to any articulation of the human body;
 - (3) The use of graded force applied across specific joint surfaces for the purpose of breaking capsular adhesions;
 - (4) The prescription of therapeutic exercise for the purpose of rehabilitation or remediation of a disorder of the human body;
 - (5) The treatment of infectious, contagious or venereal diseases;
 - (6) The prescription, dispensing, personally furnishing or administration of drugs; and

(7) The performance of surgery or practice of medicine in any other form.

(G) As used within this rule:

- (1) "External" does not prohibit a massage therapist from performing massage therapy inside the mouth or oral cavity; and
- (2) "Mechanical devices" means any tool or device which mimics or enhances the actions possible by the hands that is within the scope of practice as defined in section 4731.04 of the Revised Code and this rule.

4731-1-06

Scope of practice: naprapathy.

Naprapathy is the treatment of diseased spinal connective tissue and ligaments by hand only. A practitioner of naprapathy shall not examine patients except by written and verbal inquiry, visual inspection and observation, and touch. Such practitioners shall not diagnose a patient's condition, but may determine whether or not application of naprapathy is advisable.

4731-35-01

Consult agreements.

(A) For purposes of this chapter, practitioner includes the following:

- (1) Physician authorized to practice medicine and surgery or osteopathic medicine and surgery under Chapter 4731. of the Revised Code.
- (2) Physician assistant who is licensed to practice as a physician assistant under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority.

(B) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

- (a) Identification of the practitioner(s) and pharmacist(s) authorized to enter into the agreement. They may include:
 - (i) Individual names of practitioners and pharmacists;
 - (ii) Practitioner or pharmacist practice groups; or
 - (iii) Identification based on institutional credentialing or privileging.
 - (iv) If multiple practitioners are entering the consult agreement, identification of the primary practitioner for the patient.
- (b) A description of the patient's consent to drug therapy management pursuant to the consult agreement as set forth in paragraph (E) of rule 4729:1-06-01 of the Administrative Code.
- (c) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.
- (d) A description of the drugs or drug categories managed as part of the agreement.
- (e) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult

agreement.

- (f) A description of the types of tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the managing pharmacist as long as the tests relate directly to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated.
- (g) A description of how the managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification pursuant to agency 4729 of the Administrative Code.
- (h) A description of how communication between a managing pharmacist and practitioner acting under a consult agreement shall take place at regular intervals specified by the practitioner who authorized the agreement. The agreement may include a requirement that the managing pharmacist send a consult report to each consulting practitioner.
- (i) A provision that allows a practitioner to override a decision made by the managing pharmacist when appropriate.
- (j) An appropriate quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.
- (k) A description of a continuous quality improvement (CQI) program used to evaluate effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.
- (l) The training and experience criteria for managing pharmacists. The criteria may include privileging or credentialing, board certification, continuing education or any other training requirements. The agreement shall include a process to verify that the managing pharmacists meet the specified criteria.
- (m) A statement that the practitioners and pharmacists shall meet minimal and prevailing standards of care at all times.

- (n) An effective date and expiration date.
- (o) Any other requirements contained in rules 4729:1-6-01, 4729:1-6-02 and 4729:1-6-03 of the Administrative Code.
- (2) Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(c) to (A)(1)(f) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and available to an agent of the board upon request.
- (3) The agreement shall be signed by the primary practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:
 - (a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or
 - (b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code.
- (4) All amendments to a consult agreement shall be signed and dated by the primary practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:
 - (a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or
 - (b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code.
 - (c) Amendments to the consult agreement are required when the scope of the managing pharmacist's permitted procedures expands past what was contemplated withing the agreement
- (5) A consult agreement shall be valid for a period not to exceed two years.

- (6) Only the following Ohio licensed practitioners practicing in Ohio and Ohio licensed pharmacists may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.
 - (a) Physicians
 - (b) Physician assistants if entering into a consult agreement is authorized by one or more supervising physicians under a supervision agreement under section 4730.19 of the Revised Code; and
 - (c) Clinical nurse specialists, certified nurse-midwives, or certified nurse practitioners, if entering into a consult agreement is authorized by one or more collaborating physician.
- (C) Recordkeeping. The primary practitioner, practitioner group or institution as defined in agency 4729 of the Administrative Code shall maintain a copy of the original consult agreement, and all amendments made thereafter, and a record of actions made in consultation with the managing pharmacist regarding each patient's drug therapy. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records.
- (D) Managing drug therapy.
 - (1) For the purpose of implementing the management of a patient's drug therapy by an authorized managing pharmacist acting pursuant to a consult agreement, the primary practitioner must:
 - (a) Provide the managing pharmacist with access to the patient's medical record; and
 - (b) Establish the managing pharmacist's prescriptive authority as one or both of the following:
 - (i) A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. For all prescriptions issued by a pharmacist pursuant to this paragraph, the pharmacist shall comply with Chapter

4729:5-5 of the Administrative Code for outpatient and Chapter 4729:5-9 of the Administrative Code for inpatient; and or

- (ii) With respect to non-controlled dangerous drugs only, an agent of the consulting practitioner(s). As an agent of the consulting practitioner(s), a pharmacist is authorized to issue a drug order, on behalf of the consulting practitioner(s), in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement, and

(c) Specifically authorize the managing pharmacist's ability to:

- (i) Change the duration of treatment for the current drug therapy; adjust a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinue a drug, or to prescribe new drugs; and or
- (ii) Order tests related to the drug therapy being managed and to evaluate those results, and

(d) Identify the extent to which, and to whom, the managing pharmacist may delegate drug therapy management to other authorized pharmacists under the agreement.

(E) Review of consult agreements. Upon the request of the state medical board, the primary practitioner shall immediately provide a copy of the consult agreement, amendments, and any relating policies or documentation pursuant to this rule and section 4729.39 of the Revised Code. The state medical board may prohibit the execution of a consult agreement, or subsequently void a consult agreement, if the board finds any of the following:

- (1) The agreement does not meet the requirements set forth in section 4729.39 of the Revised Code or this division of the administrative code; or
- (2) The consult agreement, if executed, would present a danger to patient safety.

4731-35-02

Standards for managing drug therapy.

- (A) A practitioner may elect to manage the drug therapy of an established patient by entering into a consult agreement with a pharmacist. The agreement is subject, but not limited to, the following standards:
- (1) The primary practitioner must ensure that the managing pharmacist has access to the patient's medical record, the medical record is accurate, and that while transferring the medical record, the primary practitioner ensures the confidentiality of the medical record.
 - (2) The practitioner must have an ongoing practitioner-patient relationship with the patient whose drug therapy is being managed, including an initial assessment and diagnosis by the practitioner prior to the commencement of the consult agreement.
 - (3) With the exception of inpatient management of patient care at an institutional facility as defined in agency 4729 of the Administrative Code, the practitioner, prior to a pharmacist managing the patient's drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement, in such a manner that the patient or the patient's representative understands scope and role of the managing pharmacist, which includes the following:
 - (a) That a pharmacist may be utilized in the management of the patient's care;
 - (b) That the patient or an individual authorized to act on behalf of a patient has the right to elect to participate in and to withdraw from the consult agreement.
 - (c) Consent may be obtained as part of the patient's initial consent to treatment.
 - (4) The diagnosis by the practitioner must be within the practitioner's scope of practice.
 - (5) The practitioner shall meet the minimal and prevailing standards of care.
 - (6) The practitioner must ensure that the pharmacist managing the patient's drug therapy has the requisite training, and experience related to the particular diagnosis for which the drug therapy is prescribed. Practitioners practicing at institutional or ambulatory outpatient facilities may meet this requirement through institutional credentialing standards or policies.

- (7) The practitioner shall review the records of all services provided to the patient under the consult agreement.
- (B) Quality assurance mechanisms. The following quality assurance mechanisms shall be implemented to verify information contained within the consult agreement, and ensure the managing pharmacist's actions are authorized and meet the standards listed in paragraphs (A) and (B) of this rule:
- (1) Verification of ongoing practitioner-patient relationship. A practitioner-patient relationship can be established by detailing criteria set forth in paragraph (A)(2) of this rule, within the consult agreement.
 - (2) Verification that practitioner diagnosis is within the practitioner's scope of practice. Establishing that a diagnosis is within the practitioner's scope of practice may be established by detailing the criteria set forth in paragraph (A)(4) of this rule, within the consult agreement.
 - (3) Verification that pharmacist's training and experience is related to the drug therapy. Establishing that a pharmacist's requisite training and experience with a particular drug therapy is related to the diagnosis for which the drug therapy is prescribed, may be established by detailing the criteria set forth in paragraph (A)(6) of this rule, within the consult agreement.
- (C) Continuous quality improvement program. The following should be included in the development of a continuous quality improvement program in order to evaluate the effectiveness of patient care and ensure positive patient outcomes:
- (1) Notifications to primary practitioner. The managing pharmacist must notify the primary practitioner of the following situations regarding any pharmacist authorized to manage drug therapy under the agreement:
 - (a) A pharmacist has had their pharmacist license revoked, suspended, or denied by the state board of pharmacy;
 - (b) If prescribing controlled substances, a pharmacist has failed to renew their controlled substance prescriber registration;
 - (c) If prescribing controlled substances, a pharmacist fails to obtain or maintain a valid D.E.A. registration;
- (D) Overriding decisions of managing pharmacist. Any authorized practitioner identified

under the consult agreement may override any decision, change, modification, evaluation or other action by any pharmacist acting pursuant to consult agreement or under the direction of the managing pharmacist, that was made with respect to the management of the patient's drug therapy under the consult agreement.

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4731-36-01

Military provisions related to education and experience requirements for licensure.

(A) Definitions

For purposes of this chapter:

(1) "Armed forces" means any of the following:

- (a) The armed forces of the United States, including the army, navy, air force, marine corps, and coast guard;
- (b) A reserve component of the armed forces listed in paragraph (A)(1)(a) of this rule;
- (c) The national guard, including the Ohio national guard or the national guard of any other state;
- (d) The commissioned corps of the United States public health service;
- (e) The merchant marine service during wartime;
- (f) Such other service as may be designated by Congress; or
- (g) The Ohio organized militia when engaged in full-time national guard duty for a period of more than thirty days.

(2) "Board" means the state medical board of Ohio.

(3) "Service member" means any person who is serving in the armed forces.

(4) "Veteran" means any person who has completed service in the armed forces, including the national guard of any state, or a reserve component of the armed forces, who has been discharged under honorable conditions from the armed forces or who has been transferred to the reserve with evidence of satisfactory service.

(B) Education and service for eligibility for licensure.

(1) In accordance with section 5903.03 of the Revised Code, the following military programs of training, military primary specialties, and lengths of service are substantially equivalent to or exceed the educational and experience

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requirements for licensure as a physician assistant and for a prescriber number:

- (a) An individual serving in a military primary specialty listed in paragraph (B)(1)(b) of this rule must be a graduate of a physician assistant education program approved by the accreditation review commission on education for the physician assistant.
- (b) Service in one of the following military primary specialties for at least two consecutive years while on active duty, with evidence of service under honorable conditions, including any experience attained while practicing as a physician assistant at a health care facility or clinic operated by the United States department of veterans affairs, may be substituted for a master's degree for eligibility for a license to practice as a physician assistant pursuant to section 4730.11 of the Revised Code and for a prescriber number pursuant to section 4730.15 of the Revised Code;
 - (i) Army: MOS 65D;
 - (ii) Navy: NOBC 0113;
 - (iii) Air force: AFSC 42G;
 - (iv) The national guard of Ohio or any state;
 - (v) Marine: Physician assistant services are provided by navy personnel;
 - (vi) Coast guard;
 - (vii) Public health service.
- (2) For purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure as a massage therapist.
- (3) For purposes of section 5903.03 of the Revised Code, the board has determined that:

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- (a) A diploma from a military medical school or military osteopathic medical school that at the time the diploma was issued was a medical school accredited by the liaison committee on medical education or an osteopathic medical school accredited by the American osteopathic association are substantially equivalent to the medical educational requirement for licensure to practice medicine and surgery or osteopathic medicine and surgery;
 - (b) Military graduate medical education that is accredited by the accreditation council for graduate medical education is substantially equivalent to the graduate medical educational requirement for licensure to practice medicine and surgery or osteopathic medicine and surgery; and
 - (c) There are no military primary specialties or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure to practice medicine and surgery or osteopathic medicine and surgery.
- (4) For purposes of section 5903.03 of the Revised Code, the board has determined that:
- (a) A degree from a military college of podiatric medicine and surgery that at the time the degree was granted was a college of podiatric medicine and surgery accredited by the council on podiatric medical education is substantially equivalent to the medical educational requirement for licensure to practice podiatric medicine and surgery;
 - (b) Military postgraduate training in a podiatric internship, residency, or clinical fellowship program accredited by the council on podiatric medicine is substantially equivalent to the graduate medical educational requirement for licensure to practice podiatric medicine and surgery; and
 - (c) There are no military primary specialties or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure to practice podiatric medicine and surgery.
- (5) For purposes of section 5903.03 of the Revised Code, the board recognizes dietetics educational programs offered by branches of the United States military that have been issued accreditation status conferred by the Accreditation Council for Education in Nutrition and Dietetics or their successor organization that permits dietetics programs offered by the United States military to continue to enroll or graduate students. ~~has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure as a dietitian.~~

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- (6) For purposes of section 5903.03 of the Revised Code, the board recognizes respiratory care educational programs offered by branches of the United States military that have been issued provisional accreditation, initial accreditation, continuing accreditation or other accreditation status conferred by the commission on accreditation for respiratory care (CoARC) or their successor organization that permits respiratory care programs offered by the United States military to continue to enroll and/or graduate students
- (7) For purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, and lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as an acupuncturist.
- (8) For the purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as a radiologist assistant.
- (9) For the purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as a genetic counselor.

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4731-36-02

Military provisions related to renewal of license and continuing education.

(A) Renewal of an expired license or certificate to practice without a late fee or re-examination.

(1) An expired license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4761., 4762., 4774., or 4778. of the Revised Code shall be renewed upon payment of the renewal fee provided for in Chapter 4730., 4731., 4759., 4761., 4762., 4774., or 4778. of the Revised Code and without a late fee or re-examination if the holder meets all of the following requirements:

(a) The licensee is not otherwise disqualified from renewal because of mental or physical disability;

(b) The licensee meets the requirements for renewal for the particular license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4761., 4762., 4774., or 4778. of the Revised Code;

(c) Either of the following situations applies:

(i) The license was not renewed because of the licensee's service in the armed forces, or

(ii) The license was not renewed because the licensee's spouse served in the armed forces, and the service resulted in the licensee's absence from this state.

(d) The licensee or the licensee's spouse, whichever is applicable, has presented satisfactory evidence of the service member's discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.

(B) Continuing education.

(1) Extension of the continuing education period for the license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4761., 4762., or 4778. of the Revised Code:

(a) The holder of a license or certificate to practice may apply for an extension of the current continuing education reporting period in the manner provided in section 5903.12 of the Revised Code by submitting

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both of the following:

- (i) A statement that the licensee has served on active duty, whether inside or outside of the United States, for a specified period of time during the current or prior continuing education reporting period.
 - (ii) Proper documentation certifying the active duty service and the length of that active duty service.
- (b) Upon receiving the application and proper documentation, the board shall extend the current continuing education reporting period by an amount of time equal to the total number of months that the licensee spent on active duty during the current continuing education reporting period. Any portion of a month served shall be considered one full month.
- (2) The board shall consider relevant education, training, or service completed by a licensee as a member of the armed forces in determining whether a licensee has met the continuing education requirements needed to renew the license.
- (3) For purposes of sections 5903.12 and 5903.121 of the Revised Code, anesthesiologist assistants in Chapter 4731. of the Revised Code, acupuncturists in Chapter 4762. of the Revised Code, and radiologist assistants in Chapter 4774. of the Revised Code are not required to report continuing education coursework to the board.

4731-36-03

Processing applications from service members, veterans, or spouses of service members or veterans.

- (A) The board shall include questions on all applications for licensure, renewal, reinstatement or restoration of licensure for all applicants for licensure or certificate to practice pursuant to Chapters 4730., 4731., 4759., 4761., 4762., 4774., and 4778. that inquire as to whether the applicant is:
- (1) A service member;
 - (2) A veteran; or
 - (3) The spouse or surviving spouse of a service member or veteran.
- (B) If the applicant for licensure, biennial renewal, reinstatement, or restoration of licensure responds affirmatively to any of the questions discussed in paragraph (A) of this rule, the board shall process the application in the following manner:
- (1) Route the application to a board staff member who is responsible for monitoring the application and communicating with the applicant regarding the status of the application, including informing the applicant of any documentation needed for the board to process the application;
 - (2) Expedite the processing of the application, even if the application was received later in time than other applications that are pending processing;
 - (3) Provide information regarding available continuing education waivers to applicants if the applicant or the applicant's spouse will be imminently deployed; and
 - (4) Track, on an annual basis, the total number of applications submitted by service members, veterans, spouses or surviving spouses of service members or veterans, and the average number of business days expended by the board to process those applications.

4731-36-04

Temporary licensure for members of the military and spouses who are licensed in another jurisdiction.

- (A) “Military duty” has the same meaning as in section 4743.041 of the Revised Code.
- (B) Pursuant to section 4743.041 of the Revised Code, the state medical board of Ohio shall issue a temporary license or certificate to practice the professions governed by Chapters 4730., 4731., 4759., 4761., 4762., 4774., and 4778. of the Revised Code if the individual demonstrates to the satisfaction of the board all the following:
- (1) The individual holds a valid license or certificate to practice the profession issued by any other state or jurisdiction;
 - (2) The individual is in good standing in the state or jurisdiction of licensure or certification;
 - (3) The individual or the individual’s spouse is on military duty in this state.
- (C) An applicant for a temporary license or certificate must certify that, to the best of the applicant’s knowledge, the applicant is not under investigation by the licensing agency of any state or jurisdiction.
- (D) No application submitted to the board shall be considered complete until the applicant has complied with the requirements of paragraph (A) of rule 4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks.
- (E) If an applicant for a temporary license or certificate fails to complete the application process within six months of initial application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.
- (F) The board shall issue a temporary license or certificate within fourteen days of having received the results of a criminal records check, provided that the application is otherwise complete, and the applicant is not under investigation by the licensing agency of any state or jurisdiction.
- (G) The board shall process the application for a temporary license or certificate in accordance with rule 4731-36-03 of the Administrative Code.
- (H) The board shall waive all fees associated with the issuance of the temporary license

or certificate.

- (I) A temporary license or certificate issued under this section shall be valid for a two-year period unless revoked or suspended. A temporary license or certificate may not be renewed and a new temporary license may not be issued.
- (J) A holder of a temporary license or certificate may apply for licensure under Chapters 4730., 4731., 4759., 4761., 4762., 4774., and 4778. of the Revised Code at any time before or after expiration of the temporary license. A holder or previous holder of a temporary license or certificate must meet all requirements for licensure under the applicable chapter of the Revised Code and rules adopted thereunder.

4731-11-01

Definitions.

As used in Chapter 4731-11 of the Administrative Code:

- (A) "Controlled substance" means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V pursuant to the provisions of Chapter 3719. of the Revised Code and Chapter 4729:9-1 of the Administrative Code.
- (B) "Controlled substance stimulant" means any drug, compound, mixture, preparation, or substance which is classified as a stimulant in controlled substance schedule II, III, or IV listed in Chapter 4729:9-1 of the Administrative Code, or which is classified as a stimulant in controlled substances schedule II, III, or IV pursuant to Chapter 4729:9-1 of the Administrative Code.
- (C) "Cross-coverage" means an agreement between an Ohio-licensed physician and another Ohio licensed physician or healthcare provider acting within the scope of their professional license under which the physician provides medical services for an active patient, as that term is defined in paragraph (D) of rule this rule, of the other physician or healthcare provider who is temporarily unavailable to conduct the evaluation of the patient.
 - (1) This type of agreement includes on-call coverage for after hours and weekends.
 - (2) The medical evaluation required by paragraph (C) of rule 4731-11-09 of the Administrative Code may be a limited evaluation conducted through interaction with the patient.
- (D) For purposes of paragraph (D) of rule 4731-11-09 of the Administrative Code, "active patient" as that term is used in paragraph (C) of this rule, means that within the previous twenty-four months the physician or other healthcare provider acting within the scope of their professional license conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine as that term is defined in 21 C.F.R. 1300.04, in effect as of the effective date of this rule.
- (E) "Utilize a controlled substance or controlled substance stimulant" means to prescribe, administer, dispense, supply, sell or give a controlled substance or controlled substance stimulant.
- (F) "Recognized contraindication" means any contraindication to the use of a drug which is listed in the United States food and drug administration (hereinafter, "F.D.A.") approved labeling for the drug, or which the board determines to be accepted as a contraindication.

- (G) "The board" means the state medical board of Ohio.
- (H) "BMI" means body mass index, calculated as a person's weight in kilograms divided by height in meters squared.
- (I) "Physician" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.
- (J) "Board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:
- (1) Subspecialty board certification in addiction psychiatry from the american board of psychiatry and neurology;
 - (2) Board certification in addiction medicine from the american board of addiction medicine;
 - (3) Certification from the American society of addiction medicine;
 - (4) Subspecialty certification in addiction medicine from the American board of preventive medicine; or
 - (5) Board certification with additional qualification in addiction medicine from the American osteopathic association.
- (K) "Office based opioid treatment (OBOT)" "OBOT" means treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic.
- (L) "Acute pain" means pain that normally fades with healing, is related to tissue damage, significantly alters a patient's typical function and is expected to be time limited and not more than six weeks in duration.
- (M) "Minor" has the same meaning as in section 3719.061 of the Revised Code.
- (N) "Morphine equivalent daily dose (MED)" means a conversion of various opioid analgesics to a morphine equivalent dose by the use of accepted conversion tables provided by the state of Ohio board of pharmacy at: <https://www.ohiopmp.gov/>

(effective 2017).

(O) "Extended-release or long-acting opioid analgesic" means an opioid analgesic that:

- (1) Has United States food and drug administration approved labeling indicating that it is an extended-release or controlled release formulation;
- (2) Is administered via a transdermal route; or
- (3) Contains methadone.

(P) "Opioid analgesic" has the same meaning as in section 3719.01 of the Revised Code and means a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system, including but not limited to the following drugs and their varying salt forms or chemical congeners: buprenorphine, butorphanol, codeine (including acetaminophen and other combination products), dihydrocodeine, fentanyl, hydrocodone (including acetaminophen combination products), hydromorphone, meperidine, methadone, morphine sulfate, oxycodone (including acetaminophen, aspirin, and other combination products), oxymorphone, tapentadol, and tramadol.

(Q) "Hospice care program" has the same meaning as in section 3712.01 of the Revised Code.

(R) "Palliative care" has the same meaning as in section 3712.01 of the Revised Code.

(S) "Terminal condition" means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury from which, to a reasonable degree of medical certainty as determined in accordance with reasonable medical standards by a physician who has examined the patient, both of the following apply:

- (1) There can be no recovery.
- (2) Death is likely to occur within a relatively short time if life-sustaining treatment is not administered.

(T) "Medication therapy management" has the same meaning as in rule 4729:5-12-01 of the Administrative Code.

(U) "Subacute pain" means pain that has persisted after reasonable medical efforts have

been made to relieve it and continues either episodically or continuously for more than six weeks but less than twelve weeks following initial onset of pain. It may be the result of underlying medical disease or condition, injury, medical or surgical treatment, inflammation, or unknown cause.

(V) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for twelve or more weeks following initial onset of pain. It may be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(W) "Board certification in hospice and palliative care" means either of the following:

(1) Subspecialty certification in hospice and palliative medicine granted by a certification board that is a member of the American board of medical specialties.

(2) Certification of added qualification in hospice and palliative medicine by the American osteopathic association bureau of medical specialties.

(X) "Board certification in hematology" means specialty or subspecialty certification in hematology or a related hematology specialty or subspecialty by a certification board that is a member of the American board of medical specialties or by the American osteopathic association bureau of medical specialties.

(Y) "Board certification in oncology" means specialty or subspecialty certification in oncology or a related oncology specialty or subspecialty by a certification board that is a member of the American board of medical specialties or American osteopathic association bureau of medical specialties.

(Z) "Board certification in pain medicine" means any of the following:

(1) Current subspecialty certification in pain medicine by a member board of the American board of medical specialties, or current certificate of added qualification in pain medicine by the American osteopathic association bureau of osteopathic specialists;

(2) Current board certification by the American board of pain medicine; or

- (3) Current board certification by the American board of interventional pain physicians.

4731-11-13

Prescribing of opiate analgesics for acute pain.

(A) For the treatment of acute pain, the physician shall comply with the following:

- (1) Extended-release or long-acting opioid analgesics shall not be prescribed for treatment of acute pain;
- (2) Before prescribing an opioid analgesic, the physician shall first consider non-opioid treatment options. If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain, with a presumption that a three-day supply or less is frequently sufficient and that limiting the duration of opioid use to the necessary period will decrease the likelihood of subsequent chronic use or dependence;
- (3) In all circumstances where opioid analgesics are prescribed for acute pain:
 - (a) Except as provided in paragraph (B) of this rule, the duration of the first opioid analgesic prescription for the treatment of an episode of acute pain shall be:
 - (i) For adults, not more than a seven-day supply with no refills;
 - (ii) For minors, not more than a five-day supply with no refills. A physician shall comply with section 3719.061 of the Revised Code, including but not limited to obtaining from the parent, guardian, or another adult who is authorized to consent to the minor's medical treatment written consent prior to prescribing an opioid analgesic to a minor;
 - (iii) The seven-day limit for adults and five-day limit for minors may be exceeded for pain that is expected to persist for longer than seven days based on the pathology causing the pain. In this circumstance, the reason that the limits are being exceeded and the reason that a non-opioid medication was not appropriate to treat the patient's conditions shall be documented in the patient's medical record. The number of days of the prescription shall not exceed the amount required to treat the expected duration of the pain as noted in paragraph (A) (2) of this rule; and
 - (iv) If a patient is allergic to or otherwise unable to tolerate the initially prescribed opioid medication, a prescription for a different,

appropriate opioid may be issued at any time during the initial seven or five-day dosing period and shall be subject to all other provisions of this rule. The allergy and/or intolerance shall be documented in the patient's medical record. The patient or the minor patient's parent, guardian or another adult who is authorized to consent to the minor's medical treatment must be provided education of the safe disposal of the unused medication.

- (b) The patient, or a minor's parent or guardian, shall be advised of the benefits and risks of the opioid analgesic, including the potential for addiction, and the advice shall be documented in the patient's medical record; and
- (c) The total morphine equivalent dose (MED) of a prescription for opioid analgesics for treatment of acute pain shall not exceed an average of thirty MED per day, except when all of the following apply:
 - (i) The patient suffers from medical conditions, surgical outcomes or injuries of such severity that pain cannot be managed within the thirty MED average limit as determined by the treating physician based upon prevailing standards of medical care, such as:
 - (a) Traumatic crushing of tissue;
 - (b) Amputation;
 - (c) Major orthopedic surgery;
 - (d) Severe burns
 - (ii) The physician determines that exceeding the thirty MED average limit is necessary based on the physician's clinical judgment and the patient's needs.
 - (iii) The physician shall document in the patient's medical record the reason for exceeding the thirty MED average and the reason it is the lowest dose consistent with the patient's medical condition.
 - (iv) Only the prescribing physician for the conditions in paragraph (A)(3)(c)(i) of this rule may exceed the thirty MED average. The prescribing physician shall be held singularly accountable for

prescriptions that exceed the thirty MED average.

- (v) In circumstances when the thirty MED average is exceeded, the dose shall not exceed the dose required to treat the severity of the pain as noted in paragraph (A)(2) of this rule.
- (d) Prescriptions that exceed the five or seven day supply or thirty MED average daily dose are subject to additional review by the state medical board. The dosage, days supplied, and condition for which the opioid analgesic is prescribed will be considered as part of this additional review.
- (B) The requirements of paragraph (A) of this rule apply to treatment of acute pain and do not apply when an opioid analgesic is prescribed:
 - (1) To an individual who is a hospice patient or in a hospice care program;
 - (2) To an individual receiving palliative care;
 - (3) To an individual who has been diagnosed with a terminal condition; or
 - (4) To an individual who has cancer or another condition associated with the individual's cancer or history of cancer.
- (C) This rule does not apply to prescriptions for opioid analgesics for the treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic that is approved by the federal drug administration for opioid detoxification or maintenance treatment.
- (D) This rule does not apply to inpatient prescriptions as defined in Chapter 4729. of the Revised Code.

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4731-11-14

Prescribing for subacute and chronic pain.

- (A) Prior to treating, or continuing to treat subacute or chronic pain with an opioid analgesic, the physician shall first consider and document non-medication and non-opioid treatment options.
- (1) If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain and improve the patient's ability to function.
 - (2) The physician shall comply with the requirements of rule 4731-11-02 of the Administrative Code.
- (B) Before prescribing an opioid analgesic for subacute or chronic pain, the physician shall complete or update and document in the patient record assessment activities to assure the appropriateness and safety of the medication including:
- (1) History and physical examination including review of previous treatment and response to treatment, patient's adherence to medication and non-medication treatment, and screening for substance misuse or substance use disorder;
 - (2) Laboratory or diagnostic testing or documented review of any available relevant laboratory or diagnostic test results. If evidence of substance misuse or substance use disorder exists, diagnostic testing shall include urine drug screening;
 - (3) Review the results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code;
 - (4) A functional pain assessment which includes the patient's ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and the physical activity of the patient;
 - (5) A treatment plan based upon the clinical information obtained, to include all of the following components:
 - (a) Diagnosis;
 - (b) Objective goals for treatment;

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- (c) Rationale for the medication choice and dosage; and
 - (d) Planned duration of treatment and steps for further assessment and follow-up.
- (6) Discussion with the patient or guardian regarding:
 - (a) Benefits and risks of the medication, including potential for addiction and risk of overdose; and
 - (b) The patient's responsibility to safely store and appropriately dispose of the medication.
- (7) The physician shall offer a prescription for an overdose reversal drug to the patient receiving an opioid analgesic prescription under any of the following circumstances:
 - (a) The patient has a history of prior opioid overdose;
 - (b) The dosage prescribed exceeds a daily average of eighty MED or at lower doses if the patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodol, tramadol, or gabapentin; or
 - (c) The patient has a concurrent substance use disorder.
- (C) Prior to increasing the opioid dosage to a daily average of fifty MED or greater the physician shall complete and document the following in the patient's medical record:
 - (1) The physician shall review and update the assessment completed in paragraph (B) of this rule, if needed. The physician may rely on an appropriate assessment completed within a reasonable time if the physician is satisfied that he or she may rely on that information for purposes of meeting the further requirements of this chapter of the Administrative Code;
 - (2) The physician shall update or formulate a new treatment plan, if needed;
 - (3) The physician shall obtain from the patient or the patient's guardian written informed consent which includes discussion of all of the following:

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- (a) Benefits and risks of the medication, including potential for addiction and risk of overdose.
 - (b) The patient's responsibility to safely store and appropriately dispose of the medication.
 - (4) Except when the patient was prescribed an average daily dosage that exceeded fifty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall document consideration of the following:
 - (a) Consultation with a specialist in the area of the body affected by the pain;
 - (b) Consultation with a pain management specialist;
 - (c) Obtaining a medication therapy management review by a pharmacist; and
 - (d) Consultation with a specialist in addiction medicine or addiction psychiatry, if aberrant behaviors indicating medication misuse or substance use disorder are noted.
 - (5) The physician shall consider offering a prescription for an overdose reversal drug to mitigate risk of overdose.
- (D) Prior to increasing the opioid dosage to a daily average of eighty MED or greater, the physician shall complete all of the following:
- (1) Enter into a written pain treatment agreement with the patient that outlines the physician's and patient's responsibilities during treatment and requires the patient or patient guardian's agreement to all of the following provisions:
 - (a) Permission for drug screening and release to speak with other practitioners concerning the patient's condition or treatment;
 - (b) Cooperation with pill counts or other checks designed to assure compliance with the treatment plan and to minimize the risk of misuse or diversion;
 - (c) The understanding that the patient shall only receive opioid medications from the physician treating the chronic pain unless there is written

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agreement among all of the prescribers of opioids outlining the responsibilities and boundaries of prescribing for the patient; and

- (d) The understanding that the dosage may be tapered if not effective or if the patient does not abide by the treatment agreement.
- (2) Offer a prescription for an overdose reversal drug to the patient as described in paragraph (B) of this rule.
- (3) Except when the patient was prescribed an average daily dosage that exceeded eighty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall obtain at least one of the following based upon the patient's clinical presentation:
 - (a) Consultation with a specialist in the area of the body affected by the pain;
 - (b) Consultation with a pain management specialist;
 - (c) Obtain a medication therapy management review; or
 - (d) Consultation with a specialist in addiction medicine or addiction psychiatry if aberrant behavior indicating medication misuse or substance use disorder may be present.
- (E) The physician shall not prescribe a dosage that exceeds an average of one hundred twenty MED per day. This prohibition shall not apply in the following circumstances:
 - (1) The physician holds board certification in pain medicine, board certification in hospice and palliative care, board certification in hematology, or board certification in oncology;
 - (2) The physician has received a written recommendation for a dosage exceeding an average of one hundred twenty MED per day from a board certified pain medicine physician or board certified hospice and palliative care physician who based the recommendation on a face-to-face visit and examination of the patient. The prescribing physician shall maintain the written recommendation in the patient's record; or

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- (3) The patient was receiving an average daily dose of one hundred twenty MED or more prior to the effective date of this rule. The physician shall follow the steps in paragraph (E)(2) of this rule prior to escalating the patient's dose.
- (F) During the course of treatment with an opioid analgesic at doses below the average of fifty MED per day, the physician shall provide periodic follow-up assessment and documentation of the patient's functional status, the patient's progress toward treatment objectives, indicators of possible addiction, drug abuse or drug diversion and the notation of any adverse drug effects.
- (G) During the course of treatment with an opioid analgesic at doses at or above the average of fifty MED per day, the physician shall complete and document in the patient record the following no less than every three months:
 - (1) Review of the course of treatment and the patient's response and adherence to treatment.
 - (2) The assessment shall include a review of any complications or exacerbation of the underlying condition causing the pain through appropriate interval history, physical examination, any appropriate diagnostic tests, and specific treatments to address the findings.
 - (3) The assessment of the patient's adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities;
 - (4) Rationale for continuing opioid treatment and nature of continued benefit, if present.
 - (5) The results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code.
 - (6) Screening for medication misuse or substance use disorder. Urine drug screen should be obtained based on clinical assessment of the physician with frequency based upon presence or absence of aberrant behaviors or other indications of addiction or drug abuse.
 - (7) Evaluation of other forms of treatment and the tapering of opioid medication if continued benefit cannot be established.
- (H) This rule does not apply to the physician who prescribes an opioid in any of the following situations:

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- (1) The medication is for a patient in hospice care.
- (2) The patient has terminal cancer or another terminal condition, as that term is defined in rule 4731-11-01 of the Administrative Code.
- (I) This rule does not apply to inpatient prescriptions or medication orders as defined in paragraph (J) of rule ~~4729:5-9-01~~4729-17-01 of the Administrative Code.

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4731-29-01

Standards and procedures for the operation of a pain management clinic.

(A) For the purposes of this rule:

- (1) "Board" means state medical board of Ohio.
- (2) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously, or episodically, for longer than three continuous months. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.
- (3) "Hospital" means an institution or facility that provides inpatient medical or surgical services for a continuous period longer than twenty-four hours as defined in section 3722.01 ~~hospital registered with the department of health under section 3701.07 of the Revised Code.~~
- (4) "Informed consent" means a process of communication between a patient and physician that results in the patient's signed authorization or agreement to undergo a specific medical intervention after all of the following subjects are discussed:
 - (a) The patient's diagnosis;
 - (b) The nature and purpose of the proposed treatment or procedure;
 - (c) The risks and benefits of a proposed treatment or procedure;
 - (d) Alternatives regardless of their costs or the extent to which the treatment options are covered by health insurance;
 - (e) The risks and benefits of the alternative treatment or procedure; and
 - (f) The risks and benefits of not receiving or undergoing a treatment or procedure.
- (5) "Owner" means each person included on the list maintained under division (B)(5) of section 4729.552 of the Revised Code.
- (6) "Pain management clinic" means a facility in which the majority of patients of the prescribers at the facility are provided treatment for chronic pain that includes the use of controlled substances. In determining whether the facility

meets the requirements of this paragraph:

- (a) Calculation of the majority of patients will be based upon the number of patients treated in a calendar month;
- (b) Patients receiving controlled substances for treatment of an injury or illness that lasts or is expected to last thirty days or less shall not be considered in the calculation of the majority.

(7) "Pain management clinic" does not include the following:

- (a) A hospital;
- (b) A facility operated by a hospital for the treatment of pain or chronic pain;
- (c) A physician practice owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;
- (d) A school, college, university, or other educational institution or program to the extent that it provides instruction to individuals preparing to practice as physicians, podiatrists, dentists, nurses, physician assistants, optometrists, or veterinarians or any affiliated facility to the extent that it participates in the provision of that instruction;
- (e) A hospice program licensed under Chapter 3712. of the Revised Code;
- (f) An ambulatory surgical facility licensed under section 3702.30 of the Revised Code;
- (g) An interdisciplinary pain rehabilitation program with three-year accreditation from the commission on accreditation of rehabilitation facilities;
- (h) A nursing home licensed under section 3721.02 of the Revised Code or by a political subdivision certified under section 3721.09 of the Revised Code; or
- (i) A facility conducting only clinical research that may use controlled substances in studies approved by a hospital-based institutional review

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board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(8) "Physician" means an individual authorized under chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(9) "Prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(B) In the operation of a pain management clinic, the following requirements shall be met:

(1) The pain management clinic shall be owned and operated by one or more physicians. Each physician owner of a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.

(2) Each physician owner of a pain management clinic must meet one of the following requirements:

(a) Hold current subspecialty certification in pain medicine by the American board of medical specialties, or hold a current certificate of added qualification in pain medicine by the American osteopathic association bureau of osteopathic specialists; or

(b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists; or

(c) Hold current board certification by the American board of pain medicine; or

(d) Hold current board certification by the American board of interventional pain physicians; or

(e) Meet both of the following:

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- (i) Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists.
 - (ii) Demonstrate conformance with the minimal standards of care.
- (3) To demonstrate conformance with the minimal standards of care pursuant to paragraph (B)(2)(e)(ii) of this rule, the board shall conduct an inspection of the facility pursuant to division (E) of section 4731.054 of the Revised Code.
- (4) The pain management clinic shall be licensed as a category III terminal distributor of dangerous drugs with a pain management clinic classification under section 4729.552 of the Revised Code.
- (5) The pain management clinic shall be operated in compliance with ~~the drug prevention and control act, 21 U.S.C. 801 to 971, in effect as of May 1, 2016, and Chapters 3719., 4729., 4730., and 4731. of the Revised Code, and all~~ applicable provisions of federal law governing the possession, distribution or use of controlled substances.
- (6) The pain management clinic shall have proper equipment, materials, and personnel on premises to provide appropriate medical treatment, as required by the minimal standards of care.
- (C) Each physician who provides care at a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years, to include one or more courses addressing the potential for addiction. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.
- (D) No physician owner of a pain management clinic, employee of the clinic, or person with whom the clinic contracts for services shall:
 - (1) Have ever been denied a license to prescribe, dispense, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying or selling a controlled substance or other dangerous drug.

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- (2) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying, or selling a controlled substance or other dangerous drug.
 - (3) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescribers inappropriate prescribing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug.
- (E) In providing supervision, direction, and control of individuals at a pain management clinic the physician owner shall establish and ensure compliance with the following:
- (1) A requirement that a log of patients be maintained for each day the clinic is in operation.
 - (a) Each log sheet shall contain the month, day, and year;
 - (b) Each log entry shall include the legible first and last name of each patient;
 - (c) Each patient shall be required to sign the log at each visit; and
 - (d) Patient logs shall be maintained for seven years.
 - (2) A requirement that providers obtain informed consent for each patient prior to the commencement of treatment.
 - (3) An on-going quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the clinic, and provides the opportunities to improve the clinic's performance and quality of care.
 - (4) A requirement that the background, training, certification, and licensure of all clinical staff be documented. Verification of certification and licensure shall be made on an annual basis.

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- (5) A requirement that adequate billing records are maintained for all patients and made available to the board, immediately upon request.
 - (a) Billing records shall include the amount paid, method of payment, description of services, sufficient information to identify the patient, and the amounts charged to the patient for each date of service,
 - (b) Billing records shall be maintained for seven years from the last date of treatment of the patient.
- (6) A requirement that adequate patient records are maintained for all patients and made available to the board, immediately upon request.
 - (a) Patient records shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum:
 - (i) Patient history and physical examination, including history of drug abuse or dependence;
 - (ii) Diagnostic, therapeutic, and laboratory results, including drug testing results;
 - (iii) Reports of evaluations, consultations, and hospitalizations;
 - (iv) Treatment objectives, including discussion of risks and benefits;
 - (v) Records of drugs prescribed, dispensed or administered, including the date, type, and dosage;
 - (vi) Treatments;
 - (vii) Receipt and assessment of drug database or prescription monitoring program reports;
 - (viii) Copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient. Records provided by the patient shall be designated as such.

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- (b) Patient records shall be maintained for seven years from the last date of treatment of the patient.
- (c) In the treatment of chronic pain the patient records shall contain the information required in rule ~~4731-21-02~~ 4731-11-14 of the Administrative Code in lieu of the requirements of paragraphs (E)(6)(a)(i) to (E)(6)(a)(vi) of this rule.