State Medical Board of Ohio

POLICY COMMITTEE MEETING
June 12, 2019
30 East Broad Street, Columbus, OH 43215, Room 336

Members: Robert Giacalone Mark Bechtel, MD Amol Soin, MD Other Board Members present: Michael Schottenstein, MD Bruce Saferin, DPM Richard Edgin, MD Kim Rothermel, MD Harish Kakarala, MD Sherry Johnson, DO	Staff: A.J. Groeber, Executive Director Kimberly Anderson, Chief Legal Counsel Sallie J. Debolt, Senior Counsel Nathan Smith, Senior Legal and Policy Counsel Joan Wehrle, Education & Outreach Program Manager Rebecca Marshall, Chief Enforcement Attorney Joe Turek, Deputy Director David Fais, Deputy Director Jonithon LaCross, Director Public Policy and Government Affairs

Dr. Soin called the meeting to order at 9:15 a.m.

Meeting Minutes Review

Dr. Soin reported that the draft minutes of the May 8, 2019 meeting had been distributed to the committee and were included in the agenda materials.

Dr. Bechtel moved to approve the draft minutes of the May 8, 2019 Policy Committee meeting. Mr. Giacalone seconded the motion. Motion carried.

Rules Review Update

Ms. Anderson referred to the report included in the agenda materials. She noted that the dietetics rules are scheduled for committee review in July or possibly August. The controlled substance rules, which include the OARRS rule, are slated for committee review in July.

She said we are making good progress with the rules under review by Common Sense Initiative Office (CSI). The light-based medical device rules remain pending in antitrust review. Ms. Anderson reported that she, Ms. Debolt and Mr. Smith recently met with a representative from CSI about the rules. We are waiting on CSI response.

Legislative Update

Mr. LaCross reported that the Senate Substitute Budget bill was released yesterday afternoon. Three issues were removed in the Senate version: the telemedicine certificate removal, CME change, and limited certificate removal issue. We are working with Senate Policy staff to see if we can get those items restored. We had three other issues prepped addressing PAs, podiatric hyperbaric training, and teleconferencing committee meetings and these did not make it in the Senate bill either, but we are redrafting these issues and working with Senator Burke's office.

He reported that the Finance Committee just discussed lowering PA initial licensing fees at its meeting this morning, so that topic may help us with the other issues. Mr. LaCross was optimistic about getting the items inserted in the bill.

Dr. Bechtel for an update on rules/regulations for telemedicine. Mr. LaCross reported that we were trying to eliminate the telemedicine certificate because of the CME change. Telemedicine license holders were required to obtain 50 category 1 hours while other physician licensees were required to obtain a minimum of 40 hours category 1 hours. With changing the CME hours to 50 hours of Category 1 credit for all physicians, there was no need for a separate telemedicine license. If the changes are approved in the budget all telemedicine licensees will be converted to a full license.

Dr. Johnson asked what the objections were regarding the CME change. Mr. LaCross said we don't know as it seemed as if all were on board for the change.

Proposed legislative change related to loss of NCCPA certification

Mr. Turek said the licensure committee discussed this matter in May and considered legislative language that, conceptually, would differentiate between PAs who lost NCCPA certification due to discipline and those who lost certification due to failure to recertify or renew.

Licensure committee was in favor of pursuing a statutory amendment to further clarify the law. He said those who failed to recertify or renew would have 120 takes to obtain NCCPA certification or they would have to cease practice until certification was regained. A PA who had certification suspended or revoked by the NCCPA would have to immediately cease practice and inform the medical board within 14 days after the PA received the notice of change in certification status.

Mr. LaCross said that licensure committee supported the changes, so he had statutory language drafted. It is now waiting to see if he can get it in the budget bill.

Mr. Giacalone moved to approve that the board staff pursue legislative amendments to Ohio law related to loss of certification by physician assistants. Dr. Bechtel seconded the motion. Motion carried.

Changes to rule 4731-13-13, OAC Hearing Subpoenas

Ms. Anderson said that the committee reviewed the proposed amended rule last month. Rule 4731-13-13, Ohio Administrative Code, sets the timeframe for filing a subpoena requesting the production of books, records and papers (subpoenas duces tecum) for an administrative hearing. The rule is proposed to be amended at paragraph (B) to clarify the filing deadline.

No comments were received when document sent to interested parties.

Dr. Bechtel moved to recommend that the Medical Board approve the proposed amended rule to be filed with the Common Sense Initiative Office. Mr. Giacalone seconded the motion. Motion carried.

Changes to Chapters 4730-1, 4730-2 and 4730-3, OAC regarding Physician Assistants

Ms. Debolt reported that the proposed changes to the physician assistant rules reflect statutory changes enacted in Senate Bill 259. The proposed rules were circulated to interested parties and only one comment was received, which was in support of the changes.

Dr. Bechtel moved to recommend that the Medical Board approve the proposed rules to be filed with the Common Sense Initiative Office. Mr. Giacalone seconded the motion. Motion carried.

Changes to Chapter 4761, OAC regarding Respiratory Therapists

Mr. Smith said that this is the second round of respiratory care rules updated to comply with statues and medical board processes. He referred to the memorandum in the committee agenda materials that summarized the proposed changes. He noted that Rules 4761-9-01, 4761-9-04 and 4761-9-05 take the board out of the business of approving the respiratory care and professional ethics courses.

Five comments were received following initial circulation of the proposed rules. Additionally, the Respiratory Care Advisory Committee (RCAC) reviewed the draft and recommended approval to the board to file with CSI with one potential change which was also advocated for by the Ohio Society of Respiratory Care (OSRC). Most comments were positive, and a few were not related to the substance of the rules.

He said the OSRC suggested further defining "relevant college credit" so that it would be limited to respiratory care related classes. The following change is proposed to Rule 4761-9-05 Approved Sources of Respiratory Care Continuing Education (RCCE):

(A) Applicants for renewal shall successfully complete the required number of RCCE contact hours according to rule 4761-9-02 of the Administrative Code. RCCE earned from any combination of the following sources may be applicable towards meeting RCCE requirements:

(1) Relevant college credit awarded by an academic institution accredited by its regional accrediting association. **This is limited to respiratory care related classes.**

Dr. Bechtel moved to recommend that the Medical Board approve the amendment to the proposed rule and send the amended proposed rules to the full board for approval to be filed with the Common Sense Initiative Office. Mr. Giacalone seconded the motion. Motion carried.

Changes to Rules with Military Service Provisions

Mr. Smith said these rules are carrying out the board's requirement to comply with several statutes in Chapter 5903, ORC, which relates to occupational licensure, renewal of licensure, and expedited processing of licensing applications and continuing education for military members. He said we combined 14 rules in seven different OAC chapters into three rules into new chapter 4731.36 as 4731.36.01, 4731.36.02, and 4731.36.03. He reported that the Respiratory Care Advisory Council and the Dietetics Advisory Council reviewed the proposed rules and both Council's recommended board approval of filing the proposed rules with CSI.

Mr. Smith said we received 25 comments about the rules: eight were in support of the rules; several did not address the rules substantively, and two comments did not favor any changes to the rules.

The remaining relevant comments included five (5) comments that suggested explicitly recognizing the military medical school and/or military graduate medical education programs in proposed rule 4731-36-02(B)(3) for doctors. The rule as currently proposed states:

(3) For purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.

The comments suggested that the wording was confusing and that a more explicit inclusion of accredited military medical schools and accredited military graduate medical education is necessary for clarification. **The following change is proposed for rule 4731-36-02(B)(3), (4)**:

(3) For purposes of section 5903.03 of the Revised Code, the board has determined that:

> **(a) A diploma from a military medical school or military osteopathic medical school that at the time the diploma was issued was a medical school accredited by the liaison committee on medical education or an osteopathic medical school accredited by the American osteopathic association are substantially equivalent to the medical educational requirement for licensure to practice medicine and surgery or osteopathic medicine and surgery;**
>
> **(b) Military graduate medical education that is accredited by the Accreditation Council for Graduate Medical Education is substantially equivalent to the graduate medical educational requirement for licensure to practice medicine and surgery or osteopathic medicine and surgery; and**
>
> **(c) There are no military primary specialties or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure to practice medicine and surgery or osteopathic medicine and surgery.**

(4) For purposes of section 5903.03 of the Revised Code, the board has determined that:

> **(a) A degree from a military college of podiatric medicine and surgery that at the time the degree was granted was a college of podiatric medicine and surgery accredited by the Council on Podiatric Medical Education is substantially equivalent to the medical educational requirement for licensure to practice podiatric medicine and surgery;**
>
> **(b) Military postgraduate training in a podiatric internship, residency, or clinical fellowship program accredited by the Council on Podiatric Medicine is substantially equivalent to the graduate medical educational requirement for licensure to practice podiatric medicine and surgery; and**
>
> **(c) There are no military primary specialties or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure to practice podiatric medicine and surgery.**

One additional comment expressed the need for a clear definition of veteran. In response, t**he following change incorporating the definitions of “service member” and “veteran” from R.C. 5903.01 is**

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proposed to be added to the definitions in rule 4731-36-01(A):

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

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

Lastly, two comments pointed out a typographical error, and the word “free” was changed to “fee” in proposed rule 4731-36-02(A) as stated below:

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

Dr. Bechtel moved recommend that the Medical Board approve the amendment to the proposed rule and send the amended proposed rules to the full board for approval to be filed with the Common Sense Initiative Office. Mr. Giacalone seconded the motion. Motion carried.

Adjourn

Dr. Bechtel moved to adjourn the meeting. Motion seconded by Mr. Giacalone. Motion carried.

The meeting adjourned at 9:31 a.m.

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Ohio | State Medical Board of Ohio

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MEMORANDUM

TO: Robert P. Giacalone, Acting Chair, Policy Committee
Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Progress

DATE: June 26, 2019

Attached please find the Rule Review Spreadsheet and status of the rules under review.

Action Requested: No Action Requested

Legal Dept. Rules Schedule

As of 6/27/19

For July Policy Committee

4731-11-02	4731-11-03
4731-11-04	4731-11-04.1
4731-11-05	4731-11-07
4731-11-11	4730-4-01
4730-4-02	4731-33-01
4731-33-02	

For July Board Meeting

4731-18-01	4731-6-14	4731-6-31
4731-25-08	4731-6-15	4731-6-32
4731-6-01	4731-6-16	4731-6-33
4731-6-02	4731-6-21	4731-6-34
4731-6-03	4731-6-22	4731-6-35
4731-6-05	4731-24-01	4731-1-02
4731-6-07	4731-24-02	4731-16-16
4731-6-10	4731-24-03	4731-31-01
4731-34-01	4731-6-30	4731-24-05
4731-7-01		

RULES AT CSI

4731-18 Chapter (anti-trust review)

Comment Deadline 5/14/19

4731-9-01

Comment Deadline 5/13/19

4730-3-01	4730-3-02
4731-4-01	4731-4-02
4759-4-11	4774-2-01
4774-2-02	4778-2-01
4778-2-02	

Comment Deadline 4/10/19

4731-11-01	4731-35-01
4731-11-14	4731-35-02

Comment deadline (resubmitted)

4731-1-24

Comment deadline 8/24/17

4731-1-01	4731-1-13
4731-1-11	4731-1-18
4731-1-19	

Ready to File with CSI

4731-13-13	4731-33-02	4731-33-01
4761-5-01	4761-5-04	4761-5-06
4761-6-01	4761-7-04	4761-5-02
4761-9-01	4761-9-04	4761-10-03
4761-9-05	4761-9-07	4761-8-01
4761-9-02	4730 Chapters 1, 2 and 3	

Military provisions for all license types

READY TO FILE WITH JCARR

4759 Chapter

RULES AT JCARR

Hearing Held 6/5/19

4731-1-05 4731-1-24

Anticipated Schedule for 2019 Policy Committee

January:	*Consult Agreements – sent for initial comment–deadline 2/8/19*
February:	*4731-7-01 (Method of Notice of Meetings) ;4731-9-01 (Record of Board Meetings) ;4731-4-01;4731-4-02 (Criminal Records Checks) – to February Policy Committee*
March:	*Military Rules for all License Types*
April:	*Respiratory Care Rules – 4761 – 2nd group*
May:	MAT Detox Rules Hearing Rule 4731-13-13
June:	*Dietetics Rules – moved to August*
July:	4731-11-03; 4731-11-04; 4731-11-041; 4731-11-05; 4731-11-11 (Controlled Substance Rules)
August:	Dietetics Rules

Rule Number	Rule Description	Committee Agenda Date	Comm approval to send for initial comment	Sent for Initial Comment	Comm/Bd Agenda to review comments	Board Approval to File with CSI	CSI filing	CSI recom-mendation	Approved to File with JCARR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4730-1-01	Regulation of Physician Assistants - Definitions		03/09/16	03/11/16	06/12/19	6/12/19 5/11/16	08/02/17			06/20/18	07/24/18		09/12/18	09/30/18	09/30/23
4730-1-02	*Physician Assistant Practice*		*04/13/16*	*04/15/16*		*06/08/16*	*08/02/17*			*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-1-03	*Duties of a Supervising Physician*		*04/13/16*	*04/15/16*		*06/08/16*	*08/02/17*			*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-1-04	*Supervision*		*04/13/16*	*04/15/16*		*06/08/16*	*08/02/17*			*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-1-05	Quality Assurance System		03/09/16	12/22/17 3/11/2016	06/12/19	6/12/19 3/14/18	04/02/18			06/20/18	07/24/18				08/07/23
4730-1-06	Licensure as a physician assistant		04/13/16	3/22/19 6/20/17 4/15/2016	06/12/19	6/12/19 7/12/17 6/8/16	8/2/2017			07/02/18 6/20/2018	07/24/18		09/12/18	09/30/18	09/30/23
4730-1-06.1	*Military provisions related to certificate to practice as a physician assistant*			*03/22/19*	*06/12/19*	*06/12/19*				*06/20/18*	*07/24/18*				*09/30/20*
4730-1-07	Miscellaneous Provisions		04/13/16	04/15/16	06/12/19	6/12/19 6/8/2016	08/02/17			06/20/18	07/24/18		09/12/18	09/30/18	09/30/23
4730-1-08	Physician assistant delegation of medical tasks and administration of drugs		11/04/15	11/06/15	06/12/19	06/12/19	02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4730-2-01	Physician Delegated Prescriptive Authority - Definitions			05/13/16		6/12/19 8/10/16	08/02/17			06/20/18	07/24/18		09/12/18	Amended 9/30/18	03/19/19
4730-2-02	*Educational Requirements for Prescriptive Authority*		*03/09/16*	*03/11/16*		*05/11/16*	*08/02/17*			*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-2-03	*Application for a Provisional Certificate to Prescribe*			*04/15/16*		*06/08/16*	*08/02/17*			*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-2-04	Period of on-site supervision of physician-delegated prescriptive authority			12/22/17	06/12/19	6/12/19 3/14/18	04/02/18			08/20/18	09/26/18		11/14/18	11/30/18	11/15/23
4730-2-05	Addition of valid prescriber number after initial licensure			12/22/17	06/12/19	6/12/19 3/14/18	04/02/18			08/20/18	09/26/18		11/14/18	11/30/18	11/15/23
4730-2-06	Physician Assistant Formulary			05/13/16	06/12/19	06/12/19									06/30/19
4730-2-07	Standards for Prescribing			05/13/16		6/12/19 8/10/16	08/02/17			06/20/18	07/24/18			Amended 9/30/18	06/30/19
4730-2-08	*Standards for Personally Furnishing Drugs and Therapeutic Devices*			*05/13/16*		*08/10/16*	*08/02/17*			*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-2-09	*Standards for Personally Furnishing Samples of Drugs and Therapeutic Devices*			*05/13/16*		*08/10/16*	*08/02/17*			*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-2-10	Standards and Procedures for use of OARRS		03/09/16	03/11/16	06/12/19	6/12/19 5/11/16	08/02/17			06/20/18	07/24/18		09/12/18	09/30/18	09/30/23

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4730-3-01	Criminal Records Checks - (For Physician Assistants) - Definitions		04/13/16	04/15/16	06/12/19	6/12/19 6/8/16	04/23/19	05/31/19		06/20/18	07/24/18			Amended 9/30/18	06/30/19
4730-3-02	Criminal Records Checks		04/13/16	04/15/16	06/12/19	6/12/19 6/8/16	04/23/19	05/31/19		06/20/18	07/24/18			Amended 9/30/18	06/30/19
4730-4-01	Definitions			02/21/18	07/10/19	07/11/18	08/03/18			4/10/19 refiled 2/15/19 10/24/2018	11/28/18		04/10/19	04/30/19	04/30/24
4731-4-02	Standards and procedures for withdrawal management for drug or alchohol addiction				07/10/19										
4730-4-03	Office Based Treatment for Opioid addiction			02/21/18		07/11/18	08/03/18			4/10/19 refiled 2/15/19 10/24/2018	11/28/18		04/10/19	04/30/19	04/30/24
4730-4-04	Medication assisted treatment using naltrexone			02/21/18		07/11/18	08/03/18			4/10/19 refiled 2/15/19 10/24/2018	11/28/18		04/10/19	04/30/19	04/30/24
4731-1-01	Limited Practitioners - Definition of Terms			5/15/17 7/13/2016		7/12/17 9/14/2016	08/07/17	06/12/19						01/24/12	01/24/17
4731-1-02	Application of Rules Governing Limited Branches of Medicine or Surgery		12/10/14 05/13/15	05/14/18		09/14/16	09/24/18			4/10/19 7/1/2015	05/13/19		09/09/15	09/30/15	09/30/20
4731-1-03	General Prohibitions			07/13/16		09/14/16	09/26/17			08/31/18			no change		08/31/23
4731-1-04	Scope of Practice: Mechanotherapy		04/13/16	04/15/16		09/14/16	09/26/17			12/12/18 9/24/2018	10/25/18		12/12/18	12/31/18	12/31/23
4731-1-05	Scope of Practice: Massage Therapy							04/24/19	04/24/19	04/29/19	06/05/19			12/31/18	12/31/23
4731-1-06	Scope of Practice: Naprapathy		04/13/16	04/15/16		09/14/16	09/26/17			08/31/18			no change		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					09/14/16	09/26/17			09/24/18	10/25/18		12/12/18	12/31/18	12/31/23

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4731-1-08	Continuing Cosmetic Therapy Education Requirements for Registration or Reinstatement of a License to Practice Cosmetic Therapy			07/18/18		09/14/16	10/31/18 2/20/2018	06/12/19							12/31/17
4731-1-09	Cosmetic Therapy Curriculum Requirements			07/13/16		09/14/16	09/26/17			08/31/18			no change		08/31/23
4731-1-10	Distance Education			07/13/16		09/14/16	09/26/17			09/24/18	10/25/18		01/09/19	01/31/19	01/31/24
4731-1-11	Application and Certification			5/15/17 7/13/2016		07/12/17 9/14/2016	08/07/17	06/12/19							01/24/17
4731-1-12	Examination		12/09/15	12/11/15		02/10/16	03/07/16	*05/11/16*		08/16/16	09/19/16		11/09/16	11/30/16	11/30/21
4731-1-13	Examination Failure; Additional Training			5/15/17 7/13/2016		7/12/17 9/14/2016	08/07/17	06/12/19							01/24/17
4731-1-14	*Preliminary Education Certificate*					*09/14/16*									*rescinded*
4731-1-15	Determination of Standing of School, College or Institution			07/13/16		09/14/16	09/26/17			09/24/18	10/25/18		12/12/18	12/31/18	12/31/23
4731-1-16	Massage Therapy curriculum rule (Five year review)		12/09/15	6/20/18 12/11/201 5		02/10/16	8/24/18 3/7/2016	*05/11/16*		10/24/18 8/16/2016	11/28/18 9/19/2016		1/9/19 11/9/2016	01/31/19	11/30/21
4731-1-17	Instructional Staff			07/13/16		09/14/16	09/26/17			09/24/18	10/25/18		05/08/19	05/31/19	05/31/24
4731-1-18	Grounds for Suspension, Revocation or Denial of Certificate of Good Standing, Hearing Rights			5/15/17 7/13/2016		7/12/17 9/14/2016	08/07/17	06/12/19							01/24/17
4731-1- 19	Probationary Status			5/15/17 7/13/2016		7/12/17 9/14/2016	08/07/17	06/12/19							01/24/17
4731-1-23	*Home Study Schools*														*rescinded*
4731-1-24	Massage Therapy Continuing Education		2nd - 3/29/17 3/9/2016	03/09/16			10/26/16	04/24/19	04/24/19	04/29/19	06/05/19				
4731-1-25	*Determination of Equiv. Military Educ. For CT/MT*		*05/13/15*	*3/22/19* *7/23/15*	*06/12/19*	*06/12/19*	*07/23/15*			*7/1/2015* *9/24/15*	*11/02/15*		*12/09/15*	*12/31/15*	*12/31/20*
4731-2-01	Public Notice of Rules Procedure		10/14/15	04/15/16		06/08/16		11/08/17 7/12/2017		09/19/17	10/25/17			12/07/17	12/07/22
4731-4-01	Criminal Records Checks - Definitions			02/20/19			04/23/19	05/31/19							06/29/19
4731-4-02	Criminal Records Checks			02/20/19			04/23/19	05/31/19							06/29/19
4731-5-01	Admission to Examinations			2/8/17 5/13/2016		07/13/16				06/09/17	no change				06/09/22

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4731-5-02	Examination Failure; Inspection and Regrading			2/8/17 5/13/2016		07/13/16				06/09/17	no change				06/09/22
4731-5-03	Conduct During Examinations			2/8/17 5/13/2016		07/13/16				06/09/17	no change				06/09/22
4731-5-04	Termination of Examinations			2/8/17 5/13/2016		07/13/16				06/09/17	no change				06/09/22
4731-6-01	Medical or Osteopathic Licensure: Definitions			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		08/09/17	08/31/17	08/31/22
4731-6-02	Preliminary Education for Medical and Osteopathic Licensure			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19				06/09/22
4731-6-03	Eligibility for the Medical and Osteopathic Examination			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19				06/09/22
4731-6-04	Demonstration of proficiency in spoken English			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			06/09/17	no change				06/09/22
4731-6-05	Format of Medical and Osteopathic Examination			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		06/09/17	08/31/17	08/31/22
4731-6-07	Passing Average on Examination			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19				06/09/22
4731-6-10	Clinical Competency Examination			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		06/09/17	08/31/17	06/09/22
4731-6-14	Examination for physician licensure			2/26/18 2/8/2017		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19				04/29/19
4731-6-15	Eligibility for Licensure of National Board Diplomats and Medical Council of Canada Licentiates			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19				06/09/22
4731-6-16	Eligibility for Medical or Osteopathic Licensure by Endorsement of Licenses Granted by Other States			2/26/18 2/8/2017		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19				04/29/19

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4731-6-20	*Requests for medical or osteopathic licensure application*														*rescinded*
4731-6-21	Application Procedures for Certificate Issuance; Investigation; Notice of Hearing Rights			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		08/09/17	08/31/17	08/31/22
4731-6-22	Abandonment and Withdrawal of Medical and Osteopathic Licensure Applications			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		08/09/17	08/31/17	08/31/22
4731-6-30	Training Certificates			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		08/09/17	08/31/17	08/31/22
4731-6-31	Limited Preexamination Registration and Limited Certification			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19				06/09/22
4731-6-32	Visiting Faculty Certificates			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		08/09/17	08/31/17	08/31/22
4731-6-33	Special Activity Certificates			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		08/09/17	08/31/17	08/31/22
4731-6-34	Volunteer's Certificates			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 5/23/17	5/13/19 6/23/17		08/09/17	08/31/17	08/31/22
4731-6-35	*Processing applications from service members, veterans, or spouses of service members or veterans.*		*05/13/15*	*3/22/19 2/26/18 2/8/17*	*06/12/19*	*06/12/19*	*9/25/18 1/8/2015*			4/10/19 6/9/2017	05/13/19		*09/09/15*	*09/30/15*	*09/30/20*
4731-7-01	Method of Notice of Meetings								04/08/19	04/29/19	06/05/19			12/31/15	12/31/20
4731-8-01	Personal Information Systems			02/20/19										no change	04/21/21
4731-8-02	Definitions													no change	04/21/21
4731-8-03	Procedures for accessing confidential personal information													no change	04/21/21
4731-8-04	Valid reasons for accessing confidential personal information													no change	04/21/21

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4731-8-05	Confidentiality Statutes			01/15/16				04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-8-06	Restricting & Logging access to confidential personal information			01/15/16				04/13/16		04/21/16					04/21/21
4731-9-01	Record of Board Meetings; Recording, Filming, and Photographing of Meetings			02/20/19		04/08/19	04/30/19	06/13/19		06/17/19	no change			09/15/19	06/17/24
4731-10-01	Definitions		06/08/16	06/09/16		08/10/16	07/31/17			02/02/18					02/02/23
4731-10-02	Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement		06/08/16	6/20/17 6/9/2016		08/10/16	09/26/17						05/09/18	05/31/18	05/31/23
4731-10-03	CME Waiver		06/08/16	06/09/16		08/10/16	07/31/17			02/02/18			05/09/18	05/31/18	05/31/23
4731-10-04	Continuing Medical Education Requirements for Restoration of a License		06/08/16	06/09/16		08/10/16	07/31/17						05/09/18	05/31/18	05/31/23
4731-10-05	Out-of-State Licensees		06/08/16	06/09/16		08/10/16	07/31/17			02/02/18			05/09/18	05/31/18	05/31/23
4731-10-06	Licensure After Cutoff for Preparation of Registration Notices		06/08/16	06/09/16		08/10/16	07/31/17			02/02/18			05/09/18	05/31/18	05/31/23
4371-10-07	Internships, Residencies and Fellowships		06/08/16	06/09/16		08/10/16	07/31/17			02/02/18			05/09/18	05/31/18	05/31/23
4371-10-08	Evidence of Continuing Medical Education		06/08/16	6/20/17 6/9/2016		08/10/16	09/26/17						05/09/18	05/31/18	05/31/23
4731-10-09	Continuing Medical Education Requirement for Mid-term Licensees		06/08/16	6/20/17 6/9/2016		08/10/16	09/26/17						05/09/18	05/31/18	05/31/23
4731-10-10	Continuing Medical Education Requirements Following License Restoration		06/08/16	6/20/17 6/9/2016		08/10/16	09/26/17						05/09/18	05/31/18	05/31/23
4731-10-11	Telemedicine Certificates		06/08/16	06/09/16		08/10/16	07/31/17			02/02/18			05/09/18	05/31/18	05/31/23
4731-11-01	Controlled substances; General Provisions Definitions		8/13/2014 4/13/16	5/11/18 Revision 4/13/17 revision 9/19/16 1/22/15 4/15/16		6/13/18 6/8/2016	refiled 3/21/19 6/14/18 05/11/17 7/5/2016	11/08/17		Refiled 10/16/18 refiled 8/20/18 refiled 9/19/17 refiled 6-16-17 refiled 2/8/17 refiled 1/13/17 11/3/2016	9/26/18 10/25/17 07/26/17 12/8/2016		12/12/18	12/23/18	12/07/22

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4731-11-02	*Controlled Substances - General Provisions*		*10/8/14 05/13/15*	*5/11/18 Revision 4/13/17*		*06/13/18*	*6/14/18 05/11/17 1/8/2015*			*Refiled 10/16/18 8/20/18 6/16/17 8/24/15 7/1/2015*	*9/26/18 07/26/17 11/2/2015*		*12/12/18*	*4/30/19 12/23/18*	*12/31/20*
4731-11-03	Schedule II Controlled Substance Stimulants		10/8/14 5/13/15				01/08/15			8/24/15 7/1/2015	11/02/15		10/14/201 5	12/31/15	12/31/20
4731-11-04	Controlled Substances: Utilization for Weight Reduction		11/12/14 05/13/15				01/08/15			1/5/16 8/24/15 7/1/2015	11/02/15			02/29/16	02/28/21
4731-11-04.1	Controlled substances: Utilization for chronic weight management		9/10/14 05/13/15				01/08/15			8/24/15 7/1/2015	11/02/15		10/14/15	12/31/15	12/31/20
4731-11-05	*Use of Drugs to Enhance Athletic Ability*		*10/8/14 05/13/15*				*01/08/15*			*8/24/15 7/1/2015*	*11/02/15*		*12/09/15*	*12/31/15*	*rescinded*
4731-11-06	*Waivers for new uses*														*rescinded*
4731-11-07	Research Utilizing Controlled Substances		9/10/14 05/13/15				01/08/15			07/01/15			09/09/15	09/30/15	09/30/20
4731-11-08	Utilizing Controlled Substances for Self and Family Members		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		08/17/16					08/17/21
4731-11-09	Prescribing to persons the physician has never personally examined.		revision 9/19/16 1/14/15 05/13/15 10/8/14 4/13/16	1/22/2015 4/15/16		06/08/16	07/05/16			refiled 2/8/17 refiled (res &new) 1/13/17 11/3/2016	12/08/16			03/23/17	03/23/22
4731-11-11	Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).		revision 1/14/15 05/13/15 10/8/14	7/23/15 1/22/2015			07/23/15			09/24/15	11/02/15		12/09/15	12/31/15	12/31/20
4731-11-12	*Office-Based Opioid Treatment*		*08/31/14*				*rescind filing 8/3/18 3/28/2014*			*4/10/19 10/24/18 10/20/14*	*11/28/18 11/24/14*		*04/10/19*	*04/30/19*	*rescinded*
4731-11-13	Prescribing of Opioid Analgesics for Acute Pain			04/13/17			05/11/17				07/26/17		filed 8/21/17	08/31/17	08/31/22
4731-11-14	Prescribing for subacute and chronic pain			05/11/18		06/13/18	Refiled 3/21/19 6/14/2018			Refiled 10/16/18 8/20/2018	09/26/18		12/12/18	12/23/18	12/23/23

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4731-12-01	Preliminary Education for Licensure in Podiatric Medicine and Surgery		02/10/16	7/13/16 2/12/2016		04/13/16	07/11/16	09/14/16		03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-02	Standing of Colleges of Podiatric Surgery and Medicine		02/10/16	7/13/16 2/12/2016		04/13/16	07/11/16	09/14/16		03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-03	Eligibility for the Examination in Podiatric Surgery and Medicine (see note below)		02/10/16	7/13/16 2/12/2016		04/13/16	07/11/16	09/14/16		04/19/17	NA				04/19/22
4731-12-04	Eligibility of Licensure in Podiatric Medicine and Surgery by Endorsement from Another State		02/10/16	7/13/16 2/12/2016		04/13/16	07/11/16	09/14/16		03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-05	Application Procedures for Licensure in Podiatric Medicine and Surgery, Investigation, Notice of Hearing Rights.		02/10/16	7/13/16 2/12/2016		04/13/16	07/11/16	09/14/16		03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-06	Visiting Podiatric Faculty Certificates		02/10/16	7/13/16 2/12/2016		04/13/16	07/11/16	09/14/16		03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-07	Podiatric Training Certificates		02/10/16	7/13/16 2/12/2016		04/13/16	07/11/16			03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-13-01	Conduct of Hearings - Representative; Appearances		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-02	Filing Request for Hearing		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-03	Authority and Duties of Hearing Examiners		11/04/15	12/12/16 11/6/2015			7/31/17 2/1/2016	6/13/18 4/13/2016		6/20/18 5/5/2016	7/24/18 6/13/2016		09/12/18	09/30/18	07/31/21
4731-13-04	Consolidation		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-05	Intervention		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-06	Continuance of Hearing		11/04/15	11/06/15			02/01/16	04/13/16		8/4/16 5/5/2016	06/13/16		09/14/16	09/30/16	09/30/21
4731-13-07	Motions		11/04/15	12/12/16 11/6/2015			7/31/17 2/1/2016	6/13/18 4/13/2016		6/20/18 5/5/2016	07/24/18		09/12/18	09/30/18	04/21/21
4731-13-07.1	Form and page limitations for briefs and memoranda			12/12/16			07/31/17	06/13/18		06/20/18	07/24/18		09/12/18	09/30/18	09/30/23
4731-13-08	Filing		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-09	Service		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-10	Computation and Extension of Time		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-11	Notice of Hearings		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-12	Transcripts		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21

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4731-13-13	Subpoenas for Purposes of Hearing	5/8/2019	05/08/19	05/09/19	06/12/19	06/12/19									07/31/21
4731-13-14	Mileage Reimbursement and Witness Fees		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-15	Reports and Recommendations		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-16	Reinstatement or Restoration of Certificate		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-17	Settlements, Dismissals, and Voluntary Surrenders		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-18	Exchange of Documents and Witness Lists		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-16-19	*Prehearing conference*														*rescinded*
4731-13-20	Depositions in Lieu of Live Testimony and Transcripts in place of Prior Testimony		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-20.1	Electronic Testimony									05/05/16	06/13/16			07/31/16	07/31/21
4731-13-21	Prior Action by the State Medical Board		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-22	Stipulation of Facts		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-23	Witnesses		11/04/15	11/06/15			02/01/16	04/13/16		8/4/16 5/5/2016	06/13/16			09/14/16	09/30/21
4731-13-24	Conviction of a Crime		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-25	Evidence						02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-26	Broadcasting and Photographing Administrative Hearings		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-27	Sexual Misconduct Evidence		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-28	Supervision of Hearing Examiners		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-29	*Requirements for pre-hearing exchange of information*														*rescinded*
4731-13-30	Prehearing Conference		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-31	Transcripts of Prior Testimony		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-32	Prior Statements of the Respondent		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-33	Physician's Desk Physician		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-34	Ex Parte Communication		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-13-35	Severability		11/04/15	11/06/15			02/01/16	04/13/16		04/21/16	- -				04/21/21
4731-13-36	Disciplinary Actions		11/04/15	11/06/15			02/01/16	04/13/16		05/05/16	06/13/16			07/31/16	07/31/21
4731-14-01	Pronouncement of Death		11/04/15	11/06/15			02/01/16	03/09/16		03/15/16	04/20/16			06/30/16	06/30/21
4731-15-01	Licensee Reporting Requirement; Exceptions		06/08/16	06/09/16		08/10/16	07/31/17			11/17/17					11/17/22

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4731-15-02	Healthcare Facility Reporting Requirement		06/08/16	06/09/16		08/10/16	07/31/17			11/17/17					11/17/22
4731-15-03	Malpractice Reporting Requirement		06/08/16	06/09/16		08/10/16	07/31/17			11/17/17					11/17/22
4731-15-04	Professional Society Reporting		06/08/16	06/09/16		08/10/16	07/31/17			11/17/17					11/17/22
4731-15-05	Liability; Reporting Forms; Confidentially and Disclosure		06/08/16	06/09/16		08/10/16	07/31/17			11/17/17					11/17/22
4731-16-01	Rules governing impaired physicians and approval of treatments programs - Definitions		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-02	General Procedures in Impairment Cases		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-03	*Mental or physical impairment*														*rescinded*
4731-16-04	Other Violations		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-05	Examinations		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-06	Consent Agreements and Orders for Reinstatement of Impaired Practitioners		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-07	Treatment Provider Program Obligations		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-08	Criteria for Approval		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-09	Procedures for Approval		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-10	Aftercare Contracts		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-11	Revocation, Suspension, or Denial of Certificate of Good Standing		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-12	Out-of-State Impairment Cases		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-13	Patient Consent; Revocation of Consent		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-14	Caffeine, Nicotine, and Over-The Counter Drugs		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-15	Patient Rights		06/08/16	06/09/16		08/10/16	08/29/17			11/17/17					11/17/22
4731-16-16	*Practice Prohibition*		*06/08/16*	*12/17/18 6/9/2016*		*08/10/16*	*1/11/19 8/29/2017*			*4/10/19 11/17/17*	*05/13/19*				*11/17/22*
4731-16-17	Requirements for the one-bite program			03/21/18			05/30/18			10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-16-18	Eligibility for the one-bite program			03/21/18			05/30/18			10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-16-19	Monitoring organization for one-bite program			03/21/18			05/30/18			10/24/18	11/28/18		01/09/19	01/31/19	01/31/24

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4731-16-20	Treatment providers in the one-bite program			03/21/18			05/30/18			10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-16-21	Continuing care for the one-bite program			03/21/18			05/30/18			10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-17-01	Exposure-Prone Invasive Procedure Precautions - Definitions		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		10/20/16 8/16/2016	09/19/16		12/14/16	12/31/16	12/31/21
4731-17-02	Universal Precautions		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		08/16/16	09/19/16		11/09/16	11/30/16	11/30/21
4731-17-03	Hand Washing		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		08/17/16					08/17/21
4731-17-04	Disinfection and Sterilization		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		10/20/16 8/16/2016	09/19/16		12/14/16	12/31/16	12/31/21
4731-17-05	Handling and Disposal of Sharps and Wastes		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		08/17/16					08/17/21
4731-17-06	Barrier Techniques		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		08/17/16					08/17/21
4731-17-07	Violations		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		08/16/16	09/19/16		10/19/16	11/09/16	11/30/21
4731-18-01	*Standards for Surgery*			*1/17/18 1/15/2016*		*03/14/18*	*06/27/18*			*04/10/19*	*05/13/19*				*05/04/00*
4731-18-02	Use of Light Based Medical Devices			1/17/18 1/15/2016		03/14/18									06/30/05
4731-18-03	Delegation of the Use of Light Based Medical Devices			1/17/18 1/15/2016		03/14/18									06/30/05
4731-18-04	Delegation of the Use of Light Based Medical Devices; Exceptions			1/17/18 1/15/2016		03/14/18									05/31/07
4731-19-01	*Duty of License to Report HIV or HBV Infection; Confidentiality*		*12/09/15*	*12/11/15*		*02/10/16*	*03/07/16*	*05/11/16*		*08/16/16*	*09/19/16*		*Rescinded1 1/9/2016*	*11/30/16*	*Rescinded1 1/9/2016*
4731-19-02	*Licensee's Duty to Report Infection with HIV or HBV*		*12/09/15*	*12/11/15*		*02/10/16*	*03/07/16*	*05/11/16*		*08/16/16*	*09/19/16*		*Rescinded 11/9/2016*	*11/30/16*	*Rescinded 11/9/2016*
4731-19-03	*Confidentiality; Reporting by Board*		*12/09/15*	*12/11/15*		*02/10/16*	*03/07/16*	*05/11/16*		*08/16/16*	*09/19/16*		*Rescinded1 1/9/2016*	*11/30/16*	*Rescinded1 1/9/2016*
4731-19-04	*Voluntary Compliance*		*12/09/15*	*12/11/15*		*02/10/16*	*03/07/16*	*05/11/16*		*08/16/16*	*09/19/16*		*Rescinded 11/9/2016*	*11/30/16*	*Rescinded 11/9/2016*
4731-19-05	*Duty to Refrain from Certain Procedures*		*12/09/15*	*12/11/15*		*02/10/16*	*03/07/16*	*05/11/16*		*08/16/16*	*09/19/16*		*Rescinded1 1/9/2016*	*11/30/16*	*Rescinded1 1/9/2016*

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4731-19-06	*Board Procedures*		*12/09/15*	*12/11/15*		*02/10/16*	*03/07/16*	*05/11/16*		*08/16/16*	*09/19/16*		*Rescinded 11/9/2016*	*11/30/16*	*Rescinded 11/9/2016*
4731-19-07	*Confidential Monitoring Program*		*12/09/15*	*12/11/15*		*02/10/16*	*03/07/16*	*05/11/16*		*08/16/16*	*09/19/16*		*Rescinded1 1/9/2016*	*11/30/16*	*Rescinded1 1/9/2016*
4731-20-01	Surgery Privileges of Podiatrist - Definition of Foot		03/09/16	03/11/16		05/11/16	07/31/17	02/14/18					05/09/18	05/31/18	05/31/23
4731-20-02	Surgery: Ankle Joint		03/09/16	03/11/16			07/31/17	02/14/18					05/09/18	05/31/18	05/31/23
4731-21-01	*Drug Treatment of Intractable Pain - Definitions*		*03/09/16*	*7/13/16 3/11/2016*		*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*		*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-21-02	*Utilizing Prescription Drugs for the Treatment of Intractable Pain*		*03/09/16*	*7/13/16 3/11/2016*		*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*		*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-21-03	*Continuing Medical Education*		*03/09/16*	*7/13/16 3/11/2016*		*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*		*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-21-04	*Tolerance, Physical Dependence and Addiction*		*03/09/16*	*7/13/16 3/11/2016*		*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*		*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-21-05	*Violations*		*03/09/16*	*7/13/16 3/11/2016*		*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*		*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*no change*				*rescinded 12/23/18*

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4731-21-06	*Exceptions*		*03/09/16*	*7/13/16* *3/11/2016*		*06/13/18*	*6/14/18* *7/11/2016*	*10/19/16*		*Refiled 10/16/18 rescind filed 8/20/18* *5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-22-01	Emeritus Registration - Definitions		03/09/16	7/13/16 3/11/2016			07/11/16	09/14/16		(Revised 6-5-17 for XML version) 5/23/2017	06/23/17		08/09/17	08/31/17	08/31/22
4731-22-02	Application		03/09/16	7/13/16 3/11/2016			07/11/16	09/14/16		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-22-03	Status of Registrant		03/09/16	7/13/16 3/11/2016			07/11/16	09/14/16		05/12/17					05/12/22
4731-22-04	Continuing Education Requirements		03/09/16	7/13/16 3/11/2016			07/11/16	09/14/16		05/12/17					05/12/22
4731-22-05	*Documentation of Status*														*rescinded*
4731-22-06	Renewal of Cycle of Fees		03/09/16	7/13/16 3/11/2016			07/11/16	09/14/16		05/12/17					05/12/22
4731-22-07	Change to Active Status		03/09/16	7/13/16 3/11/2016			07/11/16	09/14/16		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-22-08	Cancellation of or Refusal to Issue an Emeritus Registration		03/09/16	7/13/16 3/11/2016			07/11/16	09/14/16		05/12/17					05/12/22
4731-23-01	Delegation of Medical Tasks - Definitions			01/15/16			04/04/16	05/11/16		08/16/16	09/19/16		11/09/16	11/30/16	11/30/21
4731-23-02	Delegation of Medical Tasks			01/15/16			04/04/16	05/11/16		08/16/16	09/19/16		11/09/16	11/30/16	11/30/21
4731-23-03	Delegation of Medical Tasks: Prohibitions			01/15/16			04/04/16	05/11/16		08/17/16					08/17/21
4731-23-04	Violations			01/15/16			04/04/16	05/11/16		08/17/16					08/17/21
4731-24-01	Anesthesiologist Assistants - Definitions			10/30/18			1/11/19 11/7/2013			4/10/19 2/19/14	05/13/19				03/19/19
4731-24-02	Anesthesiologist Assistants; Supervision			10/30/18			1/11/19 11/7/2013			4/10/19 2/19/14	05/13/19				03/19/19

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4731-24-03	Anesthesiologist Assistants; Enhanced Supervision			10/30/18			1/11/19 11/7/2013			4/10/19 2/19/14	05/13/19				03/19/19
4731-24-04	*Anesthesiologist Assistants; Prohibitions*						*11/07/13*			*06/17/14*	*04/23/14*		*06/11/14*	*06/17/14*	*rescinded*
4731-24-05	*Military Provisions Related to Certificate to Practice as an Anesthesiologist Assistant*			*03/22/19*	*06/12/19*	*06/12/19*	*01/11/19*		*04/08/19*	04/29/19	06/05/19				*09/30/20*
4731-25-01	Office-Based Surgery - Definition of Terms		10/19/16 05/11/16	01/15/16			07/31/17	02/14/18							03/01/23
4731-25-02	General Provisions			01/15/16		05/11/16	07/31/17	02/14/18					05/09/18	05/31/18	05/31/23
4731-25-03	Standards for Surgery Using Moderate Sedation/Analgesia			01/15/16		05/11/16	07/31/17	02/14/18					05/09/18	05/31/18	08/31/23
4731-25-04	Standards for Surgery Using Anesthesia Services			01/15/16		05/11/16	07/31/17	02/14/18					05/09/18	05/31/18	05/31/23
4731-25-05	Liposuction in the Office Setting			01/15/16		05/11/16	07/31/17	02/14/18							03/01/23
4731-25-07	Accreditation of Office Settings			01/15/16		05/11/16	07/31/17	02/14/18					05/09/18	05/31/18	05/31/23
4731-25-08	Standards for Surgery			01/17/18			06/27/18			*04/10/19*	*05/13/19*				
4731-26-01	Sexual Misconduct - Definitions		11/04/15	11/06/15			02/01/16	03/09/16		03/15/16	04/20/16			06/30/16	06/30/21
4731-26-02	Prohibitions		11/04/15	11/06/15			02/01/16	03/09/16		03/15/16	04/20/16				06/14/21
4731-26-03	Violations; Miscellaneous		11/04/15	11/06/15			02/01/16	03/09/16		03/15/16	04/20/16			06/30/16	06/30/21
4731-27-01	Definitions			05/11/18			08/03/18			02/03/19					02/02/24
4731-27-02	Dismissing a patient from the medical practice			05/11/18			08/03/18			02/06/19	03/12/19		05/08/19	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			05/11/18			08/03/18			02/06/19	03/12/19		05/08/19	05/31/19	05/31/24
4731-28-01	Mental or Physical Impairment		12/09/15	12/11/15		02/10/16	03/07/16			05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-28-02	Eligibility for confidential monitoring program			04/10/17			02/06/18			05/30/18	07/09/18		08/08/18	08/31/18	08/31/23
4731-28-03	Participation in the confidential monitoring program			04/10/17			02/06/18			05/30/18	07/09/18		08/08/18	08/31/18	08/31/23
4731-28-04	Disqualification from continued participation in the confidential monitoring program			04/10/17			02/06/18			05/30/18	07/09/18		08/08/18	08/31/18	08/31/23

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4731-28-05	Termination of the participation agreement for the confidential monitoring program			04/10/17			02/06/18			05/30/18	07/09/18		08/08/18	08/31/18	08/31/23
4731-29-01	Standards and procedures for operation of a pain management clinic.			07/13/16			07/11/16	12/14/16		03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-30-01	Internal Management Definitions												09/12/18	09/23/18	
4731-30-02	Internal Management Board Metrics												09/12/18	09/23/18	
4731-31-01	Requirements for assessing and granting clearance for return to practice or competition. (concussion rule)		05/13/15	02/26/18			5/16/18 6/2/2015			4/10/19 9/8/2015	05/13/19		09/09/15	09/18/15	09/18/20
4731-32-01	Definition of Terms						03/23/17			06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-32-02	Certificate to Recommend Medical Marijuana						03/23/17			06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-32-03	Standard of Care						03/23/17			06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-32-04	Suspension and Revocation of Certificate to Recommend						03/23/17			06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-32-05	Petition to Request Additional Qualifying Condtion or Disease						03/23/17			06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-33-01	Definitions	5/8/2019	05/08/19	05/09/19	07/10/19									04/30/19	04/30/24
4731-33-02	Standards and procedure for withdrawal managment for drug or alcohol addiction	5/8/2019	05/08/19	05/09/19	07/10/19										
4731-33-03	Office-Based Treatment for Opoid Addiction		02/14/18	02/21/18			08/03/18			4/10/19 refiled 2/15/19 10/24/2018	11/28/18		04/10/19	04/30/19	04/30/24
4731-33-04	Medication Assisted Treatment Using Naltrexone						08/03/18			4/10/19 refiled 2/15/19 10/24/2018	11/28/18		04/10/19	04/30/19	04/30/24
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.		04/11/18	04/19/18			06/27/18			04/10/19	05/13/19				

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4731-35-01	Consult Agreements			01/18/19			03/21/19								
4731-35-02	Standards for managing drug therapy			01/18/19			03/21/19								
4731-36-01	Military provisions related to education and experience requirements for licensure		03/13/19	03/22/19	06/12/19	06/12/19									
4731-36-02	Military provisions related to renewal of license and continuing education		03/13/19	03/22/19	06/12/19	06/12/19									
4731-36-03	Processing applications from service members, veterans, or spouses of service members or veterans.		03/13/19	03/22/19	06/12/19	06/12/19									
4759-1-01	*Public notice of rule adoption*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-1-02	*Notice of board meeting*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-1-03	*Personal information systems*		04/11/18	04/19/18		07/11/18	09/25/18								*To Be rescinded*
4759-2-01	Definitions		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-3-01	*Duties of Board members*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-3-02	*Executive secretary/executive director*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-3-03	*Minutes of board meetings*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-3-04	*Cooperation and communication with professional organizations*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-3-05	*Advisory committees*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-3-06	*Parliamentary procedures*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-3-07	*Adjudication hearings*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-4-01	Applications		04/11/18	04/19/18		07/11/18	09/25/18								
4759-4-02	Preprofessional experience		04/11/18	04/19/18		07/11/18	09/25/18								
4759-4-03	Examination		04/11/18	04/19/18		07/11/18	09/25/18								
4759-4-05	*Licensure by reciprocity*														*To be rescinded*
4759-4-06	*Status categories*														*To be rescinded*
4759-4-07	*Failure to maintain licensure*														*To be rescinded*
4759-4-08	Limited permit		04/11/18	04/19/18		07/11/18	09/25/18								
4759-4-09	License certificates and permits		04/11/18	04/19/18		07/11/18	09/25/18								

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4759-4-10	*Prorated initial license fee*														*To be rescinded*
4759-4-11	*Criminal records check*		04/11/18	04/19/18		07/11/18	04/23/19	*05/31/19*							*To be rescinded*
4759-4-12	*Consideration of military experience, education, training and term of service*		*04/11/18*	*3/22/19* *4/19/18*	*06/12/19*	*6/12/19* *7/11/18*	*09/25/18*								
4759-4-13	*Temporary license for military spouse*		*04/11/18*	*3/22/19* *4/19/18*	*06/12/19*	*6/12/19* *7/11/18*	*09/25/18*								
4759-5-01	Supervision of persons claiming exemption		04/11/18	04/19/18		07/11/18	09/25/18								
4759-5-02	Student practice exemption		04/11/18	04/19/18		07/11/18	09/25/18								
4759-5-03	Plan of treatment exemption		04/11/18	04/19/18		07/11/18	09/25/18								
4759-5-04	Additional nutritional activities exemption		04/11/18	04/19/18		07/11/18	09/25/18								
4759-5-05	Distribution of literature exemption		04/11/18	04/19/18		07/11/18	09/25/18								
4759-5-06	Weight control program exemption		04/11/18	04/19/18		07/11/18	09/25/18								
4759-6-01	Standards of practice innutrition care		04/11/18	04/19/18		07/11/18	09/25/18								
4759-6-02	Standards of professional performance		04/11/18	04/19/18		07/11/18	09/25/18								
4759-6-03	Interpretation of standards		04/11/18	04/19/18		07/11/18	09/25/18								
4759-7-01	*Filing of complaints*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-01	*Representatives; appearances communications; applicability*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-02	*Filing Request for Hearing*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-03	*Notice of hearings*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-04	*Authority and duties of attorney hearing examiners*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-05	*Consolidation*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-06	*Intervention*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-07	*Continuance of Hearing*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-08	*Motions*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-09	*Filing*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-10	*Service on parties*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-11	*Computation and Extension of Time*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*

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4759-8-12	*Transcripts*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-13	*Subpoenas for Purposes of Hearing*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-14	*Mileage Reimbursement and Witness Fees*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-15	*Reports and Recommendations*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-16	*Exchange of Documents and Witness Lists*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-17	*Pre-hearing conference*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-18	*Requirements for pre-hearing exchange of information*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-19	*Status conference*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-20	*Depositions and transcripts of prior testimony*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-21	*Prior action by the board*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-22	*Stipulation of Facts*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-23	*Witnesses*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-24	*Conviction of a Crime*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-25	*Rules of evidence*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-26	*Broadcasting and Photographing Administrative Hearings*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-27	*Sexual misconduct evidence*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-28	*Reinstatement of license*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-8-29	*Settlements, Dismissals, and Voluntary Surrenders*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-9-01	Severability		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-10-01	*Definitions*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-10-02	*Procedures for accessing confidential personal information*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-10-03	*Valid reasons for accessing confidential personal information*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-10-04	*Confidentiality Statutes*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*

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4759-10-05	*Restricting & Logging access to confidential personal information in computerized personal information systems*		04/11/18	04/19/18		07/11/18	09/25/18								*To be rescinded*
4759-11-01	Miscellaneous Provisions		04/11/18	04/19/18		07/11/18	09/25/18								
4761-1-01	*Public hearings on adoption, amendment, or rescission of rules: methods of public notice*													*02/28/19*	*Rescinded*
4761-1-02	*Notice of board meetings*													*02/28/19*	*Rescinded*
4761-2-01	*Board Organization*									*01/19/19*				*02/28/19*	*Rescinded*
4761-2-02	*Personnel*									*01/19/19*				*02/28/19*	*Rescinded*
4761-2-03	Board Records		04/11/18	04/19/18		07/11/18	09/25/18			11/15/18	12/17/18			02/28/19	02/28/24
4761-2-05	*Personal information systems*													*02/28/19*	*Rescinded*
4761-3-01	Definition of terms		04/11/18	04/19/18		07/11/18	09/25/18			11/15/18	12/17/18			02/28/19	02/28/24
4761-4-01	Approval of educational programs		04/11/18	04/19/18		07/11/18	09/25/18			11/15/18	12/17/18			02/28/19	02/28/24
4761-4-02	Monitoring of Ohio respiratory care educational programs									11/15/18	12/17/18			02/28/19	02/28/24
4761-4-03	*Recognition of military educational programs for active duty military members and/or military veterans*			*03/22/19*	*06/12/19*	*06/12/19*				*11/15/18*	*no change*				*11/15/23*
4761-5-01	Waiver of licensing requirements pursuant to division (B) of section 4761.04 or the Revised Code		04/10/19	04/23/19		06/12/19									04/24/18
4761-5-02	Admission to the Ohio credentialing examination		04/10/19	04/23/19		06/12/19									05/06/15
4761-5-04	License application procedure		04/10/19	04/23/19		06/12/19									
4761-5-05	*Non-resident practice of respiratory care*									*01/19/19*				*02/28/19*	*Rescinded*
4761-5-06	Respiratory care practice by polysomnographic technologists		04/10/19	04/23/19		06/12/19									12/31/17
4761-5-07	*Criminal records check*													*02/28/19*	*Rescinded*
4761-6-01	Limited permit application procedure		04/10/19	04/23/19		06/12/19									02/28/24
4761-7-01	Original license or permit, identification card or electronic license verification		04/11/18	04/19/18		07/11/18	09/25/18			11/15/18	12/17/18			02/28/19	02/28/24

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4761-7-03	Scope of respiratory care defined									11/15/18	no change				11/15/23
4761-7-04	Supervision		04/10/19	04/23/19		06/12/19									11/15/23
4761-7-05	Administration of medicines									11/15/18	no change				11/15/23
4761-8-01	Renewal of license or permits			03/22/19	06/12/19	06/12/19									08/15/18
4761-8-02	*Licenses not in active practice*									*01/19/19*				*02/28/19*	*Rescinded*
4761-9-01	Defnition of respiratory care continuing education		04/10/19	04/23/19	06/12/19	06/12/19									02/28/24
4761-9-02	Gemera; RCCE requirements and reporting mechanism			03/22/19	06/12/19	06/12/19									
4761-9-03	Activities which do not meet the Ohio RCCE requirements		04/11/18	04/19/18		07/11/18	09/25/18			11/15/18	12/17/18			02/28/19	02/28/24
4761-9-04	Ohio respiratory care law and professional ethics course criteria		04/10/19	04/23/19	06/12/19	06/12/19									02/28/24
4761-9-05	Approved sources of RCCE		04/10/19	04/23/19	06/12/19	06/12/19									02/28/24
4761-9-07	Auditing for compliance with RCCE requirements		04/10/19	04/23/19	06/12/19	06/12/19									
4761-10-01	Ethical and professional conduct		04/11/18	04/19/18		07/11/18	09/25/18			11/15/18	12/17/18			02/28/19	02/28/24
4761-10-02	Proper use of credentials									11/15/18	no change				11/15/23
4761-10-03	Providing information to the Board		04/10/19	04/23/19	06/12/19	06/12/19									
4761-11-01	*Filing of complaints*									*01/19/19*				*02/28/19*	*Rescinded*
4761-11-02	*Administrative procedure for refusal to issue or renew a license or permit, deny, suspend, or revoke a certificate or license*									*01/19/19*				*02/28/19*	*Rescinded*
4761-11-03	*Board imposition of penalties*									*02/06/19*	*03/12/19*		*05/08/19*	*05/31/19*	*To be rescinded*
4761-11-04	*Representation; appearance; communication applicability*													*02/28/19*	*Rescinded*
4761-11-05	*Authority and duties of the board or hearing examiner*													*02/28/19*	*Rescinded*
4761-11-06	*Continuance of Hearing*													*02/28/19*	*Rescinded*
4761-11-07	*Filing*									*01/19/19*				*02/28/19*	*Rescinded*
4761-11-08	*Service*													*02/28/19*	*Rescinded*
4761-11-09	*Computation and Extension of Time*													*02/28/19*	*Rescinded*

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4761-11-10	Motions													02/28/19	Rescinded
4761-11-11	Transcripts									01/19/19				02/28/19	Rescinded
4761-11-12	Subpoenas for Purposes of Hearing													02/28/19	Rescinded
4761-11-13	Mileage Reimbursement and Witness Fees									01/19/19				02/28/19	Rescinded
4761-11-14	Reports and Recommendations									01/19/19				02/28/19	Rescinded
4761-11-15	Exchange of Documents and Witness Lists													02/28/19	Rescinded
4761-11-16	Depositions and transcripts of prior testimony									01/19/19				02/28/19	Rescinded
4761-11-17	Witnesses													02/28/19	Rescinded
4761-11-18	Expert testimony									01/19/19				02/28/19	Rescinded
4761-11-19	Exhibits													02/28/19	Rescinded
4761-12-01	Initial application fee			03/22/19	06/12/19	06/12/19									
4761-12-02	Renewal fees									01/19/19				02/28/19	Rescinded
4761-12-03	Replacement of license or certificate													02/28/19	Rescinded
4761-13-01	Definitions for accessing confidential personal information									01/19/19				02/28/19	Rescinded
4761-13-02	Procedures for accessing confidential personal information									01/19/19				02/28/19	Rescinded
4761-13-03	Valid reasons for accessing confidential personal information									01/19/19				02/28/19	Rescinded
4761-13-04	Confidentiality Statutes									01/19/19				02/28/19	Rescinded
4761-13-05	Restricting & Logging access to confidential personal information in computerized personal information systems									01/19/19				02/28/19	Rescinded
4761-14-01	Accepting and storing hyperbaric technologist certifications													02/28/19	Rescinded
4761-15-01	Miscellaneous Provisions		04/11/18	04/19/18		07/11/18	09/25/18			11/15/18	12/17/18			02/28/19	02/28/24

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4762-1-01	*Military Provisions Related to Certificate to Practice Acupuncture or Oriental Medicine*		*8/6/14 05/13/15*	*03/22/19*	*06/12/19*	*06/12/19*	*1/8/2015 7/1/15*			*09/24/15*	*11/02/15*		*12/09/15*	*12/31/15*	*12/31/20*
4774-1-01	Definitions			01/15/16			04/04/16			10/20/16 8/16/2016	09/19/16		12/14/16	12/31/16	12/31/21
4774-1-02	Application for Certificate to Practice			01/15/16			04/04/16			08/16/16	09/19/16		11/09/16	11/30/16	11/31/2021
4774-1-02.1	*Military Provisions related to Certificate to Practice as a Radiologist Assistant*		*8/6/14 05/13/15*	*03/22/19*	*06/12/19*	*06/12/19*	*1/8/2015 7/1/15*						*09/09/15*	*09/30/15*	*09/30/20*
4774-1-03	Renewal of Certificate to Practice			01/15/16			04/04/16			08/16/16	09/19/16		11/09/16	11/30/16	11/30/21
4774-1-04	Miscellaneous Provisions			01/15/16			04/04/16			08/17/16					08/17/21
4774-2-01	Definitions			01/15/16			04/23/19	05/31/19							08/17/21
4774-2-02	Criminal Records Checks			01/15/16			04/23/19	05/31/19							11/30/21
4778-1-01	Definition			04/19/18			08/24/18			01/24/19					01/29/19
4778-1-02	Application			04/19/18			08/24/18			4/10/19 1/24/19			04/10/19	04/30/19	04/30/24
4778-1-02.1	Military Provisions related to Certificate to Practice as a Genetic Counselor		4/11/18 8/6/14 05/13/15	3/22/19 4/19/18	06/12/19	06/12/19	8/24/18 1/8/2015 7/1/15			4/10/19 1/24/19			04/10/19	04/30/19	04/30/24
4778-1-03	Special Activity License			04/19/18			08/24/18			01/24/19					01/29/19
4778-1-05	Collaboration Agreement		04/11/18	04/19/18			08/24/18			4/10/19 1/24/19			04/10/19	04/30/19	04/30/24
4778-1-06	Miscellaneous Provisions		04/11/18	04/19/18			08/24/18			4/10/19 1/24/19			04/10/19	04/30/19	04/30/24
4778-2-01	Definitions		04/11/18	04/19/18			04/23/19	05/31/19		4/10/19 1/24/19			04/10/19	04/30/19	04/30/24
4778-2-02	Criminal Records Check			04/19/18			04/23/19	05/31/19		4/10/19 1/24/19			04/10/19	04/30/19	04/30/24
DRAFT	Misbranded Drugs														
NOTE RE: 4731-12-03 for next review	what had been known as NBPME Parts I, II, and III will now be designated as the American Podiatric Medical Licensing Examination (APMLE) Parts I, II, and III														

Ohio | State Medical Board of Ohio

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MEMORANDUM

TO: Robert P. Giacalone, Acting Chair, Policy Committee
Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Internal Management Rule for License Approval

DATE: June 27, 2019

Changes have been made in the Budget Bill to allow the Board to delegate licensure approval in accordance with an internal management rule.

Attached please find a draft rule for your review. The rule establishes criteria for licenses which can be approved by the Secretary and Supervising Member and by the Board's Deputy Director for Licensure.

The rule requires full Board approval for licenses where the applicant is seeing a waiver or determination of equivalency to any eligibility requirement or a determination of fitness to resume practice due to inactivity. In addition, any license approval in which a disciplinary sanction is imposed must be approved by the full Board.

Approval of the following licenses and certificates may be delegated to the Secretary and Supervising Member:

- Certificate of conceded eminence
- Clinical research faculty certificate
- Visiting clinical professional development certificate
- Special activity certificate
- Special activity license to practice as a genetic counselor
- Expedited license to practice medicine and surgery or osteopathic medicine and surgery by endorsement
- Certificate to recommend medical use of marijuana

Approval of the following licenses may be delegated to the deputy director of licensure or the deputy director's designee:

- License to practice as a physician assistant
- License to practice medicine and surgery or osteopathic medicine and surgery
- License to practice a limited branch of medicine
- Training certificate
- Volunteer's certificate
- License to practice podiatric medicine and surgery
- Visiting podiatric faculty certificate
- Podiatric training certificate

- License to practice dietetics
- Limited permit to practice dietetics
- Certificate to practice as an anesthesiologist assistant
- License to practice respiratory care
- Limited permit to practice respiratory care
- Certificate to practice as an oriental medicine practitioner
- License to practice as an acupuncturist
- License to practice as a radiologist assistant
- License to practice as a genetic counselor
- Supervised practice license as a genetic counselor

Requested Action: Approve the initial circulation of the internal management rule for license approval to interested parties

4731-30-02 Approval of Licensure Applications.

(A) For purposes of this rule, routine authorization means issuance of a license or certificate to an individual pursuant to an application that meets the following criteria:

(1) The applicant meets eligibility requirements for the license or certificate under the applicable provisions of the Revised Code and Administrative Code

(2) The applicant is not seeking a waiver of, or a determination of equivalency to, any eligibility requirement, as may be provided for under the applicable provisions of the Revised Code and Administrative Code

(3) The applicant is not required to demonstrate fitness to resume practice due to inactivity under the applicable provisions of the Revised Code and Administrative Code

(4) The application presents no grounds for discipline under the applicable provisions of the Revised Code or Administrative Code.

(B) The board authorizes the secretary and supervising member of the board to issue the following routine authorizations under the provisions of the Revised Code and Administrative Code, without prior consultation or approval by the board:

(1) Certificate of conceded eminence pursuant to section 4731.297 of the Revised Code;

(2) Clinical research faculty certificate pursuant to section 4731.293 of the Revised Code;

(3) Visiting clinical professional development certificate pursuant to section 4731.298 of the Revised Code;

(4) Special activity certificate pursuant to section 4731.294 of the Revised Code;

(5) Special activity license to practice as a genetic counselor pursuant to section 4778.09 of the Revised Code.

(6) Expedited license to practice medicine and surgery or osteopathic medicine and surgery by endorsement pursuant to section 4731.299 of the Revised Code;

(7) Certificate to recommend medical use of marijuana pursuant to section 4731.30 of the Revised Code;

(C) The board authorizes the deputy director of licensure, or the deputy director’s designee, to issue the following routine authorizations under the provisions of the Revised Code and Administrative Code, without prior consultation or approval by the board:

(1) License to practice as a physician assistant pursuant to section 4730.12 of the Revised Code;

(2) License to practice medicine and surgery or osteopathic medicine and surgery pursuant to section 4731.14 of the Revised Code;

(3) License to practice limited branch of medicine pursuant to section 4731.17 of the Revised Code;

(4) Training certificate pursuant to section 4731.291 of the Revised Code;

(5) Volunteer's certificate pursuant to section 4731.295 of the Revised Code;

(6) License to practice podiatric medicine and surgery pursuant to section 4731.56 of the Revised Code;

(7) Visiting podiatric faculty certificate pursuant to section 4731.572 of the Revised Code;

(8) Podiatric training certificate pursuant to section 4731.573 of the Revised Code;

(9) License to practice dietetics and limited permit to practice dietetics pursuant to section 4759.06 of the Revised Code;

(10) Certificate to practice as an anesthesiologist assistant pursuant to section 4760.04 of the Revised Code;

(11) License to practice respiratory care and limited permit to practice respiratory care pursuant to section 4761.05 of the Revised Code;

(12) Certificate to practice as an oriental medicine practitioner pursuant to section 4762.03 of the Revised Code;

(13) License to practice as an acupuncturist pursuant to section 4762.03 of the Revised Code;

(14) License to practice as a radiologist assistant pursuant to section 4774.04 of the Revised Code;

(15) License to practice as a genetic counselor pursuant to section 4778.05 of the Revised Code;

(16) Supervised practice license as a genetic counselor pursuant to section 4778.08 of the Revised Code;

(D) An application for a license or certificate that is ineligible for routine authorization under this rule will be referred to the board for determination of whether an applicant shall be granted a license. An affirmative vote of not fewer than six members of the board is necessary for issuance of a license or certificate pursuant to an application that is not eligible for routine authorization.

(E) Notwithstanding the provisions of this rule, the secretary, supervising member and deputy director for licensure may refer any application or class of applications to the board for approval.

Effective:
Promulgated Under: 111.15
Statutory Authority: 4730.07;4731.05, 4759.05, 4760.19, 4761.03, 4762.19, 4774.11,4778.12
Rule Amplifies: 4730.12;4731.297;4731.293, 4731.298, 4731.294, 4731.299, 4731.30,

4731.14. 4731.17, 4731.291, 4731.295, 4731.56, 4731.572, 4731.573, 4759.06, 4760.04, 4761.05, 4762.03, 4762.03, 4774.04, 4778.05, 4778.08, 4778.09.

Ohio | State Medical Board of Ohio

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MEMORANDUM

TO: Robert P. Giacalone, Acting Chair, Policy Committee
Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Controlled Substance Prescribing Rules

DATE: June 26, 2019

The following controlled substance prescribing rules are due for the five-year rule review on 12/31/2020:

- 4731-11-02, OAC, General Provisions
- 4731-11-03, OAC, Utilization of anabolic steroids, schedule II controlled substances
- 4731-11-04, OAC, Controlled Substances: Utilization of short term anorexiants for weight reduction
- 4731-11-04.1, OAC, Controlled substances: utilization for chronic weight management
- 4731-11-07, OAC, Research utilizing controlled substances
- 4731-11-11, OAC, Standards and procedures for review of “Ohio Automated Rx Reporting System” (OARRS)

Copies of the rules are attached. At this time, I am requesting approval to circulate the rules to interested parties as no change rules.

Action Requested: Approve for Initial Circulation to Interested Parties

4731-11-02 General provisions.

(A) A physician shall not utilize a controlled substance other than in accordance with all of the provisions of this chapter of the Administrative Code.

(B) A physician shall not utilize a controlled substance without taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for a nontherapeutic use or to distribute to others, and the possibility of an illicit market for the drug.

(C) A physician shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients. Patient medical records shall accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized, and any additional information upon which the diagnosis is based.

(D) A physician shall obey all applicable provisions of sections 3719.06, 3719.07, 3719.08 and 3719.13 of the Revised Code and the rules promulgated thereunder, all prescription issuance rules adopted under Chapter 4729. of the Revised Code, and all applicable provisions of federal law governing the possession, distribution, or use of controlled substances.

(E) Violations of this rule:

(1) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following: "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar physicians under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

(2) A violation of paragraph (C) of this rule shall further constitute "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code.

Effective: 12/23/2018
Five Year Review (FYR) Dates: 12/31/2020
Promulgated Under: 119.03
Statutory Authority: 4730.39, 4731.05
Rule Amplifies: 3719.06, 3719.07, 3719.08, 3719.13, 4730.39, 4731.22
Prior Effective Dates: 11/17/1986, 09/01/2000, 09/30/2008, 12/31/2015, 08/31/2017

4731-11-03 Utilization of anabolic steroids, schedule II controlled substance cocaine hydrochloride, and schedule II controlled substance stimulants.

(A) A physician shall not:

(1) Utilize anabolic steroids, growth hormones, testosterone or its analogs, human chorionic gonadotropin ("HCG"), or other hormones for the purpose of enhancing athletic ability.

(2) Utilize the schedule II controlled substance cocaine hydrochloride for a purpose other than one of the following:

(a) As a topical anesthetic in situations in which it is properly indicated; or

(b) For in-office diagnostic testing for pupillary disorders.

(3) Utilize a schedule II controlled substance stimulant in any of the following circumstances:

(a) For purposes of weight reduction or control;

(b) When the physician knows or has reason to believe that a recognized contra-indication to its use exists; or

(c) In the treatment of a patient who the physician knows or should know is pregnant, except if the following criteria are met:

(i) After the physician's medical assessment the physician and patient determine that the benefits of treating the patient with a schedule II controlled substance stimulant outweigh the risks, and

(ii) The basis for the determination is documented in the patient record.

(B) Utilizing a schedule II controlled subtance stimulant:

(1) Before initiating treatment utilizing a schedule II controlled substance stimulant, the physician shall perform all of the following:

(a) Obtain a thorough history;

(b) Perform an appropriate physical examination of the patient; and

(c) Rule out the existence of any recognized contra-indications to the use of the controlled subtance stimulant to be utilized.

(2) A physician may utilize a schedule II controlled substance stimulant only for one of the following purposes:

(a) The treatment of narcolepsy, idiopathic hypersomnia, and hypersomnias due to medical conditions known to cause excessive sleepiness;

(b) The treatment of abnormal behavioral syndrome (attention deficit disorder, hyperkinetic syndrome), and/or related disorders;

(c) The treatment of drug-induced or trauma-induced brain dysfunction;

(d) The differential diagnostic psychiatric evaluation of depression;

(e) The treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as antidepressants;

(f) As adjunctive therapy in the treatment of the following:

(i) Chronic severe pain;

(ii) Closed head injuries;

(iii) Cancer-related fatigue;

(iv) Fatigue experienced during the terminal stages of disease;

(v) Depression experienced during the terminal stages of disease; or

(vi) Intractable pain, as defined in rule 4731-21-01 of the Administrative Code.

(g) The treatment of binge eating disorder.

(3) Upon ascertaining or having reason to believe that the patient has a history of or shows a propensity for alcohol or drug abuse, or that the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions, the physician shall perform both of the following;

(a) Reappraise the desirability of continued utilization of schedule II controlled substance stimulants and shall document in the patient record the factors weighed in deciding to continue their use; and

(b) Actively monitor such patient for signs and symptoms of drug abuse and drug dependency.

(C) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:

(1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;

(2) "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code;

(3) "A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

Replaces: 4731-11-02, 4731-11-03, 4731-11-05

Effective: 12/31/2015
Five Year Review (FYR) Dates: 12/31/2020
Promulgated Under: 119.03
Statutory Authority: 4731.05
Rule Amplifies: 4731.22
Prior Effective Dates: 11/17/86; 10/31/98; 9/1/00, 4/30/2009

4731-11-04 Controlled substances: Utilization of short term anorexiants for weight reduction.

(A) A physician shall utilize a schedule III or IV controlled substance short term anorexiant for purposes of weight reduction only if it has an F.D.A. approved indication for this purpose and then only in accordance with all of the provisions of this rule.

(B) Before initiating treatment for weight reduction utilizing any schedule III or IV controlled substance short term anorexiant, the physician shall complete all of the following requirements:

(1) The physician shall review the physician's own records of prior treatment or review the records of prior treatment by another treating physician, dietician, or weight-loss program to determine the patient's past efforts to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise, without the utilization of controlled substances, and that the treatment has been ineffective.

(2) The physician shall complete and document the findings of all of the following:

(a) Obtain a thorough history;

(b) Perform an appropriate physical examination of the patient;

(c) Determine the patient's BMI;

(d) Rule out the existence of any recognized contraindications to the use of the controlled substance to be utilized;

(e) Assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects.

(f) Access OARRS for the patient's prescription history during the preceding twelve month period and document in the patient's record the receipt and assessment of the report received; and

(g) Develop and record in the patient record a treatment plan that includes, at a minimum, a diet and exercise program for weight loss.

(3) The physician shall not initiate treatment utilizing a controlled substance short term anorexiant upon ascertaining or having reason to believe any one or more of the following:

(a) The patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the physician related to the patient's use of drugs or alcohol;

(b) The patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions;

(c) The physician knows or should know the patient is pregnant;

(d) The patient has a BMI of less than thirty, unless the patient has a BMI of at least twenty seven with comorbid factors;

(e) The review of the physician's own records of prior treatment or review of records of prior treatment provided by another physician, dietician, or weight-loss program indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substances.

(C) A physician may utilize a schedule III or IV controlled substance short term anorexiant, that bears appropriate F.D.A. approved labeling for weight loss, in the treatment of obesity as an adjunct, in a regimen of weight

reduction based on caloric restriction, provided that:

(1) The physician shall personally meet face-to-face with the patient, at a minimum, every thirty days when controlled substances are being utilized for weight reduction, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

(2) The controlled substance short term anorexiant is prescribed strictly in accordance with the F.D.A. approved labeling. If the F.D.A. approved labeling of the controlled substance short term anorexiant being utilized for weight loss states that it is indicated for use for "a few weeks," the total course of treatment using that controlled substance shall not exceed twelve weeks. That time period includes any interruption in treatment that may be permitted under paragraph (C)(3) of this rule.

(3) A physician shall not initiate a course of treatment utilizing a controlled substance short term anorexiant for purposes of weight reduction if the patient has received any controlled substance for purposes of weight reduction within the past six months. However, the physician may resume utilizing a controlled substance short term anorexiant following an interruption of treatment of more than seven days if the interruption resulted from one or more of the following:

(a) Illness of or injury to the patient justifying a temporary cessation of treatment; or

(b) Unavailability of the physician; or

(c) Unavailability of the patient, if the patient has notified the physician of the cause of the patient's unavailability.

(4) After initiating treatment, the physician may elect to switch to a different controlled substance short term anorexiant for weight loss based on sound medical judgment, but the total course of treatment for any short term anorexiant combination of controlled substances each of which is indicated for "a few weeks" shall not exceed twelve weeks.

(5) The physician shall not initiate or shall discontinue utilizing all controlled substance short term anorexiants for purposes of weight reduction immediately upon ascertaining or having reason to believe:

(a) That the patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the physician relating to the patient's use of drugs or alcohol;

(b) That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions;

(c) That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances over a period of thirty days during the current course of treatment, which determination shall be made by weighing the patient at least every thirtieth day, except that a patient who has never before received treatment for obesity utilizing any controlled substance who fails to lose weight during the first thirty days of the first such treatment attempt may be treated for an additional thirty days;

(d) That the patient has repeatedly failed to comply with the physician's treatment recommendations; or

(e) That the physician knows or should know the patient is pregnant.

(D) A violation of any provision of this rule, as determined by the board, shall constitute the following:

(1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;

(2) "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; and

(3) "A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

Replaces: 4731-11-04

Effective: 2/29/2016
Five Year Review (FYR) Dates: 02/28/2021
Promulgated Under: 119.03
Statutory Authority: 4731.05
Rule Amplifies: 4731.22
Prior Effective Dates: 11/17/86; 10/31/98; 6/30/00

4731-11-04.1 Controlled substances: utilization for chronic weight management.

(A) A physician shall determine whether to utilize a controlled substance anorexiant for purposes of chronic weight management as an adjunct to a reduced calorie diet and increased physical activity. The determination shall be made in compliance with the provisions of this rule.

(1) Before initiating treatment utilizing any controlled substance anorexiant, the physician shall complete all of the following requirements:

(a) Obtain a thorough history;

(b) Perform a physical examination of the patient;

(c) Determine the patient's BMI;

(d) Review the patient's attempts to lose weight in the past for indications that the patient has made a substantial good faith effort to lose weight in a regimen for weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substance anorexiants. The review shall include available records from the physician's own prior treatment of the patient, prior treatment provided by another physician, prior participation in a weight-loss program, or prior treatment by a dietitian;

(e) Rule out the existence of any recognized contraindications to the use of the controlled substance anorexiant to be utilized;

(f) Assess and document the patient's freedom from signs of drug or alcohol abuse;

(g) Access OARRS and document in the patient's record the receipt and assessment of the information received; and

(h) Develop and record in the patient record a treatment plan that includes, at a minimum, a diet and exercise program for weight loss.

(2) The physician shall not initiate treatment utilizing a controlled substance anorexiant upon ascertaining or having reason to believe any one or more of the following:

(a) The patient has a history of, or shows a propensity for, alcohol or drug abuse, or has made any false or misleading statement to the physician or physician assistant relating to the patient's use of drugs or alcohol;

(b) The patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions; or

(c) The physician knows or should know the patient is pregnant.

(3) The physician shall not initiate treatment utilizing a controlled substance anorexiant if any of the following conditions exist:

(a) The patient has an initial BMI of less than thirty, unless the patient has an initial BMI of at least twenty seven with comorbid factors.

(b) The review of the patient's attempts to lose weight in the past indicates that the patient has not made a substantial good faith effort to lose weight in a regimen for weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substance anorexiants. The review shall include available records from the physician's own prior treatment of the patient, prior treatment provided by another physician, prior participation in a weight-loss program, or prior treatment by a dietitian.

(4) The physician shall prescribe the controlled substance anorexiant strictly in accordance with the F.D.A. approved labeling;

(5) Throughout the course of treatment with any controlled substance anorexiant the physician shall comply with rule 4731-11-11 of the Administrative Code and the physician assistant shall comply with rule 4730-2-10 of the Administrative Code.

(B) A physician shall provide treatment utilizing a controlled substance anorexiant for weight management in compliance with paragraph (A) of this rule and the following:

(1) The physician shall meet face-to-face with the patient for the initial visit and at least every thirty days during the first three months of treatment. If the F.D.A. approved labeling for the controlled substance anorexiant requires induction of treatment at one dose and an increase to a higher dose after a stated period of less than thirty days, the physician may give the patient a prescription for the higher dose at the initial visit and the first thirty day period then starts from the date the prescription for the higher dose may be filled.

(2) Following the initial visit and two follow-up visits, the treatment may be continued under one of the following means:

(a) The physician may authorize refills for the controlled substance anorexiant up to five times within six months after the initial prescription date;

(b) The treatment may be provided by a physician assistant in compliance with this rule, the supervisory plan or policies of the healthcare facility, and the physician assistant formulary adopted by the board.

(3) When treatment for chronic weight management is provided by a physician assistant, the following requirements apply:

(a) The supervising physician shall personally review the medical records of each patient to whom the physician assistant has prescribed a controlled substance anorexiant following each visit; and

(b) A physician assistant shall not initiate utilization of a different controlled substance anorexiant, but may recommend such change for the supervising physician's initiation.

(4) A physician shall discontinue utilizing any controlled substance anorexiant immediately upon ascertaining or having reason to believe:

(a) That the patient has repeatedly failed to comply with the physician's treatment recommendations; or

(b) That the patient is pregnant.

(C) A violation of any provision of this rule, as determined by the board, shall constitute the following as applicable:

(1) For a physician:

(a) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;

(b) "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; and

(c) "A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

(2) For a physician assistant:

(a) "A departure from, or failure to conform to, minimal standards of care of similar physician assistants under the same or similar circumstances, regardless of whether actual injury to a patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code;

(b) "Failure to comply with the requirements of this chapter, Chapter 4731. of the Revised Code, or any rules adopted by the board," as that clause is used in division (B)(2) of section 4730.25 of the Revised Code; and

(c) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter, Chapter 4731. of the Revised Code, or the rules adopted by the board," as that clause is used in division (B)(3) of section 4730.25 of the Revised Code.

Effective: 12/31/2015
Five Year Review (FYR) Dates: 12/31/2020
Promulgated Under: 119.03
Statutory Authority: 4731.05
Rule Amplifies: 4731.22

4731-11-07 Research utilizing controlled substances.

The provisions of this chapter of the Administrative Code shall not apply to or in any way prohibit research conducted under the auspices of an accredited medical school, or research which meets both of the following conditions:

(A) The U.S. food and drug administration has approved an investigational new drug ("IND") application for the research or has notified the researchers that the proposed study is exempt from the "IND" regulations; and

(B) The research is conducted in conformance with the approval granted by either of the following:

(1) An institutional review board of a hospital or medical center accredited by the "Joint Commission," "Healthcare Facilities Accreditation Program" or other accrediting body approved by the board; or

(2) An institutional review board accredited by the association for the accreditation of human research protection programs.

Replaces: 4731-11-07

Effective: 9/30/2015
Five Year Review (FYR) Dates: 09/30/2020
Promulgated Under: 119.03
Statutory Authority: 4731.05
Rule Amplifies: 4731.22
Prior Effective Dates: 12/1/94

4731-11-11 Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).

(A) For purposes of this rule:

(1) :"Delegate" means an authorized representative who is registered with the Ohio board of pharmacy to obtain an OARRS report on behalf of a physician;

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

(3) "OARRS report" means a report of information related to a specified patient generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(4) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

(5) "Reported drugs" means all the drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code, including controlled substances in schedules II, III, IV, and V.

(B) Standards of care:

(1) The accepted and prevailing minimal standards of care require that when prescribing or personally furnishing a reported drug, a physician shall take into account all of the following:

(a) The potential for abuse of the reported drug;

(b) The possibility that use of the reported drug may lead to dependence;

(c) The possibility the patient will obtain the reported drug for a nontherapeutic use or distribute it to other persons; and

(d) The potential existence of an illicit market for the reported drug.

(2) In considering whether a prescription for or the personally furnishing of a reported drug is appropriate for the patient, the physician shall use sound clinical judgment and obtain and review an OARRS report consistent with the provisions of this rule.

(C) A physician shall obtain and review an OARRS report to help determine if it is appropriate to prescribe or personally furnish an opioid analgesic, benzodiazepine, or reported drug to a patient as provided in this paragraph and paragraph (F) of this rule:

(1) A physician shall obtain and review an OARRS report before prescribing or personally furnishing an opiate analgesic or benzodiazepine to a patient, unless an exception listed in paragraph (G) of this rule is applicable.

(2) A physician shall obtain and review an OARRS report when a patient's course of treatment with a reported drug other than an opioid analgesic or benzodiazepine has lasted more than ninety days, unless an exception listed in paragraph (G) of this rule is applicable.

(3) A physician shall obtain and review an OARRS report when any of the following red flags pertain to the patient:

(a) Selling prescription drugs;

(b) Forging or altering a prescription;

(c) Stealing or borrowing reported drugs;

(d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;

(e) Suffering an overdose, intentional or unintentional;

(f) Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;

(g) Having been arrested, convicted, or received diversion or intervention in lieu of conviction for a drug related offense while under the physician's care;

(h) Receiving reported drugs from multiple prescribers, without clinical basis;

(i) Traveling with a group of other patients to the physician's office where all or most of the patients request controlled substance prescriptions;

(j) Traveling an extended distance or from out of state to the physician's office;

(k) Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient's use of illegal or reported drugs;

(l) A known history of chemical abuse or dependency;

(m) Appearing impaired or overly sedated during an office visit or exam;

(n) Requesting reported drugs by street name, color, or identifying marks;

(o) Frequently requesting early refills of reported drugs;

(p) Frequently losing prescriptions for reported drugs;

(q) A history of illegal drug use;

(r) Sharing reported drugs with another person; or

(s) Recurring visits to non-coordinated sites of care, such as emergency departments, urgent care facilities, or walk-in clinics to obtain reported drugs.

(D) A physician who decides to utilize an opioid analgesic, benzodiazepine, or other reported drug in any of the circumstances within paragraphs (C)(2) and (C)(3) of this rule, shall take the following steps prior to issuing a prescription for or personally furnishing the opioid analgesic, benzodiazepine, or other reported drug:

(1) Review and document in the patient record the reasons why the physician believes or has reason to believe that the patient may be abusing or diverting drugs;

(2) Review and document in the patient's record the patient's progress toward treatment objectives over the course of treatment;

(3) Review and document in the patient record the functional status of the patient, including activities for daily living, adverse effects, analgesia, and aberrant behavior over the course of treatment;

(4) Consider using a patient treatment agreement including more frequent and periodic reviews of OARRS reports and that may also include more frequent office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription or personally furnishing of reported drugs, and consequences for non-compliance with the terms of the agreement. The patient treatment agreement shall be maintained as part of the patient record; and

(5) Consider consulting with or referring the patient to a substance abuse specialist.

(E) Frequency for follow-up OARRS reports:

(1) For a patient whose treatment with an opioid analgesic or benzodiazepine lasts more than ninety days, a physician shall obtain and review and OARRS report for the patient at least every ninety days during the course of treatment, unless an exception listed in paragraph (G) of this rule is applicable.

(2) For a patient who is treated with a reported drug other than an opioid analgesic or benzodiazepine for a period lasting more than ninety days, the physician shall obtain and review and OARRS report for the patient at least annually following the initial OARRS report obtained and reviewed pursuant to paragraph (C)(2) of this rule until the course of treatment utilizing the reported drug has ended, unless an exception in paragraph (G) of this rule is applicable.

(F) When a physician or their delegate requests an OARRS report in compliance with this rule, a physician shall document receipt and review of the OARRS report in the patient record, as follows:

(1) Initial reports requested shall cover at least the twelve months immediately preceding the date of the request:

(2) Subsequent reports requested shall, at a minimum, cover the period from the date of the last report to present;

(3) If the physician practices primarily in a county of this state that adjoins another state, the physician or their delegate shall also request a report of any information available in the drug database that pertains to prescriptions issued or drugs furnished to the patient in the state adjoining that county; and

(4) If an OARRS report regarding the patient is not available, the physician shall document in the patient's record the reason that the report is not available and any efforts made in follow-up to obtain the requested information.

(G) A physician shall not be required to review and assess an OARRS report when prescribing or personally furnishing an opioid analgesic, benzodiazepine, or other reported drug under the following circumstances, unless a physician believes or has reason to believe that a patient may be abusing or diverting reported drugs:

(1) The reported drug is prescribed or personally furnished to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code, or any other patient diagnosed as terminally ill;

(2) The reported drug is prescribed for administration in a hospital, nursing home, or residential care facility;

(3) The reported drug is prescribed or personally furnished in an amount indicated for a period not to exceed seven days;

(4) The reported drug is prescribed or personally furnished for the treatment of cancer or another condition associated with cancer; and

(5) The reported drug is prescribed or personally furnished to treat acute pain resulting from a surgical or other invasive procedure or a delivery.

Replaces: 4731-11-11

Effective: 12/31/2015
Five Year Review (FYR) Dates: 12/31/2020
Promulgated Under: 119.03
Statutory Authority: 4731.05, 4731.055
Rule Amplifies: 4731.055
Prior Effective Dates: 11/30/11

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MEMORANDUM

TO: Amol Soin, M.D., President
Members, State Medical Board of Ohio

FROM: Sallie Debolt, Senior Counsel

RE: Proposed detoxification rules: 4730-4-01 and 4730-4-02

DATE: June 25, 2019

Since June 10, when PAPC reviewed draft rules 4730-4-01 and 4730-4-02, the comments received on proposed rules 4731-33-01 and 4731-33-02 for physician provided detoxification (or withdrawal management) have been reviewed. Accordingly, this memo discusses the major comments and those that are reflected in proposed changes to the rules applicable to both the physician assistant and physician who is providing withdrawal management or detoxification.

Rules 4730-4-01 and 4731-33-01: Definitions

Paragraph (K). Three comments were received concerning the definitions of "withdrawal management"

Mark Pirner, M.D., Medical Officer, US WorldMeds, suggests that the definition of "withdrawal management" should state that "withdrawal management is a critical component of an overall substance abuse treatment plan but is not intended to replace additional treatment(s) needed to reduce the risk and harms of relapse and unintended overdose."

David Streem, M.D., Cleveland Clinic, commented that differentiation between a dose reduction and ambulatory detoxification is needed. Upon request, Cleveland Clinic submitted the following additional language:

Ambulatory Detoxification only occurs when two conditions are simultaneously present: 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.

Randy Jernejcic, M.D., of the Northeast Ohio Hospital Opioid Consortium, commented that additional clarification of the definition of "withdrawal management" is needed to differentiate between a dose reduction and ambulatory detoxification. Upon request, the Consortium submitted substantially the same language as the Cleveland Clinic, above.

Input on the comments was requested from Michael Schottenstein, M.D., a psychiatrist and president of the Medical Board. Accordingly, the following definition of "withdrawal management" or "detoxification" is suggested:

(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.

Paragraph L: The definition of "ambulatory detoxification."

Dr. Pirner's comments indicate a misunderstanding of the "exemptions" provided in the definition of "ambulatory detoxification." In order to clarify, the phrases "For the purpose of rule 4731-33-02 of the Administrative Code," and "For the purpose of rule 4730-4-02 of the Administrative Code," are added to clarify that the rules are not applicable to practitioners providing detoxification in the listed settings.

Rules 4730-4-02 and 4731-33-02: Standards and procedures for withdrawal management for drug or alcohol addiction.

New paragraph (A):

At the June 10, 2019 PAPC meeting, Nisha Mehta, M.D., questioned whether rule 4730-4-02 should be more detailed in setting the requirements for the physician assistant to provide ambulatory detoxification or withdrawal management.

Blair Barnhart, on behalf of Cleveland Clinic, commented that the definition of "ambulatory detoxification" in rule 4731-33-01 gives the impression that all practitioners are authorized to prescribe outpatient supplies of drugs for addiction treatment.

Accordingly, a new paragraph (A) has been added to rules 4730-4-02 and 4731-33-02 to more specifically define the qualifications of physicians and physician assistants.

New paragraph (B) – formerly paragraph (A): Concerning the providing of information to the patient prior to starting ambulatory detoxification.

Dr. Pirner suggested that paragraph (A)(1) should explicitly include "withdrawal management." After a review of the language in Sections 3719.064, 4730.55, and 4731.056 of the Revised Code, the wording has been added.

New paragraph (C):

Adrian Miranda, M.D., Chief Medical Officer of Innovative Health Solutions, suggested that the rule should reflect that there are non-pharmacological treatment options for opioid withdrawal.

The rules are being promulgated pursuant to the statutory mandate to adopt rules establishing standards for the use of drugs in medication-assisted treatment. However, new paragraph (C) is added to recognize that the rules should not be read to foreclose the use of non-pharmacological treatment options.

New paragraph (D)(2) – formerly paragraph (B)(2): reference to the ASAM levels of care.

Dr. Pirner suggested that consideration should be given to including ASAM level of care 0.5 for purposes of early intervention. No recommendation is being made by staff, but Medical Board may wish to consider this suggestion.

Paragraph (D)(10): regarding use of permissible medications for symptom relief.

For paragraph (D)(10)(a), Dr. Pirner states that the only two medications currently FDA approved for opioid withdrawal management are methadone and lofexidine (a non-controlled substance) and suggests that lofexidine should be explicitly included in paragraph (D)(10)(a)(ii).

The originally proposed wording reflects the guidance of the ASAM National Practice Guideline and SAMHSA's Tip 45. Lofexidine fits within "a drug that is specifically approved by the United States food and drug administration for the alleviation of withdrawal symptoms," and the broad language used will capture any future drug that may also be FDA approved. Therefore, it is not recommended that lofexidine be specifically named in the rule. However, the language is proposed to be amended by combining the two references to buprenorphine formulations into one provision.

For paragraph (D)(10)(c)(iv), Dr. Pirner indicated that withdrawal management lasting more than thirty days is a form of substance use disorder treatment. Upon consultation with the medical director for the Ohio Department of Mental Health and Addiction Services, paragraph (D)(10)(c)(iv) has been deleted.

The recommendation of the PAPC concerning rules 4730-4-01 and 4730-4-02 will be reported to you at the Policy Committee meeting. The PA rules are attached following the comments received.

Attached:

- Proposed rules with amendments (4730-4-01, 4730-4-02, 4731-33-01, and 4731-33-02)
- Comments received from interested parties

REQUESTED ACTION: Consider the comments received, proposed amendments, and the PAPC recommendation to determine whether rules 4730-4-01, 4730-4-02, 4731-33-01, and 4731-33-02 should be filed with the Common Sense Initiative Office as proposed or with further modification.

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 provder" 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 ~~trained practitioners~~ 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 ~~drug~~ 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

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

Rule 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) Buprenorphine without naloxone (buprenorphine mono-product) when a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record;~~

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

(~~iii~~ 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;

(~~iv~~ 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.

~~(Iv) In withdrawal management programs of more than thirty days duration, the physician may allow the patient to have the opportunity for up to thirty days of take-home medications.~~

(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) The physician shall recommend that the patient who is successfully treated for alcohol withdrawal symptoms enter a long-term treatment program to maintain abstinence.

From:	James Lindon
To:	Debolt, Sallie; Dehner, Nicole; Ghitman, Terri; Payer, Charissa; Collins, Rachael
Subject:	Re: Seeking comments on the Medical Board's initial review of rules
Date:	Thursday, May 9, 2019 8:20:35 PM
Attachments:	image001.png image003.png image004.png

Given that your group and the pharmacy board are law enforcement agencies, it's only proper that each patient/defendant be reported to state and federal authorities so they can add a felony conviction to their resumes. Let's not pretend we are doing any of this to help a patient.

On Thu, May 9, 2019 at 3:50 PM Sallie.Debolt@med.ohio.gov <Sallie.Debolt@med.ohio.gov> wrote:

> The State Medical Board of Ohio seeks public input on proposed rules several times during the rule-making process. Public input is sought after the Medical Board has conducted its initial review of rules, after rules are filed with the Common Sense Initiative Office, and at the public hearing that occurs after the rules are formally filed with the Joint Committee on Agency Rule Review. The Medical Board's initial review of rules may result in a proposal to amend current rules, rescind current rules, make no changes to current rules, and/or adopt new rules. Comments received will be reviewed and possibly result in changes to the initially proposed language before the rules are then filed with the Common Sense Initiative Office.
>
> ***At this time the Medical Board has completed its initial review of the following rules and is seeking public comment on the proposed language. The rules and a short memo are attached.***
>
> **Rule 4731-13-13**: Subpoenas for purposes of hearing
>
> **4731-33-01**: Definitions (Applicable to medication-assisted treatment rules)
>
> **4731-33-02**: Standards and procedures for withdrawal management for drug or alcohol addiction
>
> The proposed rules will also be available in the near future from the Medical Board's website under "Newly Adopted and Proposed Rules."

Deadline for submitting comments: **May 24 2019**

Comments to: Sallie Debolt, Senior Counsel

State Medical Board of Ohio

Sallie.Debolt@med.ohio.gov

Respectfully,

Sallie Debolt

Senior Counsel

State Medical Board of Ohio

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Columbus, OH 43215

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Sallie.Debolt@med.ohio.gov

--
James Lindon Ph.D, J.D.
Member National Language Service Corps

Innovative Health Solutions

www.i-h-s.com

May 22, 2019

Via Email: Sallie.Debolt@med.ohio.gov

Sallie Debolt, Senior Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215-6127

Re: Comments to State Medical Board of Ohio regarding OAC 4731-33-01 and 4731-33-02

Dear Ms. Debolt,

Innovative Health Solutions is the Indiana based manufacturer of the NSS-2 BRIDGE device, which has demonstrated highly effective results nation-wide in the treatment of Opioid Use Disorder. We are heavily vested in the state of Ohio with a regional office in Columbus, and product utilization currently in over 30 facilities in the state including The Ohio State University and Cleveland Clinic which utilize the NSS-2 BRIDGE device as a neuromodulation device to reduce the symptoms of opioid withdrawal. Multitudes of people in Ohio have been successfully treated with the NSS-2 BRIDGE product to reduce withdrawal symptoms associated with Opioid Use Disorder

We have reviewed the State Medical Board of Ohio's proposal for Ohio Administrative Code 4731-33-01 and 4731-33-02 regarding definitions, standards and procedures for withdrawal management for drug or alcohol addiction. We encourage the Board to recognize in the OAC that there are effective non-pharmacological treatment options for opioid withdrawal that should be reflected in the rule. On November 15, 2017, the FDA cleared the NSS-2 BRIDGE device (Innovative Health Solutions, Inc.) through the Denovo process as an "aid in the reduction of opioid withdrawal symptoms" based on safety and efficacy data. We feel it is important that medical providers and patients have the option of using safe and effective non-pharmacological therapies that have been approved by the FDA and validated clinically. A copy of the actual FDA indication is attached for your review.

The current language does not recognize the full array of therapeutic options for patients suffering from opioid withdrawal. We believe that non-pharmacological therapies such as the NSS-2 BRIDGE device should be included in the proposed rules as another potential tool and viable treatment option. Medical providers need to have all available therapies at their disposal which includes novel technology that may be better or equivalent to current standard of care. We respectfully request that the rule language is modified to recognize products such as the NSS-2 BRIDGE device as a treatment option for management of opioid withdrawal symptoms.

Innovative Health Solutions

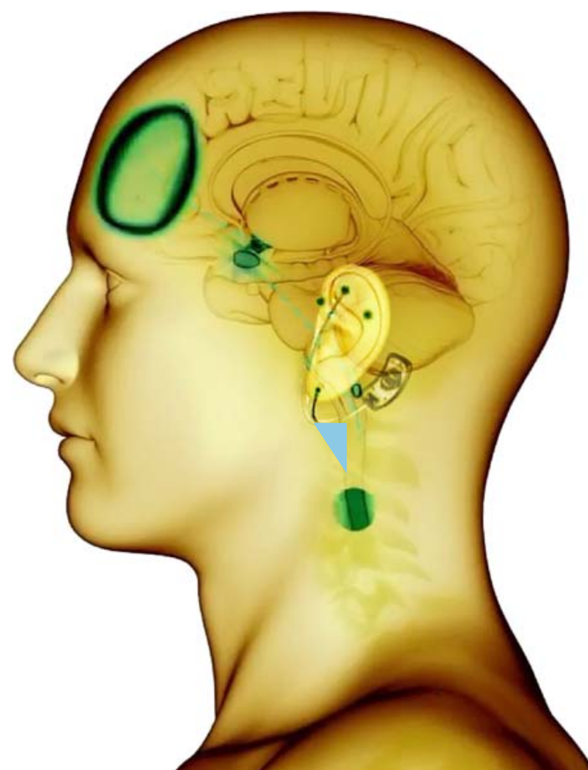
www.i-h-s.com

Thank you for your consideration of broadening the rule language to appropriately capture the full scope of FDA cleared treatment options for the indication of Opioid Use Disorder in the State of Ohio. If you have any questions, or I can provide any additional information, please do not hesitate to contact me at 414-477-0121 or drmiranda@i-h-s.com.

Sincerely,

Adrian Miranda, M.D.
Chief Medical Officer
Innovative Health Solutions

Attachment: NSS-2 BRIDGE FDA indication information



NSS-2 BRIDGE

A New Device to Reduce Opiate Withdrawal Symptoms

The NSS-2 Bridge is the latest technology to assist in alleviating many of the uncomfortable symptoms associated with withdrawal and its effects can be felt in as quickly as 30 minutes.

Call Us 888-343-5949

EVIDENCE BASED: All treatment is scientifically researched and proven.

CALL (888) 343-5949 TO FIND OUT HOW THE NSS-2 CAN HELP YOU

The NSS-2 Bridge: A New Device to Reduce Opiate Withdrawal Symptoms

Opioid withdrawal is perhaps the most difficult, painful, and frightening aspects of recovery for patients seeking treatment for prescription painkillers, heroin or other opiate-related addictions or dependencies.

The NSS-2 Bridge is the latest technology to assist in alleviating many of the uncomfortable symptoms associated with withdrawal and its effects can be felt in as quickly as 30 minutes.

Approved by the federal Food and Drug Administration (FDA) for the treatment of pain in 2014, the government agency expanded the Bridge's approval as "…the first device for use in helping to reduce the symptoms of opioid withdrawal (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm585271.htm)," in November 2017.

A small electronic stimulator the size of a hearing aid, the NSS-2 Bridge (https://i-h-s.com/) fits discreetly behind a patient's ear. Painless electrical pulses are delivered through the skin to four cranial nerves, including the occipital nerves along the cervical vertebrae.

(/insurance-form/)

(/the-joint-commission-jcaho/)

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Treating Opioid Withdrawal

A physical dependence to opioids, such as painkillers or heroin, make the brain produce high levels of noradrenaline.

Take away the opioids and the brain still pumps out large amounts noradrenaline for about a week, which is what causes the intense physical symptoms of withdrawal.

Opioid withdrawal symptoms can include some of the following:

- Anxiety
- Insomnia and sleep irregularities
- Joint pain
- Profuse sweating
- Tremors
- Extreme nausea
- Vomiting

Some people have described opioid withdrawal as the worst flu they've ever had, combined with a psychological anxiety that makes them feel as if they're going to die. Opioid withdrawal in and of itself is not usually fatal, but patients in the throes of the symptoms feel very real pain and agony in the extremes.

Detox from opiates often requires the use of other narcotics or benzodiazepines to manage symptoms that last approximately five days, before patients can move on to medically assisted treatment (https://www.inspiremalibu.com/medication-assisted-therapy/) with buprenorphine (Suboxone) or Vivitrol.

The NSS-2 Bridge, however, has the potential to ease opioid detox symptoms without the use of other medications.

How the NSS-2 Bridge Works

The small electrical pulses released by the Bridge target an area of the cranial nerve system known as the amygdala. This region of the brain regulates fear and is a key component in reward-seeking behavior related to addiction.

The amygdala is also rich in opioid receptors, which is why it produces an overabundance of stress-inducing hormones when an opioid-addicted patient stops using prescription painkillers, heroin or other opiates.

"University-based research studies indicate that the Bridge sends gentle electrical impulses to areas of the brain and branches of nerves leading into the spinal chord via [electrodes attached to the skin] near nerve endings found in and around the ear, effectively aiding in the reduction of symptoms of opioid withdrawal in often as little as 10 minutes," according to the company that developed the device.

Always on the cutting edge of addiction treatment modalities, Dr. Akikur Mohammad, founder and CEO of Inspire Malibu, has been trained in the use of the Bridge and is now making it available to patients at Inspire Malibu treatment facilities.

Call Us 888-343-5949

(/blog/)

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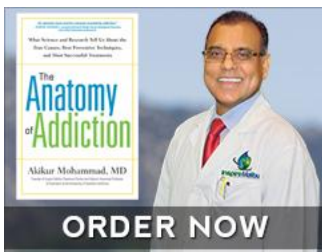

(/the-anatomy-of-addiction/)

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Summary

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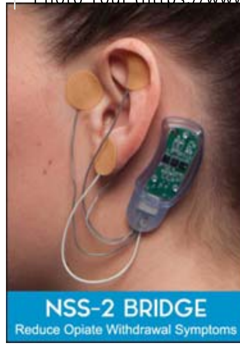

User Rating	2.5 based on **40** votes
Service Type	NNS-2 Bridge: Treating Opiate Withdrawal Symptoms
Inspire Malibu	Inspire Malibu, 30101 Agoura Court, Suite 103,Agoura Hills,CA-91301, Telephone No.(888) 343-5949
California	United States
Description	The NSS-2 Bridge is the latest technology to assist in alleviating many of the uncomfortable symptoms associated with withdrawal and its effects can be felt in as quickly as 30 minutes.

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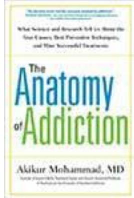
Company Info

Inspire Malibu Corporate
30101 Agoura Court, STE. 103, Agoura Hills, CA 91301
(http://maps.google.com/maps?q=30101+Agoura+Court+Suite 103,+Agoura Hills,+CA+91301)
Phone: 888-343-5949 (tel://+18883435949) www.InspireMalibu.com (https://www.inspiremalibu.com/)



(/the-anatomy-of-addiction/)

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May 24, 2019

Ms. Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Proposed Rules: 4731-33-01 and 4731-33-02

Dear Ms. Debolt:

On behalf of the Northeast Ohio Hospital Opioid Consortium, we would like to comment on the State Medical Board of Ohio's proposed rules concerning withdrawal management and ambulatory detoxification.

The Opioid Consortium is a collaborative of organizations working to significantly reduce the impact of the opioid epidemic in Northeast Ohio. Membership includes The Center for Health Affairs, University Hospitals, Cleveland Clinic, MetroHealth System, St. Vincent Charity Medical Center, VA Northeast Ohio Healthcare System and The Academy of Medicine of Cleveland & Northern Ohio.

The consensus of our membership is that it would be helpful if the Board were to provide clarification in the rules regarding what is considered withdrawal management or detoxification. Specifically, there is some question under the proposed rules whether physicians or physician assistants would be permitted to lower the dosage of prescription opiates or benzodiazepines without this action being considered "withdrawal management, detoxification or ambulatory detoxification." A clear differentiation within the rules between a dose reduction and ambulatory detoxification would facilitate providers' ability to ensure they are in compliance.

Thank you for your consideration of our input on this important topic.

Sincerely,

Randy Jernejcic, MD, MMM
Chair
Northeast Ohio Hospital Opioid Consortium

Lisa Anderson, MSN, RN
Senior Vice President
The Center for Health Affairs

From: Zalar, Camille
To: Debolt, Sallie
Cc: David Streem
Subject: RE: Proposed Rules: 4731-33-01 and 4731-33-02
Date: Thursday, June 20, 2019 4:01:39 PM
Attachments: image001.png
image003.png
image004.png

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Ms. Debolt:

Thank you for responding. The Consortium's suggested definition is below.

Ambulatory Detoxification only occurs when two conditions are simultaneously present: 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.

Rationale: If there's no substance use disorder, then the physician is not providing ambulatory detox. The provider is just tapering or reducing a medication dose.

Thank you for considering.
Camille

Camille Zalar, MHA, BSN, RN, CARN
Director, Education & Initiatives Northeast Ohio Hospital Opioid Consortium
The Center for Health Affairs
216.255.3653 | neohospitals.org | neohospitals.org/consortium | get social
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From: Sallie.Debolt@med.ohio.gov <Sallie.Debolt@med.ohio.gov>
Sent: Thursday, June 20, 2019 3:26 PM
To: Zalar, Camille <camille.zalar@chanet.org>
Subject: RE: Proposed Rules: 4731-33-01 and 4731-33-02

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Dear Ms. Zalar:

Unfortunately I did not receive suggested definitions from Dr. Streem. Please re-send today if possible. I am right now in the process of reviewing the comments received for possible amendments to the proposed rule language.

Respectfully,

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor

Columbus, OH 43215
(614) 644-7021
Sallie.Debolt@med.ohio.gov

From: Zalar, Camille <camille.zalar@chanet.org>
Sent: Thursday, June 20, 2019 3:03 PM
To: Debolt, Sallie <Sallie.Debolt@med.ohio.gov>
Subject: RE: Proposed Rules: 4731-33-01 and 4731-33-02

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Hi Ms. Debolt:

Dr. David Streem from the Cleveland Clinic sent over suggested definitions you mentioned below, at the end of May. I just want to confirm you received these.

Thank you,
Camille

Camille Zalar, MHA, BSN, RN, CARN
Director, Education & Initiatives Northeast Ohio Hospital Opioid Consortium
The Center for Health Affairs
216.255.3653 | neohospitals.org | neohospitals.org/consortium | get social
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From: Sallie.Debolt@med.ohio.gov <Sallie.Debolt@med.ohio.gov>
Sent: Thursday, May 23, 2019 2:58 PM
To: Zalar, Camille <camille.zalar@chanet.org>
Subject: RE: Proposed Rules: 4731-33-01 and 4731-33-02

This message was sent securely using ZixCorp.

Dear Ms. Zalar:

Thank you for submitting comments on the proposed rule 4731-33-02 on behalf of the Northeast Ohio Hospital Opioid Consortium. All comments will be reviewed.

The comment submitted suggests that the rule be clarified to differentiate a dose reduction from an

ambulatory detoxification. The proposed definitions of withdrawal management, detoxification, and ambulatory withdrawal are contained in Rule 4731-33-01 as follows:

(K) “Withdrawal management” or “detoxification” means the process of safely removing addictive substances from the body. It includes the term “medically-assisted stabilization,” which aims to reduce discomfort and potential physical harm for
individuals who are experiencing withdrawal. Withdrawal management 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. 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
(4) A youth services facility, as defined in section 103.75 of the Revised Code.

The first sentence of Rule 4731-33-02 references providing ambulatory detoxification as that term is defined in rule 4731-33-01. Is there suggested alternative language?

Respectfully,

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
(614) 644-7021
Sallie.Debolt@med.ohio.gov

From: Zalar, Camille <camille.zalar@chanet.org>
Sent: Thursday, May 23, 2019 11:47 AM
To: Debolt, Sallie <Sallie.Debolt@med.ohio.gov>
Subject: Proposed Rules: 4731-33-01 and 4731-33-02

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Dear Ms. Debolt:

On behalf of the Northeast Ohio Hospital Opioid Consortium, attached is the comment on the State Medical Board of Ohio's proposed rules concerning withdrawal management and ambulatory detoxification.

Thank you,
Camille Zalar

Camille Zalar, MHA, BSN, RN, CARN
Director, Education & Initiatives, Northeast Ohio Hospital Opioid Consortium
The Center for Health Affairs
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US WorldMeds
4441 Springdale Road
Louisville, KY 40241

May 23, 2019

Via Email: Sallie.Debolt@med.ohio.gov

Sallie Debolt, Senior Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215-6127

Re: Comments to State Medical Board of Ohio Rules 4731-33-01 and 02

Dear Ms. Debolt,

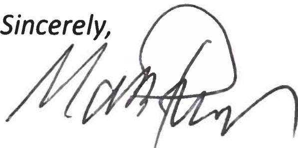
US WorldMeds is a privately-held, Kentucky-based company with approximately 260 employees specializing in development and commercialization of primarily CNS, GI and biologic medications.

Lucemyra (generic name lofexidine) was approved by FDA in May 2018 for the indication of mitigation of symptoms associated with opioid withdrawal following abrupt discontinuation in adults. Additional research is ongoing to assess Lucemyra safety and efficacy in opioid taper, transition to extended release naltrexone, pediatric and neonatal applications. Lucemyra is the only non-opioid, FDA-approved medication for opioid withdrawal treatment.

Ambulatory detoxification and withdrawal management are critical to the overall success of opioid use disorder treatment for a large majority of patients.

We thank the Ohio Medical Board for the opportunity to comment on State Medical Board of Ohio Rules 4731-33-01 and 02. We request revised language based on recent FDA approval of Lucemyra, and the importance of including an opioid-free pathway option for patients and providers.

Sincerely,



Mark Pirner, MD, PhD

Medical Officer, US WorldMeds

Concerning 4731-33-01 Definitions:

(D) "Substance use disorder" includes misuse, ~~dependence~~ *physical dependence/tolerance*, 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."
- More consistent with DSM-5 language.

(F)(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;
- Primary care providers including physicians and mid-level providers who are appropriately certified in addiction treatment and DATA waivered should not be excluded.

(K) "Withdrawal Management" or "detoxification"
Withdrawal management" or "detoxification" ~~means the process of safely removing~~ is the process of managing the signs and symptoms that result from discontinuing addictive substances from the body after dependence and tolerance have developed. It includes the term "medically-assisted stabilization," which aims to reduce discomfort, ~~and~~ potential physical harm *and enhance treatment retention* for individuals who are experiencing withdrawal. Withdrawal management ~~does not constitute substance abuse treatment or rehabilitation~~ *is a critical component of an overall substance abuse treatment plan but is not intended to replace additional trea*tment(s) needed to reduce the risk and harms of relapse and unintended overdose.
- Ambulatory detoxification is an important, initial component of a comprehensive substance abuse treatment plan that includes rehabilitation and relapse prevention.

(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. 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;~~
- Ambulatory detoxification may be performed in correctional facilities where medications are dispensed.

(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 addiction services;
- Excludes providers of both residential/inpatient and ambulatory treatment centers.

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

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

Concerning 4731-33-02

Paragraph A: *Add "All forms of evidence-based medication assisted therapy including opioid partial-agonist and opioid-antagonist treatment pathways should be offered and discussed. The mutually agreed pathway should be documented in the patient's medical record.*
- Initial management plan discussions should include both opioid agonist and opioid antagonist treatment options.

(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.
- The definition of medication-assisted treatment should include withdrawal management based on recent FDA approval of a non-opioid medication specifically indicated for opioid withdrawal management.

(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 appropriate program such as* 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 *extended-release or depot* 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.
- As noted previously, treatment may be provided by appropriately licensed and certified physicians and mid-level providers. Clarify extended-release or depot naltrexone.

Paragraph B (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 0.5, 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
- Consider inclusion of ASAM Level 0.5: "**Early Intervention for Adults and Adolescents; this level of care constitutes a service for individuals who, for a known reason, are at risk of developing substance-related problems, or a service for those for whom there is not yet sufficient information to document a diagnosable substance use disorder*** ***" to enable earlier assessment and preventive intervention in high-risk patients.***

Paragraph B (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.

- Avoid confusion between acute withdrawal management and subsequent substance use disorder treatment. Acute withdrawal management of opioid withdrawal symptoms typically requires 7-10 days for shorter-acting opioids and up to 14-21 days for buprenorphine and methadone.

- Behavioral therapy/counseling should be offered to all patients without distinction based on estimated treatment duration.

(10)*(a)* 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) Buprenorphine without naloxone (buprenorphine mono-product) when a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record;

(ii) A *non-opioid* drug specifically FDA approved for the alleviation of withdrawal symptoms *such as lofexidine*

(iii) 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/);

(iv) A combination of buprenorphine and low dose naloxone (buprenorphine/naloxone combination product)

- Is intended difference between (i) and (ii) opioid partial agonist vs. non-opioid medication? Currently only methadone and lofexidine are FDA-approved for opioid withdrawal management.

10 (c) (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. ~~(iv) In withdrawal management programs of more than thirty days duration, the physician may allow the patient to have the opportunity for up to thirty days of take home medications.~~

- Avoid confusion between acute withdrawal management and subsequent substance use disorder treatment. Acute withdrawal management of opioid withdrawal symptoms typically requires 7-10 days for shorter-acting opioids and up to 14-21 days for buprenorphine and methadone.

May 20, 2019

Ms. Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Proposed Rules: 4731-33-01 and 4731-33-02

Submitted electronically via:Sallie.Debolt@med.ohio.gov

Dear Ms. Debolt:

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching and research. Our health system is comprised of a main campus, 13 community hospitals, 19 family health centers and 3 wellness centers with over 3,600 salaried physicians and scientists. Last year, our system had over seven million patient visits and more than 229,000 hospital admissions

We appreciate the opportunity to comment on the Medical Board's proposed rules governing withdrawal management and ambulatory detoxification.

In our practice, we see patients who have a valid prescription for opiates or benzodiazepines but do not have an active substance use disorder diagnosis. In reading the proposed rules, it is not clear whether these revised rules permit a physician or PA to lower the dose of these medications without this action being considered "withdrawal management, detoxification or ambulatory detoxification." We suggest that the Board clarify how providers are to differentiate a dose reduction from an ambulatory detoxification so that providers are appropriately complying with the rules.

Thank you for conducting a thoughtful process that allows us to provide input on such important issues and for your consideration of this information. Please do not hesitate to contact me if you need additional information.

Sincerely,

David Streem, MD
Section Head, Alcohol and Drug Recovery Center

From:	Barnhart, Blair
To:	Debolt, Sallie
Subject:	RE: Proposed rules 4731-33-01 and 4731-33-02
Date:	Friday, June 21, 2019 4:06:20 PM
Attachments:	image005.png image006.png image003.png

Dear Sallie
I went back to our team to see if we could better explain our position and come up with some suggested language.

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.

It is our impression that under this definitions all practitioners are authorized to prescribe outpatient supplies of drugs for the treatment of addiction. We are uncertain who would be excluded or what activity the Board would exclude with the above statement. Perhaps clarifying language in this sentence would be beneficial.

We suggest stating that "Ambulatory Detoxification only occurs when two conditions are simultaneously present: 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." If there's no substance use disorder, then the practitioner is not providing ambulatory detox. Rather, the practitioner is just tapering or reducing a medication dose.

Is that helpful?

~blair

blair w. barnhart-hinkle, Esq. | Director | Government Relations
25875 Science Park Drive AC1-227, Beachwood, Ohio 44122
Office |216.448.0399
Mobile | 216.312.4030
Email barnhab@ccf.org

From: Sallie.Debolt@med.ohio.gov [mailto:Sallie.Debolt@med.ohio.gov]
Sent: Tuesday, May 21, 2019 4:08 PM
To: Barnhart, Blair <barnhab@ccf.org>
Subject: [EXT] RE: Proposed rules 4731-33-01 and 4731-33-02

Dear Blair:

Thank you for submitting comments on the proposed rule 4731-33-02. All comments will be reviewed.

The comment submitted suggests that the rule be clarified to differentiate a dose reduction from an ambulatory detoxification. The proposed definitions of withdrawal management, detoxification, and ambulatory withdrawal are contained in Rule 4731-33-01 as follows:

(K) “Withdrawal management” or “detoxification” means the process of safely removing addictive substances from the body. It includes the term “medically-assisted stabilization,” which aims to reduce discomfort and potential physical harm for
individuals who are experiencing withdrawal. Withdrawal management 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. 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
(4) A youth services facility, as defined in section 103.75 of the Revised Code.

Is there suggested alternative language?

Respectfully,

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215-6127
(614) 644-7021
Sallie.Debolt@med.ohio
Med.ohio.gov

From: Barnhart, Blair <barnhab@ccf.org>
Sent: Tuesday, May 21, 2019 11:26 AM
To: Debolt, Sallie <Sallie.Debolt@med.ohio.gov>
Subject: Proposed rules 4731-33-01 and 4731-33-02

Dear Sallie
Attached please find the comments of Cleveland Clinic in response to the proposed changes to rules 4731-33-01 and 4731-33-02.

Thank you for your consideration of our feedback.

Take care
~blair

---

blair w. barnhart-hinkle, Esq. | Director | Government Relations
25875 Science Park Drive AC1-227, Beachwood, Ohio 44122
Office |216.448.0399
Mobile | 216.312.4030
Email barnhab@ccf.org

Attached:/s/agencies/comment letter/2019/5_20_2019 medical board comment letter 4731_33-01 and 02 ambulatory detoxification

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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 ~~intoxification~~ 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

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

Rule 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) Buprenorphine without naloxone (buprenorphine mono-product) when a buprenorphine/naloxone combination product is contraindicated, with the contraindication documented in the patient record;~~

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

(~~iii~~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;

(~~iv~~ 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.

~~(Iv) In withdrawal management programs of more than thirty days duration, the physician assistant may allow the patient to have the opportunity for up to thirty days of take-home medications.~~

(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) The physician assistant shall recommend that the patient who is successfully treated for alcohol withdrawal symptoms enter a long-term treatment program to maintain abstinence.