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

Sections 4730.55 and 4731.056 require the Board to adopt rules that establish standards and procedures to be followed by physicians and physician assistants in the use of all drugs approved by the FDA for use in medication-assisted treatment. The rules are required to address withdrawal management, relapse prevention, patient assessment, individual treatment planning, counseling and recovery supports, diversion control and other topics selected by the board after considering best practices in medication-assisted treatment.

Physicians:

4731-33-01	Definitions	Proposed to Amend
4731-33-02	Standards and Procedures for Withdrawal Management for Substance Use Disorder	Proposed to Amend
4731-33-03	Office-Based Treatment for Opioid Addiction	Proposed to Amend
4731-33-04	Medication-Assisted Treatment Using Naltrexone	Proposed to Amend

Physician Assistants:

4730-4-01	Definitions	Proposed to Amend
4730-4-02	Standards and Procedures for Withdrawal Management For Substance Use Disorder	Proposed to Amend
4730-4-03	Office-Based Treatment for Opioid Addiction	Proposed to Amend
4730-4-04	Medication-Assisted Treatment Using Naltrexone	Proposed to Amend

The following is a short description of the proposed rule changes.

Chapter 4731-33:

4731-33-01: This rule is proposed to be amended to update terminology, and add a definition for medications for opioid use disorder.

4731-33-02: This rule is proposed to be amended to update terminology, remove the reference to DATA 2000 waiver, align requirements for treatment initiation with FDA Risk Evaluation and Mitigation Strategy ("REMS"), provide additional options for obtaining overdose reversal drug kits, and updates the clinical practice guidelines to be followed.

4731-33-03: This rule is proposed to be amended to update terminology, modified the requirements related to behavioral health treatment, update the clinical practice guidelines to be followed, provide additional options for obtaining overdose reversal drug kits, reduce restrictions for prescribing buprenorphine mono-product, and increase the minimum daily dosage with consultation with board certified addiction specialist or addiction psychiatrist.

4731-33-04: This rule is proposed to be amended to update terminology and streamline the language.

Chapter 4730-4

4730-4-01: This rule is proposed to be amended to update terminology and add a definition for medications for opioid use disorder.

4730-4-02: This rule is proposed to be amended to update terminology, remove the reference to DATA 2000 waiver, align requirements for treatment initiation with FDA Risk Evaluation and Mitigation Strategy ("REMS"), provide additional options for obtaining overdose reversal drug kits, and updates the clinical practice guidelines to be followed.

4730-4-03: This rule is proposed to be amended to update terminology, modified the requirements related to behavioral health treatment, update the clinical practice guidelines to be followed, provide additional options for obtaining overdose reversal drug kits, reduce restrictions for prescribing buprenorphine mono-product, and increase the minimum daily dosage with consultation with board certified addiction specialist or addiction psychiatrist.

4730-4-04: This rule is proposed to be amended to update terminology and streamline the language.

4730-4-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means medication-assisted treatment, as that term is defined in this rule, in a private office or public sector clinic that is not otherwise regulated, by practitioners authorized to prescribe outpatient supplies of medications approved by the United States food and drug administration for the treatment of opioid use disorder ~~addiction or dependence, prevention of relapse of opioid addiction or dependence, or both~~. OBOT includes treatment with all controlled substance medications approved by the United States food and drug administration for such treatment. OBOT does not include treatment that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) A hospital, as defined in section 3727.01 of the Revised Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addiction services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

(B) "SAMHSA" means the United States substance abuse and mental health services administration.

(C) "Medication-assisted treatment" or "MAT" means ~~alcohol or drug addiction~~ services for the treatment of substance use disorders that include ~~are accompanied by~~ medication that has been approved by the United States food and drug administration for the treatment of substance use disorders~~, prevention of relapse of substance use disorder, or both~~.

(D) "Medications for Opioid Use Disorder or "MOUD" refers to all medications approved by the United States food and drug administration for the treatment of opioid use disorder.

(E) "Substance use disorder" indicates a problematic pattern of substance use leading to clinically significant impairment or distress ~~includes misuse, dependence, and addiction to alcohol and/or legal or illegal drugs~~, as determined by application of the diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition-Text Revision" or "DSM-5-TR."

(F) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(G) For purposes of the rules in Chapter 4730-4 of the Administrative Code:

(1) "Qualified behavioral healthcare provider" means the following healthcare providers ~~who is~~ practicing within the scope of the professional license:

(a) Board certified addiction medicine specialist ~~addictionologist~~, board certified psychiatrist, or psychiatrist, licensed under Chapter 4731. of the Revised Code;

(b) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732.of the Revised Code;

(c) Licensed independent chemical dependency counselor-clinical supervisor, licensed independent chemical dependency counselor, licensed chemical dependency counselor III, or licensed chemical dependency counselor II, or licensed chemical dependency counselor assistant licensed under Chapter 4758. of the Revised Code;

(d) Professional clinical counselor, licensed professional counselor, licensed independent social worker, licensed social worker, or marriage and family therapist, licensed under Chapter 4757. of the Revised Code;

(e) Advanced practice registered nurse, licensed as a clinical nurse specialist under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health clinical nurse specialist issued by the American nurses credentialing center;

(f) Advanced practice registered nurse, licensed as a nurse practitioner under Chapter 4723. of the Revised Code, who holds certification as a psychiatric mental health nurse practitioner issued by the American nurses credentialing center; and

~~(g) Psychologist, as defined in division (A) of section 4732.01 of the Revised Code, licensed under Chapter 4732. of the Revised Code;~~

(g) Advanced practice registered nurse, licensed under Chapter 4723. of the Revised Code, who holds subspecialty certification as a certified addiction registered nurse-advanced practice issued by the addictions nursing certification board.

(2) Nothing in this paragraph shall be construed to prohibit a physician assistant licensed under Chapter 4730. of the Revised Code who practices under a supervision agreement with a board certified addiction psychiatrist, board certified addiction medicine specialist ~~addictionologist~~, or psychiatrist who is licensed as a physician under Chapter 4731. of the Revised Code, from providing services within the normal course of practice and expertise of the supervising physician, including addiction services, other mental health services, and physician delegated prescriptive services in compliance with

Ohio and federal laws and rules.

(H) "Community addiction services provider," has the same meaning as in section 5119.01 of the Revised Code.

(I) "Community mental health services provider" has the same meaning as in section 5119.01 of the Revised Code.

(J) "Induction phase" means the phase of ~~opioid~~ medication assisted treatment during which maintenance ~~medication~~ dosage levels are adjusted until a patient attains stabilization.

(K) "~~Stabilization~~ "Maintenance phase" means the medical and psychosocial process of assisting the patient through acute intoxication and withdrawal management to the attainment of a medically stable~~, fully supported substance free~~ state free of the symptoms of substance use disorder, and ~~which~~ may include the use of medications.

(L) "Withdrawal management" ~~or "detoxification"~~ is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. ~~Detoxification denotes a clearing of toxins from the body of the patient who is acutely intoxicated and/or dependent on a substance of abuse.~~ Withdrawal management seeks to minimize the physical harm caused by the intoxication and withdrawal of a substance of abuse. Withdrawal management occurs when the patient has a substance use disorder and either evidence of the characteristic withdrawal syndrome produced by withdrawal from that substance, or evidence that supports the expectation that such a syndrome would develop without the provision of medical withdrawal ~~detoxification~~ services. Withdrawal management alone does not constitute completed substance abuse treatment or rehabilitation.

(M) "Ambulatory withdrawal management ~~detoxification~~" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by trained practitioners authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of substance use disorder ~~addiction, prevention of relapse of drug addiction, or both~~. Ambulatory withdrawal management ~~detoxification~~ is the provision of medically supervised evaluation, treatment,~~withdrawal management,~~ and referral services without extended onsite monitoring. For purpose of rule 4730-4-02 of the Administrative Code, ambulatory withdrawal management ~~detoxification~~ does not include withdrawal management that occurs in the following settings:

(1) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(2) In-patient treatment in a hospital, as defined in section 3727.01 of the Revised

Code;

(3) A provider certified to provide residential and inpatient substance use disorder services, including withdrawal management, by the Ohio department of mental health and addition services;

(4) An opioid treatment program certified by SAMHSA and accredited by an independent SAMHSA-approved accrediting body; or

(5) A youth services facility, as defined in section 103.75 of the Revised Code.

4730-4-02 **Standards and procedures for withdrawal management for substance use disorder ~~drug or alcohol addiction~~.**

(A) In order to provide ambulatory ~~detoxification~~ withdrawal management, as that term is defined in rule 4730-4-01 of the Administrative Code, a physician assistant shall comply with all of the following requirements:

(1) The physician assistant shall hold a valid prescriber number.

(2) The physician assistant shall provide withdrawal management under the supervision of a physician who provides withdrawal management as part of the physician's normal course of practice and with whom the physician assistant has a supervision agreement.

(3) The physician assistant shall comply with all state and federal laws and rules applicable to prescribing~~, including holding a DATA 2000 waiver to prescribe buprenorphine if buprenorphine is to be prescribed for withdrawal management in a medical office, public sector clinic, or urgent care facility~~.

(4) The physician assistant who practices in a healthcare facility shall comply with all policies of the healthcare facility concerning the provision of withdrawal management.

(B) Prior to providing ambulatory withdrawal management ~~detoxification~~, as that term is defined in rule 4730-4-01 of the Administrative Code, for any substance use disorder the physician assistant shall inform the patient that ambulatory withdrawal management ~~detoxification~~ alone is not complete treatment for a substance use disorder ~~abuse treatment~~. If the patient prefers continuing treatment for a substance use disorder ~~abuse treatment~~, the physician assistant shall comply with the requirements of section 3719.064 of the Revised Code, by completing all of the following actions:

(1) ~~Both orally and in writing, give t~~The patient shall be provided information about all medications ~~drugs~~ approved by the United~~.~~ States~~.~~ food and drug administration for use in medication-assisted treatment, including withdrawal management and ~~. That information was given shall be~~ documented in the patient's medical record.

(2) If the patient agrees to enter ~~opioid~~ treatment for opioid use disorder and the physician assistant determines that such treatment is clinically appropriate, the physician assistant shall refer the patient to an opioid treatment program or other facility licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who ~~provides treatment using Naltrexone or who holds the DATA 2000 waiver to~~ provides office-based treatment for opioid use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, ~~and~~ the date of the referral, and confirmation of acceptance of the referral by the program, physician, physician assistant, or advanced practice

registered nurse shall be documented in the patient record.

(C) When providing withdrawal management for opioid use disorder a physician assistant may be authorized to use a medical device that is approved by the United States food and drug administration as an aid in the reduction of opioid withdrawal symptoms.

(D) Ambulatory withdrawal management ~~detoxification~~ for opioid use disorder ~~addiction~~.

(1) The physician assistant shall provide ambulatory withdrawal management ~~detoxification~~ only when all of the following conditions are met:

(a) ~~A positive and helpful support network is available to the patient~~. The patient has adequate social, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management;

(b) The patient has a high likelihood of treatment adherence and retention in treatment~~.~~; and

(c) There is little risk of medication diversion.

(2) The physician assistant shall provide ambulatory withdrawal management ~~detoxification~~ under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-~~D~~WM or II-~~D~~WM level of care, under which services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a ~~mood-altering~~ drug, and to effectively facilitate the patient's transition into treatment and recovery. The ASAM criteria, third edition, can be obtained from the website of the American society of addiction medicine at https://www.asam.org/. A copy of the ASAM criteria may be reviewed at the medical board office, 30 East Broad street, third floor, Columbus, Ohio, during normal business hours.

(3) Prior to providing ambulatory withdrawal management ~~detoxification~~, the physician assistant shall perform an assessment of the patient. The assessment shall include a thorough medical history and physical examination sufficient to assure safety in commencing ambulatory withdrawal management. The assessment must focus on signs and symptoms associated with opioid use disorder ~~addiction~~ and include assessment with a nationally recognized scale, such as one of the following:

(a) "Objective Opioid Withdrawal Scale" (OOWS);

(b) "Clinical Opioid Withdrawal Scale" (COWS); or

(c) "Subjective Opioid Withdrawal Scale" (SOWS).

(4) Prior to providing ambulatory withdrawal management ~~detoxification~~, the physician assistant shall conduct and document a biomedical and psychosocial evaluation of the patient, to include the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance use ~~abuse~~ history;

(d) Family history and assessment of psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually transmitted diseases in patients with known risk factors.

(m) For other than toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician assistant may satisfy the assessment requirements by reviewing records from an appropriate ~~physical~~ examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit. If any part of the assessment cannot be completed prior to the initiation of treatment, the physician assistant shall document the reason in the medical record.

(5) ~~The physician assistant shall request and document review of an OARRS report on the patient.~~

(6) The physician assistant shall inform the patient about the following before the patient is undergoing withdrawal from opioids:

(a) The withdrawal management ~~detoxification~~ process and importance of ~~potential~~ subsequent treatment for substance use disorder, including information about all medications ~~drugs~~ approved by the United States food and drug administration for use in medication-assisted treatment;

(b) The risk of relapse and lethal overdose following completion of withdrawal ~~detoxification~~ without entry into continuation of medication-assisted treatment;

~~(c) The high risk of overdose and death when there is a relapse following detoxification;~~

(d) The safe storage and disposal of prescribed ~~the~~ medications.

(7) The physician assistant shall not establish standardized regimens ~~routines or schedules of increases or decreases~~ of medications for management of substance withdrawal symptomatology but shall formulate an individualized treatment plan based on the needs of the specific patient.

(8) For persons projected to be involved in withdrawal management for six months or less, the physician assistant shall offer the patient counseling as described in paragraph~~s (F) and (G)~~ (E) of rule 4730-4-03 of the Administrative Code.

(9) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for ~~demonstrate the absence of~~ use of ~~alternative~~ licit and/or illicit drugs. The physician assistant shall consider revising the treatment plan or referring a patient who has a positive ~~urine/and or~~ toxicological screening result to a higher level of care, with such consideration documented in the patient's medical record, and shall confer with the supervising physician prior to prescribing the buprenorphine/naloxone combination product to the patient.

(10) The physician assistant shall comply with the following requirements for the use of medication:

(a) The physician assistant may treat the patient's withdrawal symptoms by use of any of the following medications ~~drugs~~ as determined to be most appropriate

for the patient.

(i) A medication ~~drug~~, excluding methadone, that is specifically FDA approved for the alleviation of withdrawal symptoms

(ii) An alpha-2 adrenergic agent along with other non-narcotic medications as recommended in the American society of addiction medicine's "National Practice Guideline" (https://www.asam.org/), which is available from the medical board's website at https://med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product), unless contraindicated, in which case buprenorphine mono-product may be utilized ~~. However, buprenorphine without naloxone (buprenorphine mono-product) may be used if a buprenorphine/naloxone combination product is contraindicated~~, with the contraindication documented in the patient record

(b) The physician assistant shall not use any of the following drugs to treat the patient's withdrawal symptoms:

(i) Methadone;

(ii) Anesthetic agents

(c) The physician assistant shall comply with the following:

(i) ~~The physician assistant shall not initiate treatment with buprenorphine to manage withdrawal symptoms until between twelve and eighteen hours after the last dose of short-acting agonist such as heroin or oxycodone, and twenty-four to forty-eight hours after the last dose of long-acting agonist such as methadone.~~ Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

(ii) The physician assistant shall determine on an individualized basis the appropriate dosage of medication to ensure stabilization

during withdrawal management.

(a) The dosage level shall be that which is effective in suppressing withdrawal symptoms and is well tolerated by the patient.

(b) The dosage level shall be consistent with the ~~minimal~~ currently accepted standards of care.

(iii) In withdrawal management programs of thirty days or less duration, the physician assistant shall not prescribe nor dispense ~~allow~~ more than one week of unsupervised or take-home medications for the patient.

(11) The physician assistant shall offer the patient a prescription for an overdose reversal drug ~~naloxone~~ kit, directly provide them with a kit, or direct the patient to an easily accessible source to obtain a kit, such as http://www.naloxone.ohio.gov, a local health department or other agency or facility that provides kits.

(a) The physician assistant shall ensure that the patient, and if possible, those residing with the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(b) The physician assistant shall offer the patient a new prescription for an overdose reversal drug ~~naloxone~~ upon expiration or use of the old kit.

(c) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain a kit without a prescription.

(12) The physician assistant shall take steps to reduce the risk ~~chances~~ of medication diversion by using ~~the appropriate frequency of~~ frequent office visits, pill counts, urine drug screening, and frequent ~~weekly~~ checks of OARRS.

(E) The physician assistant who provides ambulatory withdrawal management ~~detoxification with medication management for withdrawal from~~ for benzodiazepines or other sedatives shall comply with paragraphs (A), (B), and (C) of this rule and "TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/. (Search for "TIP 45") and available on the medical board's website at: https://med.ohio.gov.

(1) The physician assistant shall provide ambulatory withdrawal management ~~detoxification with medication management~~ for benzodiazepines with medication only when a patient has sufficient social, medical, and psychiatric stability ~~positive and helpful support network is available to~~

~~the patient whose~~ when their use of benzodiazepines was mainly in therapeutic ranges and when they ~~who~~ do~~es~~ not have polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical condition or severe psychiatric disorder, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management ~~detoxification~~, the physician assistant shall perform and document an assessment of the patient that focuses on signs and symptoms associated with benzodiazepine or other sedative use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Benzodiazepines" ("CIWA-B").

(3) Prior to providing ambulatory withdrawal management ~~detoxification~~, the physician assistant shall conduct and document a biomedical and psychosocial evaluation of the patient meeting the requirements of paragraph (B)(4) of this rule.

(4) The physician assistant shall instruct the patient not to drive or operate dangerous machinery during treatment.

(5) During the ambulatory withdrawal management ~~detoxification~~, the physician assistant shall regularly assess the patient ~~during the course of treatment~~ so that dosage can be adjusted if needed.

(a) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for the ~~demonstrate the absence of~~ use of ~~alternative~~ licit and/or illicit drugs.

(b) The physician assistant shall document consideration of revising the treatment plan or referring the patient who has a positive ~~urine and/or~~ toxicology screening to a higher level of care.

(c) The physician assistant shall take steps to reduce the chances of diversion by using ~~the appropriate frequency of~~ frequent office visits, pill counts, urine drug screening, and ~~weekly~~frequent checks of OARRS.

~~(F)~~ The physician assistant who provides ambulatory withdrawal ~~detoxification with medication~~ management for ~~of~~ withdrawal from alcohol addiction shall comply with paragraphs (A), (B), and (C) of this rule and "Clinical Practice Guideline on Alcohol Withdrawal Management by the American society of addiction medicine available from the American society of addiction medicine website at the following

link:http://www.asam.org/quality-care/clinical-guidelines/alcohol-withdrawal-management-guideline ~~"TIP 45, A Treatment Improvement Protocol for Detoxification and Substance Abuse Treatment" by the substance abuse and mental health services administration available from the substance abuse and mental health services administration website at the following link: https://store.samhsa.gov/ (search for "TIP 45") and available from the medical board's website at: https://med.ohio.gov.~~

(1) The physician assistant shall provide ambulatory withdrawal ~~detoxification~~ from alcohol with medication management only when patient has sufficient social, medical, and psychiatric stability ~~a positive and helpful support network is available to the patient who does~~ and when they do not have a polysubstance dependence. The patient should exhibit no more than mild to moderate withdrawal symptoms, have no comorbid medical conditions or severe psychiatric disorders, and no past history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management ~~detoxification~~, the physician assistant shall perform and document an assessment of the patient. The assessment must focus on signs and symptoms associated with alcohol use disorder and include assessment with a nationally recognized scale, such as the "Clinical Institute Withdrawal Assessment for Alcohol-revised" ("CIWA-AR").

(3) Prior to providing ambulatory withdrawal management ~~detoxification~~, the physician assistant shall perform and document a biomedical and psychosocial evaluation meeting the requirements of paragraph (D)(4) of this rule.

(4) During the course of ambulatory withdrawal management ~~detoxification~~, the physician assistant shall regularly assess the patient ~~regularly~~ so that the dosage can be adjusted if needed:

~~(a) The physician assistant shall adjust the dosage as medically appropriate;~~

(a) The physician assistant shall require the patient to undergo ~~urine and/or other~~ toxicological screenings in order to assess for the presence of alcohol metabolites, licit or ~~demonstrate the absence of~~ illicit drugs;

(b) The physician assistant shall document the consideration of revising the treatment plan or referring a patient who has a positive ~~urine and/or~~ toxicological screening test to a higher level of care; and

(c) The physician assistant shall take steps to reduce the risk of diversion by using frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(5) If the patient agrees to enter alcohol treatment and the physician assistant determines that such treatment is clinically appropriate, the physician

assistant shall refer the patient to an alcohol treatment program licensed or certified by the Ohio department of mental health and addiction services to provide such treatment or to a physician, physician assistant, or advanced practice registered nurse who provides treatment using any FDA approved forms of medication assisted treatment for alcohol use disorder. The name of the program, physician, physician assistant, or advanced practice registered nurse to whom the patient was referred, and the date of the referral shall be documented in the patient record.

(6) ~~The physician assistant shall instruct the patient not to drive or operate dangerous machinery during treatment.~~

4730-4-03 **Office-based treatment for opioid addiction.**

(A) A physician assistant who provides OBOT shall comply with the following requirements:

(1) Before initiating OBOT, the physician assistant shall comply with section 3719.064 of the Revised Code.

(2) Comply with all federal and state laws and regulations governing the prescribing of the medication;

(3) Complete at least eight hours of "Category 1" continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the continuing medical education requirement for biennial renewal of the physician assistant's license; and

(4) Only provide OBOT if the provision of OBOT is within the supervising physician's normal course of practice and expertise.

(B) The physician assistant who provides OBOT shall perform and document an assessment of the patient.

(1) The assessment shall include all of the following:

(a) A comprehensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance use disorder ~~abuse~~ history;

(d) Family history and psychosocial supports;

(e) Appropriate physical examination;

(f) Urine drug screen or oral fluid drug testing;

(g) Pregnancy test for women of childbearing age and ability;

(h) Review of the patient's prescription information in OARRS;

(i) Testing for human immunodeficiency virus;

(j) Testing for hepatitis B;

(k) Testing for hepatitis C; and

(l) Consideration of screening for tuberculosis and sexually-transmitted diseases in patients with known risk factors.

(2) For other than the toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and the pregnancy test, the physician assistant may satisfy the assessment requirements by reviewing records from an appropriate ~~physical~~ examination and laboratory testing of the patient that was conducted within a reasonable period of time prior to the visit.

(3) If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician assistant shall document the reasons in the medical record and complete as soon as possible following initiation of treatment.

(C) The physician assistant who provides OBOT shall establish and document a treatment plan that includes all of the following:

(1) The physician assistant's rationale for selection of the specific drug to be used in the medication-assisted treatment based upon discussion of all MOUDs and non-medication options with the patient;

(2) Patient education;

(3) The patient's written, informed consent;

(4) Random urine-drug screens;

(5) A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant; ~~and~~

(6) Documentation regarding ~~A plan for~~ psychosocial intervention ~~treatment~~, pursuant to paragraph (E) of this rule~~.~~; and

(7) The treatment plan shall be revised if the patient does not show improvement with the original plan.

(D) The physician assistant shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

(1) TIP 63 "Medications for Opioid Use Disorder" (2021) available from the ~~SAMHSA treatment improvement protocol publications for medication assisted treatment available from the~~ SAMHSA website at: ~~https://store.samhsa.gov/~~ https://www.samhsa.gov/resource/epb/tip-63-medications-opioid-use-disorder.

(2) ~~"National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use,"~~ "ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update", approved by the American society of addiction medicine in 2015, available from the website of the American society of addiction medicine at: https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline.

~~(E) The physician assistant shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as those terms are defined in rule 4730-4-01 of the Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.~~

~~(1) The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.~~

~~(2) The treatment shall include at least one of the following interventions, unless reasons for exception are documented in the patient record:~~

~~(a) Cognitive behavioral treatment;~~

~~(b) Community reinforcement approach;~~

~~(c) Contingency management/motivational incentives;~~

~~(d) Motivational interviewing; or~~

~~(e) Behavioral couples counseling.~~

~~(3) The treatment plan shall include a structure for revision of the treatment plan if the patient does not adhere to the original plan.~~

~~(4) When clinically appropriate or if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as defined in rule 4730-4-01 of the Administrative Code, the physician assistant shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program. If~~

~~the patient is required to participate in a twelve step program, the physician assistant shall require the patient to provide documentation of on-going participation in the program.~~

~~(5) If the physician assistant refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health services provider, the physician assistant shall document the referral and the physician assistant's maintenance of meaningful interactions with the provider in the patient record.~~

(E) The physician assistant shall do the following with respect to psychosocial treatment for patients receiving OBOT:

(1) Assess for psychosocial treatment needs in addition to medication;

(2) Offer psychosocial interventions or referrals for psychosocial interventions to all patients, but OBOT should not be declined or discontinued if the patient is unable or unwilling to engage in psychosocial interventions;

(3) Ensure that psychosocial interventions are person-centered and tailored to the patient's insight, motivation, and stage of recovery;

(4) Focus the psychosocial interventions on retaining the patient in treatment, stabilizing the patient and assisting with progress in the patient's treatment and recovery;

(5) If the psychosocial interventions are not available or if the patient declines to participate, the physician assistant shall continue to treat the patient with OBOT provided that the patient adheres to all other treatment requirements;

(6) Psychosocial treatment or intervention includes the following:

(a) Cognitive behavioral treatment;
(b) Community reinforcement approach;
(c) Contingency management and motivational incentives;
(d) Motivational interviewing;
(e) Behavioral couples counseling;
(f) Twelve-step facilitation; and
(g) Other therapies based on the patient's individual needs;

(7) When necessary, the physician assistant may make referrals for psychosocial treatment to qualified behavioral healthcare providers, community addiction services or community mental health services providers as defined in rule 4730-4-01 of the Administrative Code; and

(8) The physician assistant may also refer patients for treatment with non-licensed paraprofessionals such as case managers and peer support specialists if the physician assistant determines such intervention would benefit the patient.

(F) The physician assistant who provides OBOT shall offer the patient a prescription for an overdose reversal drug ~~naloxone~~ kit, directly provide the patient with a kit, or direct the patient to an easily accessible source to obtain a kit, such as http://www.naloxone.ohio.gov, a local health department, or other agency or facility that provides kits.

(1) The physician assistant shall ensure that the patient, and if possible, those residing with the patient, receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

(2) The physician assistant shall offer the patient a new prescription for an overdose reversal drug ~~naloxone~~ upon expiration or use of the old kit.

(3) The physician assistant shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician assistant shall provide the patient with information on where to obtain a kit without a prescription.

(G) In addition to paragraphs (A) to (F) of this rule, the physician assistant who provides OBOT using buprenorphine products shall comply with all of the following requirements:

(1) ~~The provision shall be in compliance with the United States food and drug administration approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.~~ Treatment with a buprenorphine product must be in compliance with the United States food and drug administration approved “Risk Evaluation and Mitigation Strategy” for buprenorphine products, which can be found on the United States food and drug administration website at the following address: https://www,accessdata.fda.gov/scripts/cder/rems/index.cfm. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician assistant who treats opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician assistant may ~~shall~~ prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the evidence for the decision to use buprenorphine mono-product in the medical record:

(a) When a patient is pregnant or breast-feeding;

(b) When converting a patient from buprenorphine mono-product to buprenorphine/naloxone combination product;

(c) In formulations other than tablet or film form for indications approved by the United States food and drug administration;

(d) For withdrawal management when a buprenorphine/naloxone combination product is contraindicated, with the contraindication included in the patient record; or

(e) When the patient has ~~a~~an genuine allergy to or intolerance of a buprenorphine/naloxone combination product~~, after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and with documentation included in the patient record~~.

(3) Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, gabapentin, or tramadol, the physician assistant shall only co-prescribe these substances when it is medically necessary.

(a) The physician assistant shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including whether acceptable alternative treatments are available and whether it is possible to lower the dose or discontinue ~~taper~~ the drug ~~to discontinuation~~. If the physician assistant prescribing buprenorphine is the prescriber of the other drug, the physician assistant shall also consider these options and consider consultation for another healthcare provider ~~taper the other drug to discontinuation, if it is safe to do so~~. The physician assistant shall educate the patient about the serious risks of the combined use.

(b) The physician assistant shall document the rationale for discontinuing, lowering, or continuing the medication given potential risks and benefits ~~progress with achieving the tapering plan~~.

(4) During the induction phase the physician assistant shall not prescribe a dosage that exceeds the recommendation in the United States food and drug administration approved labeling, except for medically indicated circumstances as documented in the medical record. The physician assistant shall see the patient at least once a week during this phase.

(5) During the maintenance ~~stabilization~~ phase, ~~when using any oral formulation of buprenorphine,~~ the physician assistant shall increase the daily dosage of buprenorphine in safe and effective increments to achieve an adequate ~~the lowest~~ dose that avoids intoxication or sedation, prevents withdrawal, and suppresses ~~or~~ significant drug craving.

(a) During the first ninety days of treatment, the physician assistant shall prescribe no more than a two-week supply of buprenorphine product ~~containing naloxone~~, unless utilizing a formulation with duration of action exceeding two weeks, such as injections or implants.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician assistant shall prescribe no more than a thirty-day supply of the buprenorphine product ~~containing naloxone~~ unless utilizing a formulation with duration of action exceeding thirty days, such as injections or implants.

(6) The physician assistant shall ~~take steps to~~ reduce the risk ~~chances~~ of buprenorphine diversion by using the lowest effective dose, scheduling appropriate frequency of office visits, having random pill counts, and checking ~~checks of~~ OARRS. The physician assistant shall also require urine drug testing ~~screens~~, serum medication levels, or oral fluid drug testing at least twice per quarter for the first year of treatment and at least once per quarter thereafter.

(7) When using any oral formulation of buprenorphine, the physician assistant shall document in the medical record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the physician assistant obtains a consultation from a board certified addiction specialist or addiction psychiatrist recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day.

(8) The physician assistant shall incorporate relapse prevention strategies into the counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(9) The physician assistant may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

(a) The physician assistant shall strictly comply with any required risk evaluation and mitigation strategy for the drug.

(b) The physician assistant shall prescribe an extended-release buprenorphine product strictly in accordance with the United States food and drug

administration's approved labeling for the drug's use.

(c) The physician assistant shall document in the patient record the rationale for the use of the extended-release buprenorphine product.

(d) The physician assistant who orders or prescribes an extended release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care provider acting in accordance with the scope of their professional license.

4730-4-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements in paragraphs (A) to (F) of rule 4730-4-03 of the Administrative Code, the physician assistant using naltrexone to treat opioid use disorder shall comply with all of the following requirements:

~~(1) Prior to treating a patient with naltrexone, the physician assistant shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician assistant shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.~~ Before initiating naltrexone, the physician assistant shall take measures to ensure that the patient is opioid abstinent for an adequate period of time after completing opioid withdrawal to avoid precipitated withdrawal. The physician assistant shall alert the patient of the risk of potentially lethal opioid overdose if they stop naltrexone and use opioids.

(2) The physician assistant shall use oral naltrexone only for treatment of patients who can be closely supervised and who are highly motivated.

(a) The dosage regime shall strictly comply with the United States food and drug administration approved labeling for naltrexone hydrochloride tablets.

(b) The patient shall be encouraged to have a support person administer and supervise the medication. Examples of a support person are a family member, close friend, or employer.

(c) The physician assistant shall require urine drug screens, serum medication levels, or oral fluid drug testing at least every three months for the first year of treatment and at least every six months thereafter.

(d) The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

(B) The physician assistant may treat a patient with extended-release naltrexone for opioid dependence or for co-occurring opioid and alcohol use disorders.

(1) The physician assistant should consider treatment with extended-release naltrexone for patients who have difficulties ~~issues~~ with treatment adherence.

(2) The injection dosage shall strictly comply with the United States food and drug administration approved labeling for extended-release naltrexone.

(3) The physician assistant shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4730-4-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.