State Medical Board of Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
www.med.ohio.gov

Rules & Policies Agenda for Board Meeting
October 9, 2024

A. Rule Review Update

B. Office-Based Opioid Treatment Rules

State Medical Board of Ohio

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Columbus, Ohio 43215
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MEMORANDUM

TO: Jonathan Feibel, M.D., President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Update

DATE: September 17, 2024

Attached please find the rule spreadsheet and rule schedule for October 2024.

Requested Action: No action requested.

Legal Dept. Rules Schedule

As of September 17, 2024

Rules Filed with JCARR-Ready for Final Adoption

Office-Based Opioid Treatment Rules

Chapter 4730-4

Chapter 4731-33

Rules Proposed for Approval to File with CSI

Dietetics Rules

4759-2-01
4759-4-01
4759-4-02
4759-4-03
4759-4-04
4759-4-08
4759-4-09
4759-5-01
4759-5-02
4759-5-03
4759-5-04
4759-5-05
4759-5-06
4759-6-01
4759-6-02
4759-6-03
4759-9-01

Rules Approved to File with CSI:

Notice of Meetings

4731-7-01

Recordation of Meetings

4731-9-01

Termination of Physician-Patient Relationship

4731-27-01

4731-27-02

4731-27-03

Return of Athlete to Practice of Competition

4731-31-01

Standards for Prescribing Dangerous Drugs for Administration By Injection by a Pharmacist

4731-34-01

Physician Assistant Rules

4730-1-06
4730-2-04
4731-2-05
4731-2-10

Anesthesiologist Assistant Rules

4731-24-01

4731-24-02

4731-24-03

Genetic Counselor Rules

4778-1-01
4778-1-02
4778-1-03
4778-1-05
4778-1-06

Rules Approved for Initial Circulation:

Respiratory Care Rules (Chapter 4761)

Criminal Records Checks

4731-4-01

4731-4-02

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4730-1-01	Regulation of Physician Assistants - Definitions		06/12/19	07/16/19	11/07/19	06/18/20	No change rule			09/16/20	06/18/25	
4730-1-05	Quality Assurance System		06/12/19	07/16/19	11/07/19	06/19/20	No change rule			09/17/20	06/19/25	
4730-1-06	Licensure as a physician assistant	04/01/24									03/28/24	Extension given for Review Date
4730-1-07	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	02/28/28	
4730-2-01	Physician Delegated Prescriptive Authority - Definitions		06/12/19	07/16/19	11/07/19	06/18/20	No change rule	01/30/23	02/08/23	02/28/23	02/28/28	
4730-2-04	Period of on-site supervision of physician-delegated prescriptive authority	04/01/24									11/15/23	
4730-2-05	Addition of valid prescriber number after initial licensure	04/01/24									09/30/23	
4730-2-07	Standards for Prescribing	02/12/22	05/11/22	05/16/22	09/22/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4730-2-10	Standards and Procedures for use of OARRS	04/01/24									03/28/24	Extension given for Review Date
4730-4-01	Definitions	09/15/23	03/13/24	04/04/24	07/15/24	07/25/24	08/29/24	09/09/24			04/30/24	
4730-4-02	Standards and procedures for withdrawal management for drug or alcohol addition	09/15/23	03/13/24	04/04/24	07/15/24	07/25/24	08/29/24	09/09/24			10/31/25	
4730-4-03	Office Based Treatment for Opioid addiction	09/15/23	03/13/24	04/04/24	07/15/24	07/25/24	08/29/24	09/09/24			04/30/24	
4730-4-04	Medication assisted treatment using naltrexone	09/15/23	03/13/24	04/04/24	07/15/24	07/25/24	08/29/24	09/09/24			04/30/24	
4731-1-01	Limited Practitioners - Definition of Terms	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-1-02	Application of Rules Governing Limited Branches of Medicine or Surgery	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	07/31/24	
4731-1-03	General Prohibitions	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-1-04	Scope of Practice: Mechanotherapy	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-1-05	Scope of Practice: Massage Therapy	06/17/21		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	11/05/24	
4731-1-06	Scope of Practice: Naprapathy									08/31/18	08/31/23	
4731-1-07	*Eligibility of Electrologists Licensed by the Ohio State Board of Cosmetology to Obtain Licensure as Cosmetic Therapists Pursuant to Chapter 4731 ORC and Subsequent Limitations*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-1-08	*Continuing Cosmetic Therapy Education Requirements for Registration or Reinstatement of a License to Practice Cosmetic Therapy*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-09	*Cosmetic Therapy Curriculum Requirements*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-10	*Distance Education*	*06/17/21*		09/22/22	*10/31/22*	*11/29/22*	*01/04/23*	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-11	*Application and Certification for certificate to practice cosmetic therapy*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-12	*Examination*			09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*	*02/28/28*	
4731-1-15	*Determination of Standing of School, College or Institution*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-16	*Massage Therapy curriculum rule (Five year review)*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-17	*Instructional Staff*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1-18	*Grounds for Suspension, Revocation or Denial of Certificate of Good Standing, Hearing Rights*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-1- 19	*Probationary Status of a limited branch school*	*06/17/21*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-2-01	Public Notice of Rules Procedure	05/15/22			10/31/22	09/28/22				09/28/22	09/28/27	
4731-4-01	Criminal Records Checks - Definitions	03/04/24	04/10/24							09/30/19	09/30/24	
4731-4-02	Criminal Records Checks	03/04/24	04/10/24							09/30/19	09/30/24	
4731-5-01	*Admission to Examinations*	*05/15/22*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-5-02	*Examination Failure; Inspection and Regrading*	*05/15/22*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-5-03	*Conduct During Examinations*	*05/15/22*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-5-04	*Termination of Examinations*	*05/15/22*		09/22/22	*10/31/22*	11/29/22	01/04/23	*01/30/23*	*02/08/23*	*02/28/23*		*Rescinded*
4731-6-01	Medical or Osteopathic Licensure: Definitions				10/31/22					07/31/19	07/31/24	
4731-6-02	Preliminary Education for Medical and Osteopathic Licensure				10/31/22					07/31/19	07/31/24	
4731-6-04	Demonstration of proficiency in spoken English	05/15/22		09/22/22	10/31/22	11/14/22			no change	11/14/22	11/14/27	
4731-6-05	Format of Medical and Osteopathic Examination		09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	01/31/27	
4731-6-14	Examination for physician licensure	09/03/20								07/31/19	07/31/24	
4731-6-15	Eligibility for Licensure of National Board Diplomats and Medical Council of Canada Licentiates									07/31/19	07/31/24	
4731-6-21	Application Procedures for Certificate Issuance; Investigation; Notice of Hearing Rights									07/31/19	07/31/24	

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4731-6-22	Abandonment and Withdrawal of Medical and Osteopathic Licensure Applications									07/31/19	07/31/24	
4731-6-30	Training Certificates									07/31/19	07/31/24	
4731-6-31	Limited Preexamination Registration and Limited Certification									07/31/19	07/31/24	
4731-6-33	Special Activity Certificates									07/31/19	07/31/24	
4731-6-34	Volunteer's Certificates									07/31/19	07/31/24	
4731-7-01	Method of Notice of Meetings	03/04/24	04/10/24							07/31/19	07/31/24	
4731-8-01	Personal Information Systems	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26	
4731-8-02	Definitions	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26	
4731-8-03	Procedures for accessing confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26	
4731-8-04	Valid reasons for accessing confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-8-05	Confidentiality Statutes	04/29/20		10/05/20	11/18/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-8-06	Restricting & Logging access to confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26	
4731-9-01	Record of Board Meetings; Recording, Filming, and Photographing of Meetings	03/04/24	04/10/24							09/15/19	06/17/24	
4731-10-01	Definitions	10/25/19		05/26/20		Revised filing 11/3/20 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26	
4731-10-02	Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement	10/25/19		05/26/20		Revised filing 11/3/20 10/30/20	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-10-03	CME Waiver	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26	
4731-10-04	Continuing Medical Education Requirements for Restoration of a License	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26	

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4371-10-08	Evidence of Continuing Medical Education	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-11-01	Controlled substances; General Provisions Definitions	02/12/22								10/31/20	10/31/25	
4731-11-02	Controlled Substances - General Provisions	07/26/19	11/13/19	10/05/20		05/27/21			no change		05/27/26	
4731-11-03	Schedule II Controlled Substance Stimulants			09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-11-04	Controlled Substances: Utilization for Weight Reduction			09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-11-04.1	Controlled substances: Utilization for chronic weight management			09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	Recinded	Rescinded
4731-11-07	Research Utilizing Controlled Substances	07/26/19	11/13/19	10/05/20		05/27/21			no change		05/27/26	
4731-11-08	Utilizing Controlled Substances for Self and Family Members	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26	
4731-11-09	Controlled Substance and telehealth prescribing	02/12/22	05/11/22	05/16/22	09/22/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-11-11	Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).	07/26/19	11/13/19	10/05/20		05/27/21	06/28/21		09/08/21	09/30/21	09/30/26	
4731-11-13	Prescribing of Opioid Analgesics for Acute Pain									08/31/17	08/31/22	
4731-11-14	Prescribing for subacute and chronic pain	11/18/22				04/17/23	05/24/23	06/01/23			12/23/23	
4731-12-01	Preliminary Education for Licensure in Podiatric Medicine and Surgery	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-12-02	Standing of Colleges of Podiatric Surgery and Medicine	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/02/23	02/28/28	
4731-12-03	Eligibility for the Examination in Podiatric Surgery and Medicine	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-12-04	Eligibility of Licensure in Podiatric Medicine and Surgery by Endorsement from Another State	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23		Rescinded
4731-12-05	Application Procedures for Licensure in Podiatric Medicine and Surgery, Investigation, Notice of Hearing Rights.	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-12-06	Visiting Podiatric Faculty Certificates	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23		Rescinded
4731-12-07	Podiatric Training Certificates	04/18/22		09/22/22	10/31/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-13-01	Conduct of Hearings - Representative; Appearances	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	

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4731-13-02	Filing Request for Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	No change				04/12/26	
4731-13-03	Authority and Duties of Hearing Examiners	08/26/20	10/14/20	amended filing 1/6/21 10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-04	Consolidation	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-05	Intervention	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-06	Continuance of Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-07	Motions	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-07.1	Form and page limitations for briefs and memoranda	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-08	Filing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-09	Service	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-10	Computation and Extension of Time	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-11	Notice of Hearings	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-12	Transcripts	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-13	Subpoenas for Purposes of Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-14	Mileage Reimbursement and Witness Fees	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-15	Reports and Recommendations	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-16	Reinstatement or Restoration of Certificate	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-17	Settlements, Dismissals, and Voluntary Surrenders	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-18	Exchange of Documents and Witness Lists	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-20	Depositions in Lieu of Live Testimony and Transcripts in place of Prior Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-20.1	Electronic Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-21	Prior Action by the State Medical Board	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-22	Stipulation of Facts	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-23	Witnesses	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-24	Conviction of a Crime	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	

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4731-13-25	Evidence	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-26	Broadcasting and Photographing Administrative Hearings	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-27	Sexual Misconduct Evidence	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-28	Supervision of Hearing Examiners	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-30	Prehearing Conference	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-31	Transcripts of Prior Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-32	Prior Statements of the Respondent	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-33	Physician's Desk Physician	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-13-34	Ex Parte Communication	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-35	Severability	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26	
4731-13-36	Disciplinary Actions	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26	
4731-14-01	Pronouncement of Death	01/25/21	03/10/21	03/18/21		05/27/21	06/28/21		09/08/21	09/30/21	09/30/26	
4731-15-01	Licensee Reporting Requirement; Exceptions	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-15-02	Healthcare Facility Reporting Requirement	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/12	11/30/23	11/30/28	
4731-15-03	Malpractice Reporting Requirement	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-15-04	Professional Society Reporting	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-15-05	Liability; Reporting Forms; Confidentially and Disclosure	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-01	Rules governing impaired physicians and approval of treatments programs - Definitions	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-02	General Procedures in Impairment Cases	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-04	Other Violations	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-05	Examinations	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-06	Consent Agreements and Orders for Reinstatement of Impaired Practitioners	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-07	Treatment Provider Program Obligations	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-08	Criteria for Approval	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-09	Procedures for Approval	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-10	Aftercare Contracts	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	

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4731-16-11	Revocation, Suspension, or Denial of Certificate of Good Standing	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-12	Out-of-State Impairment Cases	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-13	Patient Consent; Revocation of Consent	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-14	Caffeine, Nicotine, and Over-The Counter Drugs	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-15	Patient Rights	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-17	Requirements for the one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-18	Eligibility for the one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-16-19	Monitoring organization for one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-20	Treatment providers in the one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4731-16-21	Continuing care for the one-bite program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/24	Rescinded	
4731-17-01	Exposure-Prone Invasive Procedure Precautions - Definitions	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-17-02	Universal Precautions	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26	
4731-17-03	Hand Washing	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26	
4731-17-04	Disinfection and Sterilization	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-17-05	Handling and Disposal of Sharps and Wastes	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-17-06	Barrier Techniques	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26	
4731-17-07	Violations	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-18-01	Definitions			09/22/22	12/22/22	03/06/23	02/10/23	03/06/23	04/12/23	04/30/23	04/30/28	
4731-18-02	Use of Light Based Medical Devices			09/22/22	12/22/22	03/06/23	02/10/23	03/06/23	04/12/23	04/30/23	04/30/28	
4731-18-03	Delegation of the Use of Light Based Medical Devices			09/22/22	12/22/22	03/06/23	02/10/23	03/06/23	04/12/23	04/30/23	04/30/28	
4731-18-04	Delegation of phototherapy and photodynamic therapy	01/10/18	01/20/20	05/12/20	04/05/21	04/09/21	refiled 6-9-21 5/17/2021	06/25/21	07/14/21	07/31/21	07/31/26	
4731-20-01	Surgery Privileges of Podiatrist - Definition of Foot	10/16/23	11/08/23	11/09/23		01/23/24		04/15/24			01/23/29	
4731-20-02	Surgery: Ankle Joint	10/16/23	11/08/23	11/09/23		01/23/24		04/15/24			01/23/29	
4731-22-01	Retired License Status	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	02/29/24	02/28/29	
4731-22-02	Application	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-22-03	Status of Registrant	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		

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4731-22-04	Continuing Education Requirements	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-22-06	Renewal of Cycle of Fees	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-22-07	Change to Active Status	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-22-08	Cancellation of or Refusal to Issue an Emeritus Registration	09/15/23	10/11/23	11/02/23	11/27/23	11/28/23	01/04/24	01/08/24	02/14/24	rescinded		
4731-23-01	Delegation of Medical Tasks - Definitions	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26	
4731-23-02	Delegation of Medical Tasks	01/25/21	03/10/21	03/18/21	04/23/21	refiled 7/14/21 5/27/2021	06/28/21		09/08/21	09/30/21	09/30/26	
4731-23-03	Delegation of Medical Tasks: Prohibitions	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26	
4731-23-04	Violations	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26	
4731-24-01	Anesthesiologist Assistants - Definitions	04/01/24									07/31/24	
4731-24-02	Anesthesiologist Assistants; Supervision	04/01/24									07/31/24	
4731-24-03	Anesthesiologist Assistants; Enhanced Supervision	04/01/24									07/31/24	
4731-25-01	Office-Based Surgery - Definition of Terms	06/16/23									03/01/23	
4731-25-02	General Provisions	06/16/23	01/10/24	01/19/24	02/15/24	02/16/24	03/27/24	04/15/24		05/18/24	05/18/29	
4731-25-03	Standards for Surgery Using Moderate Sedation/Analgesia	06/16/23								05/31/18	08/31/23	
4731-25-04	Standards for Surgery Using Anesthesia Services	06/16/23								05/31/18	05/31/23	
4731-25-05	Liposuction in the Office Setting	06/16/23								03/01/18	03/01/23	
4731-25-07	Accreditation of Office Settings	06/16/23								05/31/18	05/31/23	
4731-25-08	Standards for Surgery	06/16/23								09/30/19	09/30/24	
4731-26-01	Sexual Misconduct - Definitions	01/25/21	03/10/21	03/18/21	04/23/21	refiled 7/14/21 5/27/2021	06/28/21		09/08/21	09/30/21	09/30/26	
4731-26-02	Prohibitions	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21	06/28/21		09/08/21	09/30/21	09/30/26	
4731-26-03	Violations; Miscellaneous	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21	06/28/21		09/08/21	09/30/21	09/30/26	
4731-27-01	Definitions	03/04/24								02/04/19	02/02/24	
4731-27-02	Dismissing a patient from the medical practice	03/04/24								05/31/19	05/31/24	
4731-27-03	Notice of termination of physician employment or physician leaving a practice, selling a practice, or retiring from the practice of medicine	03/04/24								05/31/19	05/31/24	see comments for future folder

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4731-28-01	Mental or Physical Impairment	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-28-02	Eligibility for confidential monitoring program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-28-03	Participation in the confidential monitoring program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-28-04	Disqualification from continued participation in the confidential monitoring program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-28-05	Termination of the participation agreement for the confidential monitoring program	07/28/23	08/09/23	08/11/23	08/31/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	Rescinded	
4731-29-01	Standards and procedures for operation of a pain management clinic.									06/30/17	06/30/22	
4731-30-01	Internal Management Definitions									09/23/18	09/23/23	
4731-30-02	Internal Management Board Metrics	07/26/19								09/23/18	09/23/23	
4731-30-03	Approval of Licensure Applications	08/28/23							10/11/23	10/31/23	10/17/24	
4731-30-04	Maintenance of List of Disqualifying Criminal Offenses	08/13/21				refiled 11-4-21			09/08/21	12/31/21	12/31/26	
4731-31-01	Requirements for assessing and granting clearance for return to practice or competition. (concussion rule)	03/04/24	04/10/24							11/30/19	11/30/24	
4731-32-01	Definition of Terms	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	01/04/24	01/08/24	02/14/24	02/29/24	02/28/29	
4731-32-02	Certificate to Recommend Medical Marijuana	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	01/04/24	01/08/24	02/14/24	02/29/24	02/28/29	
4731-32-03	Standard of Care	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	01/04/24	01/08/24	02/14/24	02/29/24	02/28/29	
4731-32-04	Suspension and Revocation of Certificate to Recommend	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	No change rule	01/08/24	N/A	02/27/24	11/28/28	
4731-32-05	Petition to Request Additional Qualifying Condtion or Disease	02/09/23	03/08/23	03/30/23	08/31/23	11/28/23	No change rule	01/08/24	N/A	02/27/24	11/28/28	
4731-33-01	Definitions	09/15/23	03/13/24	04/04/24	07/15/24	07/25/24	08/29/24	09/09/24			04/30/24	
4731-33-02	Standards and procedures for withdrawal managment for drug or alcohol addiction	09/15/23	03/13/24	04/04/24	07/15/24	07/25/24	08/29/24	09/09/24			10/31/25	
4731-33-03	Office-Based Treatment for Opioid Addiction	09/15/23	03/13/24	04/04/24	07/15/24	07/25/24	08/29/24	09/09/24			04/30/24	
4731-33-04	Medication Assisted Treatment Using Naltrexone	09/15/23	03/13/24	04/04/24	07/15/24	07/25/24	08/29/24	09/09/24			04/30/24	

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4731-34-01	Standards and Procedures to be followed by physicians when prescribing a dangerous drug that may be administered by a pharmacist by injection.	03/04/24	04/10/24							07/31/19	07/31/24	
4731-35-01	Consult Agreements	01/25/21	04/14/21	04/26/21	06/04/21	09/22/21	10/29/21	11/08/21	12/08/21	12/31/21	10/31/25	
4731-35-02	Standards for managing drug therapy	01/25/21	04/14/21	04/26/21	06/04/21	09/22/21	10/29/21	11/08/21	12/08/21	12/31/21	10/31/25	
4731-36-01	Military provisions related to education and experience requirements for licensure	06/17/21	09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	10/29/21	and 1/31/27
4731-36-02	Military provisions related to renewal of license and continuing education	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25	
4731-36-03	Processing applications from service members, veterans, or spouses of service members or veterans.	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25	
4731-36-04	Temporary license for military spouse	02/11/20	02/12/20	02/14/20		02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4731-37-01	Telehealth	02/12/22	05/11/22	05/16/22	09/22/22	11/29/22	01/04/23	01/30/23	02/08/23	02/28/23	02/28/28	
4731-38-01	Licenses Issued or Renewed Under the Interstate Medical Licensure Compact	11/12/21	01/12/22	01/14/22	02/14/22	02/18/22	03/25/22		05/11/22	05/31/22	05/31/27	
4731-38-02	Issuance of Licenses to Out-of-State Licensees or Certificate Holders	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4759-2-01	Definitions	03/04/24								11/30/19	11/30/24	
4759-4-01	Applications	03/04/24								11/30/19	11/30/24	
4759-4-02	Preprofessional experience	03/04/24									08/28/24	
4759-4-03	Examination	03/04/24								11/30/19	11/30/24	
4759-4-04	Continuing Education	03/04/24								07/31/21	07/31/26	
4759-4-08	Limited permit	03/04/24								07/31/21	07/31/26	
4759-4-09	License certificates and permits	03/04/24								11/30/19	11/30/24	
4759-5-01	Supervision of persons claiming exemption	03/04/24								08/28/19	08/28/24	
4759-5-02	Student practice exemption	03/04/24								11/30/19	11/30/24	
4759-5-03	Plan of treatment exemption	03/04/24								11/30/19	11/30/24	
4759-5-04	Additional nutritional activities exemption	03/04/24									07/01/24	
4759-5-05	Distribution of literature exemption	03/04/24									07/01/24	
4759-5-06	Weight control program exemption	03/04/24									07/01/24	
4759-6-01	Standards of practice innutrition care	03/04/24								11/30/19	11/30/24	
4759-6-02	Standards of professional performance	03/04/24								07/31/21	07/31/26	
4759-6-03	Interpretation of standards	03/04/24								11/30/19	11/30/24	
4759-9-01	Severability	03/04/24								11/30/19	11/30/24	
4759-11-01	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	*11/08/23*	11/30/23	11/30/28	
4761-2-03	Board Records									02/28/19	02/28/24	
4761-3-01	Definition of terms									02/28/19	02/28/24	
4761-4-01	Approval of educational programs									02/28/19	02/28/24	

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4761-4-02	Monitoring of Ohio respiratory care educational programs									02/28/19	02/28/24	
4761-5-01	Waiver of licensing requirements pursuant to division (B) of section 4761.04 or the Revised Code	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-5-02	Admission to the Ohio credentialing examination	04/23/19	06/12/19	11/06/19	01/10/20	06/19/20	No change rule			09/19/20	06/19/25	
4761-5-04	License application procedure	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-5-06	Respiratory care practice by polysomnographic technologists	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	No change rule			09/18/20	06/18/25	
4761-6-01	Limited permit application procedure	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	02/28/24	
4761-7-01	Original license or permit, identification card or electronic license verification									02/28/19	02/28/24	
4761-7-03	Scope of respiratory care defined										11/15/23	
4761-7-04	Supervision			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-7-05	Administration of medicines										11/15/23	
4761-8-01	Renewal of license or permits	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25	
4761-9-01	Defnition of respiratory care continuing education			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	02/28/24	
4761-9-02	General RCCE requirements and reporting mechanism	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25	
4761-9-03	Activities which do not meet the Ohio RCCE requirements									02/28/19	02/28/24	
4761-9-04	Ohio respiratory care law and professional ethics course criteria			11/06/19	01/10/20	Refiled 8/24/20 6/18/2020	9/24/20 7/23/2020	08/17/20	11/10/20		02/28/24	Look at adding OOA as an approving organization
4761-9-05	Approved sources of RCCE			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	02/28/24	Look at adding OOA as an approving organization
4761-9-07	Auditing for compliance with RCCE requirements			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-10-01	Ethical and professional conduct									02/28/19	02/28/24	
4761-10-02	Proper use of credentials										11/15/23	
4761-10-03	Providing information to the Board	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25	
4761-15-01	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4774-1-01	Definitions	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21			no change	02/11/21	02/11/26	
4774-1-02	Application for Certificate to Practice	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4774-1-03	Renewal of Certificate to Practice	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26	
4774-1-04	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	
4778-1-01	Definition	04/01/24									01/24/24	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recom-mendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4778-1-02	Application	04/01/24									04/30/24	
4778-1-03	Special Activity License	04/01/24									01/24/24	
4778-1-05	Collaboration Agreement	04/01/24									04/30/24	
4778-1-06	Miscellaneous Provisions	06/21/23	07/12/23	07/25/23	08/11/23	08/31/23	10/04/23	10/30/23	11/08/23	11/30/23	11/30/28	

State Medical Board of Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
www.med.ohio.gov

MEMORANDUM

TO: Jonathan Feibel, M.D., President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Opioid Treatment Rules Chapter 4730-4 and 4731-33

DATE: September 20, 2024

This memo proposes adoption and rescission for rules as listed below at the monthly Board meeting on October 9, 2024.

The public hearing was held on August 29, 2024. The hearing report is attached. The rules were considered at the JCARR meeting on September 9, 2024. JCARR jurisdiction ends on September 28, 2024.

Physicians:

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

Physician Assistants:

4730-4-01	Definitions	Proposed New Rule
4730-4-01	Definitions	Proposed to Rescind

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

Requested Motion: I move to adopt, rescind, and amend the rules as described in this memorandum from Ms. Anderson and to assign each rule action the effective date of October 31, 2024.

SUMMARY OF THE AUGUST 29, 2024 PUBLIC HEARING REGARDING PROPOSED CHANGES TO THE OHIO ADMINISTRATIVE CODE

Pursuant to Section 119.03, Ohio Revised Code, a public hearing was held on August 29, 2024 to hear comments concerning proposed changes to the administrative rules of the State Medical Board of Ohio ("Board"). James Wakley, Chief Hearing Examiner, presided.

PURPOSE OF THE HEARING

The following changes are proposed:

Chapter 4731-33

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

Chapter 4730-01

4730-4-01	Definitions	Proposed New Rule
4730-4-01	Definitions	Proposed to Rescind
4730-4-02	Standards and Procedures for Withdrawal Management For Substance Use Disorder	Proposed New Rule

PROCEDURAL MATTERS

The record was held open until 5:00 p.m. on August 29. 2024, for the purpose of receiving written comments concerning the proposed changes to the Ohio Administrative Code. At 3:58PM on August 29, 2024, Kimberly Anderson received written testimony from Nita Bhatt, M.D. on behalf of the Ohio Psychiatric Physicians Association. That testimony will be admitted as Exhibit 10.

TESTIMONY HEARD

Kimberly Anderson, Chief Legal Counsel for the Board. Kristanna Deppen, M.D., on behalf of the Ohio Society of Addiction Medicine.

EXHIBITS EXAMINED

Exhibit 1: Copy of the rules originally filed in Package 203770 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule-Filing System on July 25, 2024, and a copy of the confirmation of filing.

Exhibit 2: Copy of the rules originally filed in Package 203771 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule-Filing System on July 25, 2024, and a copy of the confirmation of filing.

Exhibit 3: Copy of the Notice of Public Hearing for the rules in Packages 203770 and 203771 showing it was filed on July 25, 2024.

Exhibit 4: Copies of the address portion of e-mails sent to persons and organizations pursuant to their standing request to be notified when the Medical Board proposes rules.

Exhibit 5: Copy of an e-mail providing copies of the proposed rules to Dr. Delos Reyes in response to a request for an update on the status of the rules.

Exhibit 6: Copy of a question regarding the rules and the Board's response to Carolyn Chan, M.D.

Exhibit 7: Copy of a letter received from Krisanna Deppen, M.D., President, Ohio Society of Addiction Medicine.

Exhibit 8: Copy of a letter received from Tracy Vanneman, Executive Director of the Ohio Association of Physician Assistants.

Exhibit 9: Copy of a letter received from Carolyn Chan, M.D. and Alexis Kimmel, M.D.

Exhibit 10: Copy of a letter received from Nita Bhatt, M.D., President of the Ohio Psychiatric Physicians Association.

SUMMARY OF EVIDENCE

1. Kimberly Anderson, Chief Legal Counsel for the Board, identified Exhibits 1 through 9. She further testified with respect to the notice that the Board provided to the public and interested parties regarding the proposed rule changes, and with respect to other procedural matters. *See* Hearing Transcript ("T.") at 7-9.

2. A request for copies of the rules was received by the Board from Dr. Christina Delos Reyes. A copy of the draft rules was sent to Dr. Delos Reyes on August 9, 2024.

3. Comments on the rules were made by Dr. Kristanna Deppen, M.D., President of the Ohio Society of Addiction Medicine. *See* T. at 13-17.

CONCLUSION

The requirements of Chapter 119, Ohio Revised Code, have been satisfied. The Board may proceed to take action regarding the proposed recission of Rules 4731-33-01, 4731-33-02, 4731-33-03, 4731-33-04, and 4730-4-01 and the proposed adoption of new Rules 4731-33-01, 4731-33-02, 4731-33-03, 4731-33-04, 4730-4-01, and 4730-4-02.

/s/ James T. Wakley
James T. Wakley
Chief Hearing Examiner

STATE MEDICAL BOARD OF OHIO

- - -

Public Rules Hearing

- - -

PROCEEDINGS

Before Mr. James Wakley, Hearing Examiner, held at the offices of the State Medical Board of Ohio, 30 East Broad Street, Hearing Room 420, Columbus, Ohio, on Thursday, August 29, 2024, at 1:30 P.M.

- - -

Armstrong & Okey, Inc.
222 East Town Street, 2nd Floor
Columbus, Ohio 43215
(614) 224-9481

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INDEX TO WITNESSES

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INDEX TO EXHIBITS

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Thursday Afternoon,

August 29, 2024.

- - -

HEARING EXAMINER: Good afternoon, everyone. The public hearing for the State Medical Board of Ohio is now in session.

Let the record show that this public hearing is convened at 1:30 p.m. on Thursday, August 29, 2024. This public hearing was called pursuant to Section 119.03 of the Ohio Revised Code.

I am James Wakley, Chief Hearing Examiner for the State Medical Board of Ohio. I am conducting this public rules hearing on behalf of the Board. The members of the Board will review the report concerning this hearing, including any written materials submitted as evidence and have the transcript of today's hearing available for review.

The following rules are proposed. For Physicians, Rule 4731-33-01, Definitions as a proposed new rule.

Rule 4731-33-01, Definitions proposed to rescind.

Rule 4731-33-02, Standards and

Procedures for Withdrawal Management for Substance Use Disorder, proposed new rule.

Rule 4731-33-02, Standards and Procedures for Withdrawal Management for Drug and Alcohol Addiction, proposed to rescind.

Rule 4731-33-03, Office-Based Opioid Treatment, proposed new rule.

Rule 4731-33-03, Office-Based Treatment for Opioid Addiction, proposed to rescind.

Rule 4731-33-04, Medication-Assisted Treatment Using Naltrexone as a proposed new rule.

And Rule 4731-33-04, Medication-Assisted Treatment Using Naltrexone, as proposed to rescind.

For Physician Assistants. Rule 4730-4-01, proposing to rescind the old rule and adopt the new rule.

Rule 4730-4-02, proposing to rescind the old rule and propose the new rule.

Rule 4730-4-03, proposed new rule for Office-Based Opioid Treatment.

Rule 4730-4-03, proposed to rescind prior Office-Based treatment for Opioid

Addiction rule.

And Rule 3730-4-04, proposed to rescind the old Medication-Assisted Treatment Using Naltrexone and adopt the new rule.

The purpose of this hearing today is to provide an opportunity for any person affected by the proposed rules to be heard. Any affected person may present his or her positions, arguments, or contentions orally or in writing, and present evidence tending to show that the proposed adoption of the rules as proposed will be unreasonable or unlawful.

If you have a written copy of your testimony submission of the written copy will assist the Board in the review of your comments. Written statements may also be submitted today without testimony. If you have any written comments you wish to submit please send electronic copies of your comments to my e-mail address, James.wakley@med.ohio.gov. I will repeat that address during the proceedings so there is no need to write it down now.

I now recognize Kim Anderson, Chief Legal Counsel for the Medical Board for the presentation of testimony on the Board's

compliance with the legal requirements in this matter.

(WITNESS SWORN)

- - -

KIMBERLY C. ANDERSON

called as a witness, being first duly sworn, testified as follows:

DIRECT EXAMINATION

By the Hearing Examiner:

Q. Please state your name and how you are employed.

A. Kim Anderson, Chief Legal Counsel, State Medical Board of Ohio.

Q. Are you familiar with the filings and other actions taken for purposes of the rules being considered today?

A. Yes.

Q. What part did you play in the filing of the rules?

A. I participated in the filing and the distribution of the notice of public hearing.

Q. Can you identify the documents that have been marked as exhibits, please?

A. Yes. Exhibit 1 is a copy of the

rules originally filed in Package 203770 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule Filing System on July 25th, 2024, and a copy of the confirmation of filing.

Exhibit 2 is the copy of the rules originally filed in Package 203771 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Filing System on July 25th, 2024, and a copy of the confirmation of filing.

Exhibit 3 is a copy of the Notice of Public Hearing for the rules in Packages 203770 and 203771 showing it was filed on July 25th, 2024.

Exhibit 4 contains copies of the address portion of e-mails sent to persons and organizations pursuant to their standing request to be notified when the Medical Board proposes rules.

Exhibit 5 is a copy of the e-mail providing copies of the proposed rules to Dr. Delos Reyes in response to a request for an update on the status of the rules.

Exhibit 6 is a copy of a question

regarding the rules and the Board's response to Carolyn Chan, M.D.

Exhibit 7 is a copy of a letter received from Krisanna Deppen, M.D., President, Ohio Society of Addiction Medicine.

Exhibit 8 is a copy of the letter received from Tracy Vannerman, Executive Director of the Ohio Association of Physician Assistants.

Exhibit 9 is a copy of a letter received from Carolyn Chan, M.D. and Alexis Kimmel, M.D.

Q. Thank you. Was public notice of the rules that are subject of this hearing today given in the Register of Ohio at least 30 days prior to today?

A. Yes. Exhibit 3 is a copy of the Notice of Public Hearing for the rules in Package 203700 and 203771 showing it was filed on July 25th, 2024.

Q. Was notice of the proposed rules provided to any persons or organizations?

A. Yes. Exhibit 4 contains copies of the address portion of e-mails sent to persons and organizations pursuant to their standing

request to be notified when the Medical Board proposes rules.

Q. Were any requests for copies of the proposed rules received in the Board office?

A. Yes. Exhibit 5 is a copy of a response to Dr. Delos Reyes providing a copy of the proposed rules.

Q. Were any written comments on the proposed rules received in the Board office?

A. Yes. Exhibit 6 is a copy of a question regarding the rules from Carolyn Chan, M.D. and the Medical Board's response.

Exhibit 7 is a copy of the letter receive from Krisanna Deppen, M.D., President of the Ohio Society of Addiction Medicine.

Exhibit 8 is a copy of a letter received from Tracy Vannerman, Executive Director of the Ohio Association of Physician Assistants.

And Exhibit 9 is a copy of a letter received from Carolyn Chan, M.D. and Alexis Kimmel, M.D.

HEARING EXAMINER: Thank you. Exhibits 1 through 9 are admitted into the record.

(EXHIBITS ADMITTED INTO THE RECORD)

HEARING EXAMINER: Is now time to receive testimony on the proposed rules from interested parties. Please remember that the purpose of this hearing is to receive ideas, comments and concerns regarding the proposed rules. It is not the appropriate time to seek debate on those proposed rules.

Moreover, the Board reserves the right to limit the testimony of any witness if the testimony appears to be irrelevant or cumulative.

If a witness has a written copy of his or her testimony or other documents that you wish to have marked as exhibits, again the documents should be e-mailed to me at James.wakley@med.ohio.gov at the conclusion of your testimony.

If you have a written statement that you wish to submit without giving testimony please e-mail me the written statement at the e-mail address stated before so it can be marked as an exhibit.

Witnesses will be called to

testimony in the order they registered. Keep in mind that some persons may have registered prior to today's hearing.

To facilitate the receipt of testimony, each witness will be allowed five minutes in which to provide testimony.

The first individual who has registered is Dr. Krisanna Deppen. Doctor, would you please come over here and take a seat?

DR. DEPPEN: Sure

(WITNESS SWORN)

KRISANNA DEPPEN, M.D.

called as a witness, being first duly sworn, testified as follows:

HEARING EXAMINER: Doctor Deppen, please state your name and address for the record.

DR. DEPPEN: My name is Dr. Krisanne Deppen. My home address?

HEARING EXAMINER: Whatever address you want the Board to have.

DR. DEPPEN: 44 Wilson Avenue, Columbus, Ohio 43205.

HEARING EXAMINER: Are you appearing on behalf of an organization today?

DR. DEPPEN: Yes. On behalf of the Ohio Society of Addiction Medicine.

HEARING EXAMINER: Please go ahead.

DR. DEPPEN: Good afternoon. I am Dr. Krisanna Deppen. I am an addiction medicine physician and President of the Ohio Society of Addiction Medicine.

We represent healthcare providers dedicated to improving addiction treatments and education in Ohio. As the program director of an addiction medicine fellowship I lead a team training future specialists and educating providers cross multiple disciplines in caring for our patients with substance use disorders. In fact, some of our fellows are with me today.

I think their presence underscores the importance of this issue not just for our current providers, but for the next generation of addiction specialists who will be at the forefront of addressing Ohio's opioid crisis.

My clinical focus and professional passion is caring for pregnant and post-partum women with substance use disorders, particularly opioid addiction.

We support these women and their

infants for up to a year after they deliver, and then we work to help them transition to longer term care. We do the primary care provider and often including prescription of Buprenorphine.

However, we face a significant challenge. Many primary care physicians are reluctant to accept these patients back into their practices. The main barrier, fear of navigating Ohio's complex rules for prescribing Buprenorphine. This issue is even more pronounced in under-served areas and rural areas of our States.

We commend the Medical Board for updating office-based opioid treatment rules to align with evidence-based practices and national standards.

Reducing documentation burdens, modifying behavioral health requirements and allowing flexibility in Buprenorphine prescribing duration are all positive steps. These changes will empower providers to meet patients where they are and deliver this life saving treatment more affectivity.

Yet significant obstacles remain. Many of our highly capable colleagues in primary

care, hospitals and emergency medicine face unnecessary regulatory hurdles that undermine their confidence in prescribing Buprenorphine to those in desperate need.

To address this we are proposing three crucial changes.

First, removing the biennial eight-hour CME Requirement.

2, updating clinical references for starting Buprenorphine.

3, allowing for higher Buprenorphine dosing limits for all providers.

While continuing education is vital, the current eight-hour biennial CME requirement for Buprenorphine prescribing is redundant and creates uncertainty and hesitation among providers.

With the DEA already mandated eight-hour addiction related CME, and medical schools increasingly incorporating this education, this additional requirement becomes a barrier rather than an asset.

Furthermore, the rise of Fentanyl has dramatically altered our approach to Buprenorphine initiation and prescribing. The

current clinical guidelines referenced in the Medical Board's rules lack the flexibility to accommodate high or low dose induction methods, both of which can be crucial for rapidly stabilizing our patients.

Many individuals, especially those transitioning from Fentanyl use, may require doses exceeding 24 milligrams. We need the freedom to adapt our practices to the latest medical evidence and the realities of the current drug supply.

In light of these challenges the Ohio Society of Addiction Medicine urges you to reconsider three key areas in the updated rules.

Eliminate the biennial 8-hour CME requirement, expand and update clinical references, and increase the dosing cap to 32 milligrams for all providers.

These changes will empower more healthcare providers to offer compassionate evidenced-based care to some of Ohio's most vulnerable patients.

By removing these barriers we can expand access to life saving treatment and make significant strides in addressing the opioid

crisis in our state.

Thank you for your ongoing efforts to improve patient care and for the opportunity to speak today.

HEARING EXAMINER: Thank you very much, Doctor. Do you wish to submit your written comments?

DR. DEPPEN: No.

HEARING EXAMINER: Okay. Thank you. The next witness will be Megan Zaworski.

DR. DEPPEN: We actually had one person sign the witness form.

HEARING EXAMINER: Okay. Are there any other witnesses who would like to testify today?

I believe Exhibits 1 through 9 have already been admitted into the record.

The record will be held open until 5:00 P.M. today for the sole purpose of receiving any additional written comments on the proposed rules. Please send them to my e-mail address, James.wakley@med.ohio.gov.

I thank you all for attending this public hearing. The Board will weigh the testimony and evidence presented today before

considering action on the proposed rules.

Any further action by the Board on these proposed rules will take place at a regular monthly meeting of the Board which is open to the public.

Any formal action by the Board will comply with Chapter 119 of the Ohio Revised Code.

This public hearing is concluded at 1:44 P.M. Thank you.

(At 1:44 P.M. the hearing was concluded)

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CERTIFICATE

I do hereby certify that the foregoing is a true and correct transcript of the proceedings taken by me in this matter on August 29, 2024, and carefully compared with my original stenographic notes.

Michael O. Spencer,
Registered Professional
Reporter.

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TO BE RESCINDED

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 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 Stated 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" means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of substance use disorder, prevention of relapse of substance use disorder, or both.

(D) "Substance use disorder" includes misuse, dependence, and addiction to alcohol and/or legal or illegal drugs, as determined by diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition" or "DSM-5."

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

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

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

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

(b) 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;

(c) 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;

(d) 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;

(e) 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;

(f) 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 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 cmpliance with Ohio and federal laws and rules.

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

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

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

(J) "Stabilization 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, which may include the use of medications.

(K) "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 detoxification services. Withdrawal management alone does not constitute substance abuse treatment or rehabilitation.

(L) "Ambulatory 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 addiction, prevention of relapse of drug addiction, or both. Ambulatory detoxification is the provision of medically supervised evaluation, withdrawal management, and referral services without extended onsite monitoring. For purpose of rule 4730-4-02 of the Administrative Code, ambulatory 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.

Effective:

Five Year Review (FYR) Dates: 7/25/2024

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	4730.07, 4730.55
Rule Amplifies:	4730.55, 4730.56
Prior Effective Dates:	04/30/2019, 10/31/2020

4730-4-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means pharmacotherapy, 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. 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

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

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

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

(C) "Addiction specialist physician" means a physician who holds one of the following medical subspecialty certifications:

(1) Subspecialty board certification in addiction medicine by the American board of preventative medicine (“ABPM”);

(2) Subspecialty board certification in addiction psychiatry by the American board of psychiatry and neurology (“ABPN”);

(3) Subspecialty board certification in addiction medicine by the American osteopathic association (“AOA”); or

(4) Certification by the American board of addiction medicine ("ABAM")

(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, 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 this chapter:

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

(a) Addiction medicine specialist physician or board certified 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, 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) 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, 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 MOUD during which the patient is started on an FDA-approved medication for substance use disorder treatment.

(K) "Stabilization phase" means the period of time following the induction phase, when medication doses are adjusted to target a reduction in substance use disorder symptoms.

(L) "Maintenance phase" means the ongoing period of time when the patient's medication dose reaches a therapeutic level, allowing the patient to focus on other recovery activities.

(M) "Withdrawal management" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. 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 management services. Withdrawal management alone does not constitute completed substance use disorder treatment or rehabilitation.

(N) "Ambulatory withdrawal management" 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. Ambulatory withdrawal management is the provision of medically supervised evaluation, treatment, and referral services without extended onsite monitoring. For purpose of rule 4730-4-02 of the Administrative Code, ambulatory withdrawal management 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;

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

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

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TO BE RESCINDED

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

(A) In order to provide ambulatory detoxification, 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 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 detoxification alone is not substance abuse treatment. If the patient prefers substance 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 the patient information about all drugs approved by the U.S. food and drug administration for use in medication-assisted treatment, including withdrawal management. That information was given shall be documented in the patient's medical record.

(2) If the patient agrees to enter opioid treatment and the physician assistant determines that such treatment is clinically appropriate, the physician assistant shall refer the patient to an opioid 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 Naltrexone or who holds the DATA 2000 waiver to provide 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 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 detoxification for opioid addiction.

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

(a) A positive and helpful support network is available to the patient.

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

(c) There is little risk of medication diversion.

(2) The physician assistant shall provide ambulatory detoxification under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-D or II-D 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 detoxification, the physician assistant shall perform an assessment of the patient. The assessment shall include a thorough medical history and physical examination. The assessment must focus on signs and symptoms associated with opioid 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 detoxification, the physician assistant shall conduct 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 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.

(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 a 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 detoxification process and potential subsequent treatment for substance use disorder, including information about all drugs approved by the

United States food and drug administration for use in medication-assisted treatment;

(b) The risk of relapse following detoxification without entry into 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 the medications.

(7) The physician assistant shall not establish standardized routines or schedules of increases or decreases of medications but shall formulate a 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 paragraphs (F) and (G) 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 demonstrate the absence of use of alternative licit and/or illicit drugs. The physician assistant shall consider referring a patient who has a positive urine/and or toxicological screening 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 drugs as determined to be most appropriate for the patient.

(i) A 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). 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 well tolerated by the patient.

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

(iii) In withdrawal management programs of thirty days or less duration, the physician assistant shall not 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 a naloxone kit.

(a) The physician assistant shall ensure that 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 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 chances of medication diversion by using the appropriate frequency of office visits, pill counts, and weekly checks of OARRS.

(E) The physician assistant who provides ambulatory detoxification with medication management for withdrawal from 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 detoxification with medication management only when a positive and helpful support network is available to the patient whose use of benzodiazepines was mainly in therapeutic ranges and who does 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 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 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 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 demonstrate the absence of use of alternative licit and/or illicit drugs.

(b) The physician assistant shall document consideration of 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 office visits, pill counts, and weekly checks of OARRS.

(F) The physician assistant who provides ambulatory detoxification with medication management of withdrawal from alcohol addiction 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 from the medical board's website at: https://med.ohio.gov.

(1) The physician assistant shall provide ambulatory detoxification from alcohol with medication management only when a positive and helpful support network is available to the patient who does 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 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 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 detoxification, the physician assistant shall assess the patient regularly:

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

(b) The physician assistant shall require the patient to undergo urine and/or other toxicological screenings in order to demonstrate the absence of illicit drugs;

(c) The physician assistant shall document the consideration of referring a patient who has a positive urine and/or toxicological screening to a higher level of care;

(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.

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4730-4-02 **Standards and procedures for withdrawal management for substance use disorder.**

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

(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 for any substance use disorder the physician assistant shall inform the patient that ambulatory withdrawal management alone is not complete treatment for a substance use disorder. If the patient prefers continuing treatment for a substance use disorder, the physician assistant shall comply with the requirements of section 3719.064 of the Revised Code.

(C) The physician assistant shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(D) 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.

(E) Ambulatory withdrawal management for opioid use disorder.

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

(a) The patient has adequate social, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management; and

(b) There is little risk of medication diversion.

(2) The physician assistant shall provide ambulatory withdrawal management under a defined set of policies and procedures or medical protocols, with patient placement in outpatient or residential settings consistent with American society of addiction medicine's level of care criteria. Such services are designed to treat the patient's level of clinical severity, to achieve safe and comfortable withdrawal from a drug, and to effectively facilitate the patient's transition into treatment and recovery. In the event that ambulatory withdrawal management is unsafe or inappropriate for a patient, referral to a higher level of care, such as inpatient hospitalization shall be completed. The ASAM criteria 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, the physician assistant shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history and physical examination sufficient to assure safety in commencing ambulatory withdrawal management and shall include a review of the patient’s prescription history in OARRS. The assessment must focus on signs and symptoms associated with opioid use disorder 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) If any part of the assessment cannot be completed prior to the initiation of treatment, the physician assistant shall complete as soon as possible following initiation of treatment.

(5) The physician assistant shall inform the patient about the following before treatment for opioid withdrawal is initiated:

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

(b) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of MOUD treatment;

(c) The safe storage and disposal of prescribed medications.

(6) The physician assistant shall not establish standardized regimens of medications for management of substance withdrawal symptomatology but shall formulate an individualized treatment plan based on the needs of the specific patient.

(7) 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 (D) of rule 4730-4-03 of the Administrative Code.

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

(9) 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 with any of the following medications as determined to be most appropriate for the patient.

(i) A medication that is specifically FDA approved for the alleviation of withdrawal symptoms. Methadone may only be utilized with strict adherence to the stipulations of 21 C.F.R. 1306.07(b).

(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.

(b) The physician assistant shall not use anesthetic agents to treat the patient's withdrawal symptoms.

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

(i) 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 currently accepted standards of care.

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

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

(a) The physician assistant shall ensure that the patient and, if possible, those residing with the patient receive instruction on the drug’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 upon expiration or use.

(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 the overdose reversal drug without a prescription.

(11) The physician assistant shall take steps to reduce the risk of medication diversion by doing one or more of the following: frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(F) The physician assistant who provides ambulatory withdrawal management 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 for benzodiazepines with medication only when a patient has sufficient social, medical, and psychiatric stability when their use of benzodiazepines was primarily in therapeutic dose ranges and when they do 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 history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician assistant shall perform 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, the physician assistant shall conduct and document a biomedical and psychosocial evaluation of the patient to gather sufficient information and data to justify the use of this treatment intervention.

(4) The physician assistant shall instruct the patient about the following before treatment for benzodiazepine withdrawal management is initiated:

(a) Not to drive or operate dangerous machinery during treatment;.

(b) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in substance use disorder treatment;

(c) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of treatment for substance use disorder; and

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

(5) During the ambulatory withdrawal management, the physician assistant shall regularly assess the patient so that medication 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 use of licit and/or illicit drugs.

(b) The physician assistant shall consider revising the treatment plan or referring the patient who has a positive toxicology screening to a higher level of care.

(c) The physician assistant shall take steps to reduce the chances of diversion by doing one or more of the following: frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(G) The physician assistant who provides ambulatory withdrawal management for 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.

(1) The physician assistant shall provide ambulatory withdrawal from alcohol only when:

(a) The patient has sufficient social, medical, and psychiatric stability to adhere to prescribed treatments and successfully complete withdrawal with minimal risk of complications;

(b) The patient is not at risk for serious withdrawal from substances other than alcohol; and

(c) The patient has no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician assistant shall perform 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, the physician assistant shall perform a biomedical and psychosocial evaluation to gather sufficient information and data to justify the use of this treatment intervention.

(4) During the ambulatory withdrawal management, the physician assistant shall regularly assess the patient so that the dosage can be adjusted if needed.

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

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

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

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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 comprenhensive medical and psychiatric history;

(b) A brief mental status exam;

(c) Substance 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 a 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.

(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;

(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) A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.

(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) SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at: https://store.samhsa.gov/.

(2) "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," 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/.

(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 servics provider, the physician assistant shall document the referral and the physician assistant's maintenance of meaningful interactions with the provider in the patient record.

(F) The physician assistant who provides OBOT shall offer the patient a prescription for a naloxone kit.

(1) The physician assistant shall ensure that 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 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. 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 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 an 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, 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 it is possible to taper the drug to discontinuation. If the physician assistant prescribing buprenorphine is the prescriber of the other drug, the physician assistant shall 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 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 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 the lowest dose that avoids intoxication, withdrawal, 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.

(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.

(6) The physician assistant shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The physician assistant shall also

require urine drug 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.

(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.

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Five Year Review (FYR) Dates: 7/25/2024

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Certification

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Date

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

(A) A physician assistant who provides office-based opioid treatment ("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 use disorder 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;

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

(5) The physician assistant who provides OBOT shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history, examination, and laboratory testing. If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician assistant shall complete as soon as possible following initiation of treatment; and

(6) The physician assistant shall provide accurate, objective, and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(B) The physician assistant who provides OBOT shall establish a treatment plan that includes the following:

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

(2) Patient education;

(3) Random urine-drug screens;

(4) A signed treatment agreement that outlines the responsibilities of the patient and the physician assistant, and documents the patient’s consent for treatment;

(5) Documentation regarding psychosocial intervention, pursuant to paragraph (D) of this rule; and

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

(C) 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 https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder- Full-Document/PEP21-02-01-002.

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

(D) 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.

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

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

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

(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 overdose reversal drugs without a prescription.

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

(1) 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 prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations:

(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; or

(d) When the patient has a genuine allergy to or intolerance of a buprenorphine/naloxone combination product.

(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 the drug. 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. 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.

(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 phase, the physician assistant shall prescribe a dosage of buprenorphine that avoids intoxication or sedation, prevents withdrawal, and suppresses significant drug craving. For the first twelve months of treatment, the physician assistant shall prescribe no more than a one-month supply of the buprenorphine product unless utilizing a formulation with duration of action exceeding one month, such as injections or implants.

(6) The physician assistant shall reduce the risk of buprenorphine diversion by using the lowest effective dose, and by using one or more of the following: scheduling appropriate frequency of office visits, conducting random pill counts, and checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.

(7) When using any sublingual formulation of buprenorphine, 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 addiction specialist physician 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 use disorder 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 within the scope of their professional license.

Replaces: 4731-33-03

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Certification

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Date

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TO BE RESCINDED

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.

(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 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.

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

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

(1) 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 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 use disorder counseling.

(B) The physician assistant may treat a patient with extended-release naltrexone for opioid or alcohol 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 with treatment adherence.

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

(3) The physician assistant shall determine the effectiveness of treatment with extended-release naltrexone by utilizing drug testing, serum medication levels, and oral fluid testing throughout the course of treatment.

(4) 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 use disorder counseling.

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TO BE RESCINDED

4731-33-01 **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 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" means alcohol or drug addiction services that are accompanied by medication that has been approved by the United States food and drug administration for the treatment of substance use disorder, prevention of relapse of substance use disorder, or both.

(D) "Substance use disorder" includes misuse, dependence, and addiction to alcohol and/or legal or illegal drugs, as determined by diagnostic criteria in the "Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition" or "DSM-5."

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

(F) For purposes of the rules in Chapter 4731-33 of the Administrative Code:

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

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

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

(c) 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;

(d) 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.

(e) 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;

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

(g) An 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 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.

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

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

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

(J) "Stabilization 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, which may include the use of medications.

(K) "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 or detoxification 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 detoxification services. Withdrawal management alone does not constitute substance abuse treatment or rehabilitation.

(L) "Ambulatory detoxification" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by a physician authorized to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of addiction, prevention of relapse of addiction, or both. Ambulatory detoxification is the provision of medically supervised evaluation, withdrawal management, and referral services without extended onsite monitoring. For the purpose of rule 4731-33-02 of the Administrative Code, ambulatory 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.

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4731-33-01 **Definitions.**

(A) "Office-based opioid treatment" or "OBOT" means pharmacotherapy 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. 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;

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

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

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

(C) "Addiction specialist physician" means a physician who holds one of the following medical subspecialty certifications:

(1) Subspecialty board certification in addiction medicine by the American board of preventative medicine ("ABPM");

(2) Subspecialty board certification in addiction psychiatry by the American board of psychiatry and neurology ("ABPN");

(3) Subspecialty board certification in addiction medicine by the American osteopathic association ("AOA"); or

(4) Certification by the American board of addiction medicine ("ABAM")

(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 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 this chapter:

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

(a) Addiction medicine specialist physician, or board-certified 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, 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) An 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, 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 MOUD during which the patient is started on an FDA-approved medication for substance use disorder treatment.

(K) "Stabilization phase" means the period of time following the induction phase, when medication doses are adjusted to target a reduction in substance use disorder symptoms.

(L) "Maintenance phase" means the ongoing period of time when the patient’s medication dose reaches a therapeutic level, allowing the patient to focus on other recovery activities.

(M) "Withdrawal management" is a set of medical interventions aimed at managing the acute physical symptoms of intoxication and withdrawal. 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 management services. Withdrawal management alone does not constitute completed substance use disorder treatment or rehabilitation.

(N) "Ambulatory withdrawal management" means withdrawal management delivered in a medical office, public sector clinic, or urgent care facility by a physician authorized

to prescribe outpatient supplies of drugs approved by the United States food and drug administration for the treatment of substance use disorder. Ambulatory withdrawal management is the provision of medically supervised evaluation, treatment, and referral services without extended onsite monitoring. For the purpose of rule 4731-33-02 of the Administrative Code, ambulatory withdrawal management 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;

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

(6) An emergency medical services agency as authorized under chapter 4729 of the Revised Code.

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TO BE RESCINDED

4731-33-02 **Standards and procedures for withdrawal management for drug or alcohol addiction.**

(A) A physician who provides withdrawal management, as that term is defined in rule 4731-33-01 of the Administrative Code, shall comply with all federal and state 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.

(B) Prior to providing ambulatory detoxification, as that term is defined in rule 4731-33-01 of the Administrative Code, for any substance use disorder the physician shall inform the patient that ambulatory detoxification alone is not substance abuse treatment. If the patient prefers substance abuse treatment, the physician 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 the patient information about all drugs approved by the U.S. food and drug administration for use in medication-assisted treatment, including withdrawal management. That information was given shall be documented in the patient's medical record.

(2) If the patient agrees to enter opioid treatment and the physician determines that such treatment is clinically appropriate, the physician shall refer the patient to an opioid 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 Naltrexone or who holds the DATA 2000 waiver to provide 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 shall be documented in the patient record.

(C) When providing withdrawal management for opioid use disorder the physician may 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 detoxification for opioid addiction.

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

(a) A positive and helpful support network is available to the patient.

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

(c) There is little risk of medication diversion.

(2) The physician shall provide ambulatory detoxification under a defined set of policies and procedures or medical protocols consistent with American society of addiction medicine's level I-D or II-D 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 detoxification, the physician shall perform an assessment of the patient. The assessment shall include a thorough medical history and physical examination. The assessment must focus on signs and symptoms associated with opioid 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 detoxification, the physician shall conduct 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 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.

(m) For other than toxicology tests for drugs and alcohol, appropriate history, substance abuse history, and pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a 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 shall document the reason in the medical record.

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

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

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

(b) The risk of relapse following detoxification without entry into 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 the medications.

(7) The physician shall not establish standardized routines or schedules of increases or decreases of medications but shall formulate a 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 shall offer the patient counseling as described in paragraphs (F) and (G) of rule 4731-33-03 of the Administrative Code.

(9) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to demonstrate the absence of use of alternative licit and/or illicit drugs. The physician shall consider referring a patient who has a positive urine/and or toxicological screening to a higher level of care, with such consideration documented in the patient's medical record.

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

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

(i) A 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 on the Medical Board’s website at: https://www.med.ohio.gov;

(iii) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product). 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 shall not use any of the following drugs to treat the patient’s withdrawal symptoms:

(i) Methadone;

(ii) Anesthetic agents

(c) The physician shall comply with the following:

(i) The physician 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 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 well tolerated by the patient.

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

(iii) In withdrawal management programs of thirty days or less duration, the physician shall not allow more than one week of unsupervised or take-home medications for the patient.

(11) The physician shall offer the patient a prescription for a naloxone kit.

(a) The physician shall ensure that 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 shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

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

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

(E) The physician who provides ambulatory detoxification with medication management for withdrawal from 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 shall provide ambulatory detoxification with medication management only when a positive and helpful support network is available to the patient whose use of benzodiazepines was mainly in therapeutic ranges and who does 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 detoxification, the physician 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 detoxification, the physician 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 shall instruct the patient not to drive or operate dangerous machinery during treatment.

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

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

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

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

(F) The physician who provides ambulatory detoxification with medication management of withdrawal from alcohol addiction 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 shall provide ambulatory detoxification from alcohol with medication management only when a positive and helpful support network is available to the patient who does 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 detoxification, the physician 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 detoxification, the physician 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 detoxification, the physician shall assess the patient regularly:

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

(b) The physician shall require the patient to undergo urine and/or other toxicological screenings in order to demonstrate the absence of illicit drugs;

(c) The physician shall document the consideration of referring a patient who has a positive urine and/or toxicological screening to a higher level of care;

(5) If the patient agrees to enter alcohol treatment and the physician determines that such treatment is clinically appropriate, the physician 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 shall instruct the patient not to drive or operate dangerous machinery during treatment.

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Prior Effective Dates:	10/31/2020

4731-33-02 **Standards and procedures for withdrawal management for substance use disorder.**

(A) A physician who provides withdrawal management, as that term is defined in rule 4731-33-01 of the Administrative Code, shall comply with all federal and state laws and rules applicable to prescribing.

(B) Prior to providing ambulatory withdrawal management for any substance use disorder the physician shall inform the patient that ambulatory withdrawal management alone is not complete treatment for a substance use disorder. If the patient prefers continuing treatment for a substance use disorder, the physician shall comply with the requirements of section 3719.064 of the Revised Code.

(C) The physician shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(D) When providing withdrawal management for opioid use disorder the physician may 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.

(E) Ambulatory withdrawal management for opioid use disorder.

(1) The physician shall provide ambulatory withdrawal management only when the following conditions are met:

(a) The patient has adequate social, medical, and psychiatric stability to engage in and safely complete ambulatory withdrawal management; and

(b) There is little risk of medication diversion.

(2) The physician shall provide ambulatory withdrawal management under a defined set of policies and procedures or medical protocols, with patient placement in outpatient or residential settings consistent with American society of addiction medicine's level of care criteria. Such services are designed to treat the patient’s level of clinical severity, to achieve safe and comfortable withdrawal from a drug, and to effectively facilitate the patient’s transition into treatment and recovery. In the event that ambulatory withdrawal management is unsafe or inappropriate for a patient, referral to a higher level of care, such as inpatient hospitalization shall be completed. The ASAM criteria 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, the physician shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history and physical examination sufficient to assure safety in commencing ambulatory withdrawal management and shall include a review of the patient's prescription history in OARRS. The assessment must focus on signs and symptoms associated with opioid use disorder 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) If any part of the assessment cannot be completed prior to the initiation of treatment, the physician shall complete as soon as possible following initiation of treatment.

(5) The physician shall inform the patient about the following before treatment for opioid withdrawal is initiated:

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

(b) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of MOUD treatment;

(c) The safe storage and disposal of prescribed medications.

(6) The physician shall not establish standardized regimens of medications for management of substance withdrawal symptomatology but shall formulate an individualized treatment plan based on the needs of the specific patient.

(7) For persons projected to be involved in withdrawal management for six months or less, the physician shall offer the patient counseling as described in paragraph (D) of rule 4731-33-03 of the Administrative Code.

(8) The physician shall require the patient to undergo urine and/or other toxicological screenings during withdrawal management in order to assess for use of licit and/or illicit drugs. The physician shall consider revising the treatment plan or

referring a patient who has a positive toxicological screening result to a higher level of care.

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

(a) The physician may treat the patient's withdrawal symptoms with any of the following medications as determined to be most appropriate for the patient.

(i) A medication that is specifically FDA approved for the alleviation of withdrawal symptoms. Methadone may only be utilized with strict adherence to the stipulations of 21 C.F.R. 1306.07(b).

(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 on the Medical Board's website at: https://www.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.

(b) The physician shall not use anesthetic agents to treat the patient's withdrawal symptoms.

(c) The physician shall comply with the following:

(i) 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 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 currently accepted standards of care.

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

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

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

(b) The physician shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

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

(11) The physician shall take steps to reduce the risk of medication diversion by doing one or more of the following: frequent office visits, pill counts, urine drug screening, and frequent checks of OARRS.

(F) The physician who provides ambulatory withdrawal management 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 shall provide ambulatory withdrawal management for benzodiazepines with medication only when a patient has sufficient social, medical, and psychiatric stability when their use of benzodiazepines was primarily in therapeutic dose ranges and when they do 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 history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician shall perform 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, the physician shall conduct a biomedical and psychosocial evaluation of the patient to gather sufficient information and data to justify the use of this treatment intervention.

(4) The physician shall instruct the patient about the following before treatment for benzodiazepine withdrawal management is initiated:

(a) Not to drive or operate dangerous machinery during treatment;

(b) The withdrawal management process and importance of subsequent treatment for substance use disorder, including information about all medications approved by the United States food and drug administration for use in substance use disorder treatment;

(c) The risk of relapse and lethal overdose following completion of withdrawal without entry into continuation of treatment for substance use disorder; and

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

(5) During the ambulatory withdrawal management, the physician shall regularly assess the patient so that medication dosage can be adjusted if needed.

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

(b) The physician shall consider revising the treatment plan or referring the patient who has a positive toxicology screening to a higher level of care.

(c) The physician shall take steps to reduce the risk of diversion by doing one or more of the following: frequent office visits, pill counts, urine drug screening and frequent checks of OARRS.

(G) The physician who provides ambulatory withdrawal management for withdrawal from alcohol 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: https://www.asam.org/quality-care/clinical -guidelines/alcohol- withdrawal-management-guideline.

(1) The physician shall provide ambulatory withdrawal from alcohol only when:

(a) The patient has sufficient social, medical, and psychiatric stability to adhere to prescribed treatments and successfully complete withdrawal with minimal risk of complications;

(b) The patient is not at risk for serious withdrawal from substances other than alcohol; and

(c) The patient has no history of withdrawal seizures or withdrawal delirium.

(2) Prior to providing ambulatory withdrawal management, the physician shall perform 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, the physician shall perform a biomedical and psychosocial evaluation to gather sufficient information and data to justify the use of this treatment intervention.

(4) During the ambulatory withdrawal management, the physician shall regularly assess the patient so that the dosage can be adjusted if needed.

(a) The physician shall require the patient to undergo toxicological screenings in order to assess for the presence of alcohol metabolites, licit or illicit drugs;

(b) The physician shall consider revising the treatment plan or referring a patient who has a positive toxicological screening test to a higher level of care; and

(c) The physician shall take steps to reduce the risk of diversion by doing one or more of the following: frequent office visits, pill counts, urine drug screening and frequent checks of OARRS.

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4731-33-03 **Office-based treatment for opioid addiction.**

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

(1) Before initiating OBOT, the physician 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; and

(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 physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license.

(B) The physician 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 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 pregnancy test, the physician may satisfy the assessment requirements by reviewing records from a 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 shall document the reasons in the medical record.

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

(1) The physician's rationale for selection of the specific drug to be used in the medication-assisted treatment;

(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; and

(6) A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.

(D) The physician 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) SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at: https://store.samhsa.gov.

(2) "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," 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/.

(E) Except if the physician providing OBOT is a board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, the physician 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 4731-33-01 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 and 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 4731-33-01 of the Administrative Code, the physician shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program or appropriate self-help recovery program. If the patient is required to participate in a twelve step program or self-help recovery program, the physician shall require the patient to provide documentation of on-going participation in the program.

(5) Additional requirements related to the provider of behavioral health services:

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

(b) If the physician refers the patient to a qualified behavioral healthcare provider, community addiction services provider, or community mental health services provider, the physician shall document the referral and the

physician's maintenance of meaningful interactions with the provider in the patient record.

(F) The physician who provides OBOT shall offer the patient a prescription for a naloxone kit.

(1) The physician shall ensure that 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 shall offer the patient a new prescription for naloxone upon expiration or use of the old kit.

(3) The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician 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 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. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician who treats the opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician 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 documented in the patient record; or

(e) When the patient has an 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 documenation 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, or tramadol, the physician shall only co-prescribe these substances when it is medically necessary.

(a) The physician 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 it is possible to taper the drug to discontinuation. If the physician prescribing buprenorphine is the prescriber of the other drug, the physician shall taper the other drug to discontinuation, if it is safe to do so. The physician shall educate the patient about the serious risks of the combined use.

(b) The physician shall document progress with achieving the tapering plan.

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

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

(a) During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.

(b) Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

(6) The physician shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The physician shall require urine drug screens, serum medication levels, or oral fluid 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 shall document in the medical record the rationale for prescribed doses exceeding sixteen milligrams of buprenorphine per day. The physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

(8) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

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

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

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

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

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4731-33-03 **Office-based opioid treatment.**

(A) A physician who provides office-based opioid treatment ("OBOT") shall comply with the following requirements:

(1) Before initiating OBOT, the physician 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 use disorder and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license;

(4) The physician who provides OBOT shall perform an assessment of the patient to gather sufficient information and data to justify the use of this treatment intervention. The assessment shall include a thorough medical history, examination and laboratory testing. If any part of the assessment cannot be completed prior to the initiation of OBOT, the physician shall complete as soon as possible following initiation of treatment; and

(5) The physician shall provide accurate, objective and complete documentation of all patient encounters, including referrals, test results, and significant changes to the treatment plan.

(B) The physician who provides OBOT shall establish a treatment plan that includes the following:

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

(2) Patient education;

(3) Random urine-drug screens;

(4) A signed treatment agreement that outlines the responsibilities of the patient and the physician, and documents the patient’s consent for treatment;

(5) Documentation regarding psychosocial interventions, pursuant to paragraph (D) of this rule; and

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

(C) The physician 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 https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use- Disorder-Full-Document/PEP21-02-01-002.

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

(D) The physician 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 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 may make referrals for psychosocial treatment to qualified behavioral healthcare providers, community addiction services or community mental health services providers as defined in rule 4731-33-01 of the Administrative Code; and

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

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

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

(2) The physician shall offer the patient a new prescription for an overdose reversal drug upon expiration or use.

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

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

(1) 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 who treats the opioid use disorder with a buprenorphine product shall only prescribe buprenorphine/naloxone combination products for use in OBOT.

(2) The physician may prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situation:

(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; or

(d) When the patient has a genuine allergy to or intolerance of a buprenorphine/naloxone combination product.

(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 shall only co-prescribe these substances when it is medically necessary.

(a) The physician 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 the drug. If the physician prescribing buprenorphine is the prescriber of the other drug, the physician shall also consider these options and consider consultation with another healthcare provider. The physician shall educate the patient about the serious risks of the combined use.

(b) The physician shall document the rationale for discontinuing, lowering, or continuing the medication given potential risks and benefits.

(4) During the induction phase the physician 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 patient record. The physician shall see the patient at least once a week during this phase.

(5) During the maintenance phase, the physician shall prescribe a dosage of buprenorphine that avoids intoxication or sedation, prevents withdrawal, and suppresses significant drug craving. For the first twelve months of treatment,

the physician shall prescribe no more than a one-month supply of the buprenorphine product unless utilizing a formulation with duration of action exceeding one month, such as injections or implants.

(6) The physician shall reduce the risk of buprenorphine diversion by using the lowest effective dose, and by using one or more of the following: scheduling appropriate frequency of office visits, conducting random pill counts, checking OARRS and utilizing drug testing, serum medication levels, and oral fluid testing to assess for patient adherence to prescribed buprenorphine treatment.

(7) When using any sublingual formulation of buprenorphine, the physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day, unless the prescriber is an addiction specialist physician, or a consultation has been obtained from such a specialist recommending the higher dose. Dosage shall not exceed thirty-two milligrams of buprenorphine per day.

(8) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

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

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

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

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

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TO BE RESCINDED

4731-33-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements of paragraphs (A) to (F) of rule 4731-33-03 of the Administrative Code, the physician 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 shall inform the patient about the risk of opioid overdose if the patient ceases naltrexone and then uses opioids. The physician shall take measures to ensure that the patient is adequately detoxified from opioids and is no longer physically dependent prior to treatment with naltrexone.

(2) The physician 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 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 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 shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualifed behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

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

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

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

(3) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as

defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

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4731-33-04 **Medication-assisted treatment using naltrexone.**

(A) In addition to the requirements of paragraphs (A) to (E) of rule 4731-33-03 of the Administrative Code, the physician using naltrexone to treat opioid use disorder shall comply with the following requirements:

(1) Before initiating naltrexone, the physician 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 shall alert the patient of the risk of potentially lethal opioid overdose if they stop naltrexone and use opioids.

(2) The physician shall use oral naltrexone only for treatment of patients who are highly motivated.

(a) The dosage regime shall strictly comply with the 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 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 shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

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

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

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

(3) The physician shall determine the effectiveness of treatment with extended-release naltrexone by utilizing drug testing, serum medication levels, and oral fluid testing throughout the course of treatment.

(4) The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance use disorder counseling.

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