CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: STATE MEDICAL BOARD OF OHIO

Regulation/Package Title: OFFICE BASED OPIOID TREATMENT

Rule Number(s): 4731-11-01, 4731-11-12

Date: _____

Rule Type:

- ✓ New
- ✓ Amended
- ✓ 5-Year Review
- Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

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Rule 4731-11-12 provides treatment parameters for prescribers who wish to treat opiate addiction via office-based treatment with schedule III, IV, or V controlled substance narcotics that have been specifically approved by the U.S. Food and Drug Administration (hereinafter "FDA"). At this time the only approved drugs are buprenorphine products, including the drug with the brand name of Suboxone. In this document schedule III, IV, or V controlled substance narcotics that have been specifically approved by the FDA for the maintenance and treatment of opioid addiction will be referred to as "specifically approved buprenorphine products." The need for regulation is urgent, as specifically approved buprenorphine products are being diverted at increasing levels as their availability increases (Available from the Ohio Department of Mental Health and Drug Addiction at the following link: http://mha.ohio.gov/Default.aspx?tabid=180). There are also reports that some specifically approved buprenorphine products prescribers are setting up "pill mills" around specifically approved buprenorphine products dispensing, similar to the "pill mills" involving other prescription opiates such as OxyContin and Vicodin (see http://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-bupe-can-be-savior-or-menace.html?_r=1&). Recognizing the constellation of factors related to opiate addiction, treatment, and illegal activity, the rule attempts to strike a proper balance between access to opiate addiction treatment and diversion of specifically approved buprenorphine products by setting forth the requirements for treating opiate addiction in a non-institutional setting so that the treatment can be performed in a safe manner for the patient and reduce the risk of unlawful behavior of patients, practitioners, and others.

2. **Please list the Ohio statute authorizing the agency to adopt this regulation.**

   The rule is authorized by sections 4731.05 and 4731.055, O.R.C.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   The rule does not implement a federal requirement.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   This question is not applicable.

5. **What is the public purpose for this regulation (i.e., why does the agency feel that there needs to be any regulation in this area at all)?**

   Ohio is experiencing an epidemic of opiate abuse and overdose deaths. Specifically approved buprenorphine products have been used successfully for the maintenance treatment

for opioid dependence as part of a treatment plan that includes counseling and psychosocial support. However, specifically approved buprenorphine products are themselves opioids that are subject to abuse. Concerns have been brought forward by law enforcement, treatment providers, and governmental agencies that office based maintenance treatment with specifically approved buprenorphine products may be contributing to the opiate problem in Ohio. Protection of the public, in general, and persons with opiate addiction, in particular, necessitates that the Medical Board regulate the office based maintenance treatment of persons with opiate addiction in a safe manner, yet at the same time providing greater access to that treatment in Ohio.

6. **How will the agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees, medical practices, and medical facilities regarding the provisions of the rule.

Development of the regulation

7. **Please list the stakeholders included by the agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   An initial draft of the rule was developed by Medical Board staff based ~~in part~~ on concerns raised by providers of office based treatment for opioid addiction using specifically approved buprenorphine products, the Medical Board's investigative and legal staff, and law enforcement relating to substandard practices in the treatment of opiate addiction with specifically approved buprenorphine products. A panel of five independent experts in addiction medicine was subsequently convened to provide input as to the best current practices in treating opiate addiction. Other participants and interested parties included other addiction medicine practitioners, representatives from the Governor's Cabinet Opiate Action Team, the Ohio legislature, the Ohio Department of Health, the Ohio State Board Of Pharmacy, the Ohio Board Of Nursing, Ohio Osteopathic Association, the Academy of Medicine of Cleveland and Northern Ohio, Ohio Department of Mental Health and Addiction Services, the office of Representative Sprague, Representative Terry Johnson, D.O., Ohio State Medical Association, Ohio Bureau of Workman's Compensation, the Ohio Academy of Family Physicians, the Ohio Psychiatric Physicians Association, the Ohio Association of County Behavioral Health Authorities, Ohio Physicians Health Program, and others. The panel members and representatives of the above named groups were invited to participate in

a teleconference on January 15, 2014, to discuss the issues associated with treating opiate addiction in an office-based setting. Multiple e-mail communications followed in the effort to craft a rule reflecting the input of the experts and other interested parties. In February 2014, the Medical Board approved the draft rule for filing with CSI. However, the Medical Board then received notice from the Governor's Cabinet Opiate Action Team that there were potentially new treatment parameters. A teleconference was convened on March 5, 2014 in order to evaluate whether there is a need to further refine the draft rule. Based on the input from the teleconference participants, it was determined that no additional refinement was necessary.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the agency?

The panel of independent experts reviewed the first draft of the rule and offered various suggestions for changes which were, for the most part, incorporated into the current draft of rule 4731-11-12. One expert panel member suggested that the generic form of buprenorphine be included in the medications that could be used in the outpatient office based treatment of addiction. The Medical Board concluded that the restriction in the draft rule to specifically approved buprenorphine products and other specifically approved buprenorphine products-like formulations is appropriate, as specifically approved buprenorphine products and some other medications are specifically approved by the FDA for use in the maintenance and detoxification of opiate addiction while generic buprenorphine is not. Federal law prohibits the use of generic products to treat opiate addiction. See 21 CFR 1301.28.

The first draft exempted from the rule physicians practicing at hospitals, a physician practice owned by a hospital, the medical practice of physicians having completed specified clinical training and/or attained specified certification credentials, and others. The Ohio Academy of Family Physicians and others objected to the exemptions as discriminating against private practice physicians. It was also pointed out that exempting physicians from the proposed rule also exempted them from being required to check the OARRS database when prescribing specifically approved buprenorphine products, although the physicians would continue to be covered under Rule 4731-11-11, OAC (the rule setting the standards and procedures for use of OARRS). Another comment was that it not necessary for the physician to have obtained the specified certification credentials. The exemptions were removed from the draft rule.

One physician suggested that there should be a separate provision addressing specifically approved buprenorphine products treatment for pregnant women. In order to ensure the

safety of the unborn child, the panel supported language that will allow a pregnant woman to be treated with specifically approved buprenorphine products even if the woman does not participate in what is otherwise mandatory behavioral health counseling or addiction treatment. The suggested was adopted and is reflected in paragraph (B) of the proposed rule.

Two physicians stated that the requirement for patient participation in behavioral counseling or addiction treatment presents a hardship to many patients who may not have transportation or in areas where there are not resources offering structured treatment programs. It was discussed that the twelve-step programs are available everywhere. The Medical Board staff agreed that the implementation of the proposed rule would reflect that participation in a twelve-step program would meet the requirement for addiction treatment.

The version of the rule under consideration in January had originally limited the dosage amount that can be prescribed to no more than twelve milligrams of specifically approved buprenorphine products per day. The Ohio Department of Mental Health and Addiction Services offered its "low dose protocol" as an example, stating that with good counseling there can be success with a maximum of eight milligrams per day dosage. One physician commented that a dosage of twelve milligrams is sufficient for a family practice physician to prescribe. Other physicians offered their experiences that sometimes sixteen milligrams per day is required. All panel members agreed a prescription above 16 milligrams of specifically approved buprenorphine products per day was not commonly necessary and with a dosage of more that sixteen milligrams per day the patient is more inclined to sell the drug. One physician commented that the language did not encompass the personally furnishing of specifically approved buprenorphine products. Accordingly, the final draft rule reflects a prohibition against prescribing, personally furnishing, or administering a dosage of specifically approved buprenorphine products greater than sixteen milligrams per day, except after a consultation with an addictionologist who recommends a higher dosage.

There was considerable discussion on the question of what, if any, laboratory tests should be run before specifically approved buprenorphine products is prescribed. The original version of the rule required that numerous laboratory tests be conducted prior to the first prescription, followed by toxicological screening no less frequently than monthly. Physicians on the panel commented that the array of tests were not necessary and too expensive for patients. There was support for requiring a drug screen via urine analysis, however. The tests other than the urine analysis were deleted from the rule. Although some panel members commented that requiring that the urine analysis be "witnessed," would be a financial and/or practice hardship, the Medical Board determined, based upon its experience monitoring persons with opioid dependence, that the urine collection should be witnessed in order to decrease cheating on the urine screens.

In February 2014, the Medical Board approved the draft rule for filing with CSI. However, the Medical Board then received notice from the Governor's Cabinet Opiate Action Team that there were potentially new treatment parameters. The study at issue was circulated to all members of the expert panel and interested parties. A teleconference was convened on March 5, 2014, in order to evaluate whether there was a need to further refine the draft rule. Based on the input from the teleconference participants and written comments received, it was determined that the study at issue was not based on current science and no additional refinement was necessary.

What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data in the form of the review of addiction practice journal articles and real world experience held by the expert panel, non-physician addiction experts, and other providers formed a majority of the input for the current draft rule. For example, one of the members of the expert panel was the first Ohio physician meeting requirements to train other physicians in appropriate treatment for detoxification and maintenance using specifically approved buprenorphine products.

9. **What alternative regulations (or specific provisions within the regulation) did the agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the agency consider regulatory alternatives?**

   As discussed in the response to Question 8 above, the proposed rule is significantly changed from the original draft in reflection of the input of addiction experts, physicians who provide the treatment, and other interested parties, including law makers and the Ohio Department of Mental Health and Addiction Services. The proposed rule balances the Medical Board's duty to protect the public with the need for wider access to opiate addiction treatment.

10. **Did the agency specifically consider a performance-based regulation? Please explain.** ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

    Rule 4731-11-12 is not a performance based regulation. The intention of the rule is to safely regulate the practice of treating persons addicted to opiates in order to provide wider access to addiction treatment while reducing the risk of abuse and diversion of controlled substances. The proposed rule sets parameters without dictating the process by the physician must use to achieve compliance.

11. **What measures did the agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The rule sets out the requirements for physicians who provide office-based opioid treatment. The Medical Board is the only agency that regulates physicians in Ohio.

12. **Please describe the agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    The rule will be posted on the Medical Board's website, information concerning the rule will be included in informational materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician practice regulations.

Adverse impact to business

13. **Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**
    a. **Identify the scope of the impacted business community;**
    b. **Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
    c. **Quantify the expected adverse impact from the regulation.**
    The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

a. The business community impacted by rule 4731-11-12 will include all physicians who choose to treat persons with opiate addiction.

b. Violation of the rule may result in administrative licensure discipline for the physician. Discipline might include reprimand, suspension of the license, required course work, and/or revocation of the license. The cost of course work is borne by the licensee.

   There are fees connected with a licensee obtaining and maintaining several licenses or registrations, as well as required education, which are detailed below. There will be licensee and/or staff time associated with completing the paperwork described below, as well as time related to obtaining and reviewing an OARRS report and drug screens. There will be some cost associated with the drug screens as explained below.

c. The U.S. Drug Enforcement Administration (DEA) requires, pursuant to 21 USC § 823(g)(2), that a physician who intends to prescribe certain controlled substance medications for the purposes of maintenance and detoxification of opiate addiction receive a waiver from special registration requirements (waiver). There is no fee associated with applying for the waiver. A physician who intends to prescribe specifically approved buprenorphine products, which are a schedule III, IV, or V controlled substance, must have a current DEA certificate of registration (also known as a DEA number). The fee associated with the DEA number is $731.00 for the initial application and for every three year renewal cycle. In order to qualify for a waiver, the physician must obtain and maintain a certain enumerated specialty certification required by the DEA or eight hours of training approved by certain associations (See http://buprenorphine.samhsa.gov/SMA-167_Increase_Patients.pdf).

The quantifiable costs associated with becoming licensed as a physician are, respectively, $335.00 for the licensee fee, a $22 fee for the Ohio Bureau of Criminal Identification and Investigation (BCII), and a $24 fee for the federal bureau of investigation (FBI). The BCII and FBI fees are required by Section 4776.02, ORC. Maintaining licensure in Ohio involves a biennial renewal fee of $305.00.

The costs of first level drug screens required by proposed 4731-11-12(A)(12) varies widely, from $4.14 per screen (www.cliawaived.com) to $10.75 (www.drugteststrips.com). The drug tests included testing for most drugs of abuse, and also include specifically approved buprenorphine products and methadone so that the treating physician can determine if the patient is compliant with treatment and to ensure that other potentially dangerous controlled substance medications are not being taken by the patient. After the second failed drug screen, where the drug screen results are inconsistent with the treatment plan, the rule requires that the failed result be further screened by way of Gas Chromatography/Mass Spectrometry ("GC/MS") method or the Liquid Chromatography/Mass Spectrometry ("LC/MS") method. These costs vary widely as well, from $32.95 plus shipping costs (www.meditests.com) to $125.00 per test plus shipping/handling (www.questdiagnostics.com). Should the treating physician decide to pass these costs off to the patient, the patient's cost can vary, ranging from no cost for a patient covered by Medicaid who uses a physician's office which is certified by the Ohio Department of Mental Health and Addiction Services to private insurers such as United Healthcare which, for state employees, covers in network laboratories at a deductible of the first $200.00 and then eighty percent thereafter; and covers out of network laboratories at a deductible of the first $400 and then sixty percent thereafter.

14. Why did the agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

See the answer to question 5.

Regulatory flexibility

15. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The treatment of opiate addiction is a complex and potentially dangerous endeavor, and public safety requirements relative to the rule require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

16. How will the agency apply Ohio revised code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The medical board does not have authority to fine physicians or impose penalties for paperwork violations.

17. **What resources are available to assist small businesses with compliance of the regulation?**

Medical board staff members are available by telephone and e-mail to answer questions. Medical board staff members also give presentations to groups and associations who seek an update on physician practice regulations.

DRAFT - NOT FOR FILING

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.

(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 section 3719.41 of the Revised Code, or which is classified as a stimulant in controlled substances schedule II, III, or IV pursuant to section 3719.43 or 3719.44 of the Revised Code.

(C) "Utilize a controlled substance or controlled substance stimulant" means to prescribe, administer, dispense, supply, sell or give a controlled substance or controlled substance stimulant.

(D) "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.

(E) "The board" means the state medical board of Ohio.

(F) "BMI" means body mass index, calculated as a person's weight in kilograms divided by height in meters squared.

(G) "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.

(H) "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; OR

(4) BOARD CERTIFICATION WITH ADDITIONAL QUALIFICATION IN ADDICTION MEDICINE FROM THE AMERICAN OSTEOPATHIC ASSOCIATION.

(I) "OFFICE BASED OPIOID TREATMENT", OR "OBOT", MEANS TREATMENT OF OPIOID ADDICTION UTILIZING A SCHEDULE III, IV OR V CONTROLLED SUBSTANCE NARCOTIC.

(J) "OPIOID TREATMENT PROGRAM", OR "OTP", SOMETIMES REFERRED TO AS A "METHADONE CLINIC", MEANS A PROGRAM LICENSED BY THE STATE TO ADMINISTER OR DISPENSE SCHEDULE II CONTROLLED SUBSTANCE NARCOTICS IN THE MAINTENANCE OR DETOXIFICATION TREATMENT OF OPIOID ADDICTION.

DRAFT - NOT FOR FILING

4731-11-12 Office Based Opioid Treatment.

(A) For the purposes of this rule:

(1) "Office Based Opioid Treatment", or "OBOT", means treatment of opioid addiction utilizing a schedule iii, iv or v controlled substance narcotic.

(2) "Opioid Treatment Program", or "OTP", sometimes referred to as a "methadone clinic", means a program licensed by the state to administer or dispense schedule ii controlled substance narcotics in the maintenance or detoxification treatment of opioid addiction.

(3) "board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

(a) subspecialty board certification in addiction psychiatry from the American board of psychiatry and neurology;

(b) board certification in addiction medicine from the American board of addiction medicine;

(c) certification from the American society of addiction medicine; or

(d) board certification with additional qualification in addiction medicine from the American osteopathic association.

(B) A physician shall not provide OBOT other than in compliance with all of the provisions of this rule.

(1) The physician shall meet all applicable requirements of 21 CFR part 1301;

(2) Prior to providing OBOT, the physician shall conduct a proper assessment.

(a) The assessment shall include, at a minimum, complete history and physical, mental status exam, substance use history, appropriate lab tests, pregnancy test for women of childbearing years, toxicology tests for drugs and alcohol, and hepatitis b and c screens.

(b) All urine toxicology tests shall be directly witnessed.

(3) The physician shall practice in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance and tapering. Acceptable protocols are the "Clinical Guidelines For the Use of Buprenorphine in the Treatment of Opioid Addiction" protocol approved by the substance abuse and mental health services administration in 2004, (available from the substance abuse and mental health services administration website at http://samhsa.gov/) and the low dose protocol approved by the Ohio department of alcohol and drug abuse services in or about 2011 (available from the Ohio department of mental health and addiction services website at http://mha.ohio.gov/).

(4) The physician shall diagnose an opioid disorder utilizing the criteria contained in the diagnostic and statistical manual of mental disorders, 4th or 5th edition.

(5) The physician shall develop an individualized treatment plan for each patient, and at each visit shall document that the patient is attending sufficient behavioral health treatment.

(6) The physician shall require each patient to actively participate in appropriate behavioral counseling or treatment for their addiction.

(a) The physician shall maintain meaningful interactions with the qualified chemical dependency professional, addiction treatment provider, or other behavioral health professional who is treating the patient.

(b) If the physician is a board certified addictionologist or addiction psychiatrist, the physician may personally provide behavioral health treatment for the addiction.

(c) If the physician determines that the patient cannot reasonably be required to obtain professional treatment, the physician shall require the patient to actively participate in alcoholics anonymous, narcotics anonymous, other appropriate twelve step program, or similar recovery program, and to document attendance at program meetings at least three times weekly.

(d) The physician may permit a patient to substitute twelve step participation for continuing professional behavioral health treatment if a behavioral health professional who has provided at least twelve consecutive months of treatment to the patient notifies the physician in writing that, in the professional's opinion, twelve step participation will be sufficient to support a good prognosis.

(7) The physician shall not provide OBOT utilizing a product containing a controlled substance that has not been specifically approved by the United States food and drug administration for use in maintenance and detoxification treatment, notwithstanding the fact that another product containing the same narcotic has been approved for such use.

(8) The physician shall comply with all of the following:

(a) During the first eighteen months of treatment, the physician shall not prescribe, personally furnish, or administer more than a thirty day supply of OBOT medications at a time.

(b) The physician shall personally meet with and evaluate the patient at each visit during the first eighteen months of OBOT, and shall document an assessment and plan for continuing treatment.

(c) After eighteen months of OBOT, the physician shall personally meet with and evaluate the patient at least every three months, unless more frequent meetings are indicated.

(9) The physician shall not provide OBOT to a patient who the physician knows or should know is receiving other controlled substances for more than twelve consecutive weeks on an outpatient basis from any provider, without having consulted with a board certified addictionologist or addiction psychiatrist, who has recommended the patient receive OBOT.

(10) The physician shall not prescribe, personally furnish, or administer greater than 16 milligrams of buprenorphine per day to a patient, except in one of the following situations:

(a) The dosage greater than 16 milligrams was established before the effective date of this rule; or

(b) The physician has consulted with a board certified addictionologist or addiction psychiatrist, who has recommended the dosage greater than 16 milligrams.

(11) The physician shall access OARRS and document receipt and assessment of the information received at each visit and no less frequently than monthly for each patient.

(12) The physician shall provide ongoing toxicological testing at each visit and no less frequently than monthly, and shall assure that any in-office kit used is "Clinical Laboratory Improvement Amendments"

waived.

(a) Each failed screen after the first failed screen shall be confirmed by the gas chromatography/mass spectrometry ("GC/MS") method or the liquid chromatography/mass spectrometry ("LC/MS") method. A screen is failed if the result is inconsistent with the treatment plan.

(b) All urine toxicology tests shall be directly witnessed.

(13) Each physician who provides OBOT shall complete at least twelve hours of category i continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this rule shall be accepted toward meeting the physician's category i continuing medical education requirement for biennial renewal of the physician's certificate.

(C) notwithstanding the provisions of this rule, a physician may provide OBOT to a pregnant patient during the term of the pregnancy, in compliance with the minimal standards of care.

(D) A violation of any provision of this rule, as determined by the board, shall constitute "failure to maintain minimal standards applicable to the selection or administration of drugs," and "failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in division (b)(2) of section 4731.22 of the Revised Code, and " a departure from, or the failure to conform to, minimal standards of care of similar physicians under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (b)(6) of section 4731.22 of the Revised Code. A violation of paragraph (B)(7) of this rule shall further constitute "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (b)(3) of section 4731.22 of the Revised Code.