

State Medical Board of Ohio
POLICY COMMITTEE MEETING
August 14, 2019
30 East Broad Street, Columbus, OH 43215, Room 336

<p>Members: Robert Giacalone Mark Bechtel, MD Richard Edgin, MD</p> <p>Other Board Members present: Michael Schottenstein, MD Bruce Saferin, DPM Kim Rothermel, MD Jonathan Feibel, MD Sherry Johnson, DO</p>	<p>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</p>
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Mr. Giacalone called the meeting to order at 9:15 a.m.

Meeting Minutes Review

Mr. Giacalone reported that the draft minutes of the July 10, 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 July 10, 2019 Policy Committee meeting. Dr. Edgin seconded the motion. Motion carried.

Legislative Update

Mr. Groeber provided the legislative update. He reported that we are working on the action items that were included in the budget bill which goes into effect October 16, 2019.

Rules Review Update

Ms. Anderson referred to the report included in the agenda materials. She noted that the dietetic rules went to Licensure Committee instead of Policy Committee as the rules dealt more with licensure issues. Ms. Anderson said that we continue to be on schedule and continue to make progress with the rules.

Proposed Amendments to Rules 4731-11-01 and 4731-11-14 (prescribing for acute and chronic pain)

Ms. Debolt said the rules as proposed to be amended were filed with CSI. CSI has asked the board to respond to the comments received. She explained that her memorandum has 13 recommendations. She believes that recommendations 8 through 12 are questions for

clarification and are suitable for FAQs. The committee needed to address the other recommendations and possibly amend the currently proposed rules.

Additional amendments to be adopted:

- 1) **Recommendation: That the definitions of “Board certification in oncology’ and “Board certification in hematology” proposed by Mr. McGlone from the Ohio Hospital Association be approved. The proposed definition of Board certification in oncology will include “board certified radiation oncologist.”**
- 2) Regarding the suggested definition that “pain management specialist” be defined as: *A board certified or board eligible pain physician or board certified or board eligible hospice and palliative medicine physician.*

Ms. Debolt explained that “pain management specialist” is not defined in the rule. The term is used in 4731-11-14(C)(4)(b), as an option for consultation prior to increasing dosage to greater than 50 MED, and in 4731-11-14(D)(3), as an option for consultation prior to increasing dosage to greater than 80 MED. However, for prescribing a dosage that exceeds an average of 120 MED rule 4731-11-14(E) requires “board certification in pain medicine.”

Recommendation: That the suggested definition for “pain management specialist” not be adopted as it would require that a pain management specialist be board certified in pain medicine for consultation at the 50 MED and 80 MED decision points as well.

- 3) Regarding the request to add board-eligible status to the qualifications of physicians able to prescribe above 120 MED or recommend prescribing at such dosage.

Ms. Debolt reported that board eligibility is not a verifiable status. Adding this status as a qualification could result in a board-eligible physician prescribing at the 120 MED dosage, fail to complete the certification process within the allotted timeframe, and lose board-eligible status thus being no longer able to prescribe the 120 MED dosage.

Recommendation: Board-eligible status should not be added as a qualification for prescribing above 120 MED or recommending that a patient be prescribed at such a dosage.

- 4) Regarding the suggested addition of primary care physicians, APRN-CNPs and APRN CNS who are board-certified in hematology or oncology, and board-certified anesthesiologists to the list of those who can prescribe at 120 MED or above.

Ms. Debolt reported that primary care physicians may prescribe a high dosage for non-terminal cancer if the dosage is recommended by a board-certified pain medicine physician or board-certified hospice and palliative care physician who based the recommendation on a face-to-face visit and examination of the patient. There is no prohibition against a primary care physician prescribing a high dose to a patient with terminal cancer.

It was noted that the Medical Board has historically chosen to determine qualifications for prescribers based on an accredited residency or fellowship and passage of a certification

examination. A review of the requirements for the suggested APRN – CNP and APRN-CNS board certifications finds that they do not meet the standard applied by the Medical Board.

Ms. Debolt said the Medical Board may want to consider whether to add board-certified anesthesiologists. Dr. Schottenstein said that anesthesiologists can pursue a recognized subspecialty in pain management. He did not support adding anesthesiologists to the list. Through discussion, it was noted that the comment received regarding adding anesthesiologists did not provide a rationale for the suggestion.

Recommendation: The listing of prescribers who may recommend an average daily dosage of 120 MED or more should not be expanded to include primary care physicians, APRN – CNPs and APRN-CNS who are board-certified in oncology and/or rheumatology, and board-certified anesthesiologists.

5 &6) Ms. Debolt noted that Dr. Stroom from the Cleveland Clinic suggested an amendment to rule 4731-11-14 (C)(4) to reflect that a physician who is either a specialist in the area of the body affected by the pain or a pain management specialist should not be required to “consider” or “obtain” a referral from a specialist in the area of the body affected by the pain or a pain management specialist because such a referral would be redundant.

Recommendation: Amend 4731-11-14(C)(4) to read:

(4) Except when the patient was prescribed an average daily dosage that exceeded fifty MED before the effective date of this rule, the physician who is neither a specialist in the area of the body affected by the pain nor a pain management specialist shall document consideration of the following:

- (a) Consultation with a specialist in the area of the body affected by the pain;**
- (b) Consultation with a pain management specialist;**
- (c) ...;**
- (d) ...**

7) **Definition of “terminal condition.** Ms. Debolt explained that the proposal to amend the definition of “terminal condition” by no longer referring to the definition in Section 2133.01 was made at the behest of practitioners who state that the requirement for a second physician’s opinion of the patient’s condition hampers appropriate, timely pain relief due to a shortage of doctors and lack of transportation, particularly in more rural and economically depressed areas of the state. Requiring a second physician to examine the patient also leads to additional medical costs.

Recommendation: It is recommended that the proposed amended definition of “terminal condition” be retained without further amendment.

8) **Specialist in area of the body affected by the pain.**

Ms. Debolt noted that question had been raised as to whether oncology specialists (radiation oncology, medical oncology, surgical oncology) are considered “specialists in the area of the body affected by the pain.”

She recommended that the response be provided as a FAQ

Recommendation: It is not unusual for an oncologist to specialize in specific types of cancer. An oncologist should be considered to be a specialist in the area of the affected by pain that is related to the oncologist’s specialty. For example, an oncologist who specializes in gynecological cancers would not be considered a specialist in pain stemming from lung cancer.

Dr. Rothermel asked about when a tumor metastases to another area of body. She cautioned that we must be careful not to restrict patient care.

9) Does a telehealth visit meet the requirement for a face-to-face visit and examination for prescribing to a patient at 120MED or higher?

Recommendation: The requirement of a face-to-face visit and examination is not met via a telehealth visit.

The committee agreed with the recommendation.

Dr. Bechtel said he realized that there must be a formal doctor/patient relationship when prescribing. He asked if Ohio statutes allow for real-time telehealth interactions between a patient and physician.

Ms. Debolt said that for purposes of prescribing an opiate analgesic which is a controlled substance by telehealth, the federal controlled substances law and the federal regulations apply. Ms. Debolt said that there are ways that it can be done if the patient is in the presence of a physician who has a special DEA registration and they are conferring with a remote physician. Additionally, the equipment must meet the standards set in the federal requirements for telehealth. Ms. Debolt noted that rule 4731-11-14 (E)(2) requires a face-to-face visit and examination of the patient.

10) Expand exception provided in 4731-11-14(H) and (I) to specifically except the physician prescribing for a patient with “another condition associated with the individual’s cancer or history of cancer.”

Ms. Debolt explained that this statement had been included in the old version of the chronic pain rules. She said it was a deliberate decision not to include that language in this rule to facilitate the state policy that prescribing opiate analgesics should be limited to the lowest dosage consistent with the patient’s medical condition. A patient may have a remote history of cancer but have another health issue for which opiate analgesics are prescribed.

Recommendation: No change in recommended.

- 11) Regarding use of the term “incurable cancer” rather than “terminal cancer” in 4731-11-14(H)(2).

Recommendation: No change is recommended. Ms. Debolt report that because of significant medical advances a cancer may be incurable, but not terminal. The incurable cancer may cause the patient great pain. However, the exceptions provided in paragraphs (H) and (I) were limited to reflect the state policy that prescribing opioid analgesics should be limited to the lowest dosage consistent with the patient’s medical condition.

- 12) Regarding whether a hospital-based physician must follow the rule when writing an opioid prescription at the time of hospital discharge.

Ms. Debolt said that the rule does not apply while the patient is in the hospital. However, the rule applies when writing a prescription for use out of the hospital. The memorandum in the agenda materials contains an explanation of this topic.

Recommendation: No recommendation is made.

- 13) Technical amendment to correct citation error:

Recommendation: Approve amending paragraph 4731-11-14 (I) to refer to “Rule 4729-17-01 of the Administrative Code.”

Ms. Debolt said that one of the recommendations had been to include a definition of “board-certified pain management physician” in rule 4731-11-01. A handout with a proposed definition was distributed to the committee. Ms. Debolt said the proposed definition is consistent with what we had in the pain management rules. The proposed definition:

Board certification in pain medicine means:

- (a) Current subspecialty certification in pain medicine by a member board of the American board of medical specialties, or hold a current certificate of added qualification in pain medicine by the American osteopathic association bureau of osteopathic specialists;
- (b) Current board certification by the American board of pain medicine; or
- (c) Current board certification by the American board of interventional pain physicians.

Although this information would not be included in the definition, Ms. Debolt explained to the committee that (a) would include subspecialty certification in pain medicine by any of the following ABMS boards:

- American Board of Anesthesiology
- American Board of Emergency Medicine
- American Board of Family Medicine

- American Board of Physical Medicine and Rehabilitation
- American Board of Psychiatry and Neurology
- American Board of Radiology

Dr. Feibel questioned the American Board of Radiology. Ms. Debolt responded that the ABMS boards listed offer a pain management subspecialty.

General discussion was held regarding training requirements for board certification and subspecialty certification.

Mr. Giacalone asked about the American Board of Pain Medicine (ABPM) It was noted that the American Board of Pain Medicine is not an ABMS recognized board as non-fellowship trained physicians and those who have completed unaccredited fellowships may sit for the ABPM examination.

Dr. Bechtel moved to accept the recommendations as proposed, including the definition of board certification in pain management. Dr. Edgin seconded the motion. Motion carried.

Proposed Internal Management Rule 4731-30-02 Approval of Licensure Applications

Ms. Anderson said the committee discussed the proposed internal management rule 4731-30-02, Approval of Licensure Applications, at its July meeting. The rule allows for the delegation of the routine authorization of most license types and reflects the Board's commitment to reducing processing times for licensure issuance. Ms. Anderson said that this rule is one that we want to get in place before the budget bill goes into effect on October 16, 2019.

The proposed rule was sent to interested parties and we received two comments.

The Ohio Academy of Nutrition and Dietetics indicated general approval of the rule, but expressed concern that Rule 4731-30-02(E) which would permit the Board Secretary and Supervising Member or the Deputy Director of licensure to refer an application or class of applications to the Board for review, which could result in delay for those license applicants.

We also received comments from the Ohio Society for Respiratory Care expressing approval for the rule and that it will be beneficial for employers, applicants for licensure, and the board.

Ms. Anderson addressed the comments from the Ohio Academy of Nutrition and Dietetics. She suggested that wording in paragraph E be changed to:

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

Ms. Anderson said she did not believe such situation would happen very often. However, when new license types have been added, such as certificates to recommend medical marijuana, or the conceded eminence certificates, the board initially wanted to review the applications. As the board became more familiar with the applications for these certificates, the board delegated

review and approval to the Secretary and Supervising Member. She said putting the power with the board would address concerns raised about paragraph E.

Discussion followed. Concerns were raised about the potential delay in review of applications by the board. Ms. Anderson suggested that such applications could go to the licensure committee for review and recommendation to the full board.

Ms. Anderson said that she would prepare language for the board to consider this afternoon.

Motion was made by Dr. Edgin to conditionally approve the rule and to recommend to the full Board to authorize filing with JCARR, LSC and the Secretary of State's office to be effective October 16, 2019. Dr. Bechtel seconded the motion. Motion carried.

Mr. Groeber announced a change in meeting times to begin in September. The Policy Committee will meet at 9 a.m. and the board meeting will begin at 9:45 a.m.

Ms. Giacalone announced that Sallie Debolt, Senior Counsel, will be retiring the end of August. He expressed appreciation for her invaluable help, and all agreed she will be greatly missed.

Adjourn

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

The meeting adjourned at 9:49 a.m.

jkw

MEMORANDUM

TO: Amol Soin, M.D., Chair, Policy Committee
Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Progress

DATE: September 3, 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 8/30/19

For September Policy Committee

None

For September Board Meeting

4731-1-05	4731-18-01	4731-25-08
4731-1-08	4731-1-01	4731-1-11
4731-1-13	4731-1-18	4731-1-19
4731-4-01	4731-4-02	4730-3-01
4730-3-02	4759-4-11	4774-2-01
4774-2-02	4778-2-01	4778-2-02

Sent for Initial Comment – Deadline 9/13/19

4759-4-04 4759-4-08

Sent for Initial Comment – Deadline 8/9/19

4731-11-02	4731-11-03	4731-11-04
4731-11-04.1	4731-11-07	4731-11-11

RULES AT CSI

4731-18 Chapter (anti-trust review)

Comment Deadline 4/10/19

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

Comment Deadline 7/31/19

4731-13-13

Comment deadline 8/1/19

4730 Chapters 1, 2 and 3

Approved to File with CSI

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	4730-4-01	4730-4-02

Military provisions for all license types

RULES AT JCARR

No Change Rules – Jurisdiction ends 11/26/19

4759-4-02 4759-5-01

No Change Rule – Jurisdiction ends 9/19/19

4731-1-05

No Change Rule – jurisdiction ends 9/15/19

4731-9-01

No Change Rules – jurisdiction ends 9/30/19

4759-5-04 4759-5-05 4759-5-06

HEARING SCHEDULED 10/2/19

4759 Chapter 4731-31-01

Final Filed 8/20/19 – effective 10/17/19

4731-30-03

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 recommendation	Standing Authority to File with JCAAR	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	09/15/19
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									12/27/19
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	12/27/19
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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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		07/05/19 6/20/18	08/09/19 7/24/18			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 alcohol 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		07/05/19	08/09/19			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		07/10/19	07/31/19	07/31/24
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	Refiled 8/20/19 4/29/19	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

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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
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		07/05/19	08/09/19				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		07/05/19	08/09/19				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	<i>Preliminary Education Certificate</i>					09/14/16									<i>rescinded</i>
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 12/11/2015		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		07/05/19	08/09/19				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		07/05/19	08/09/19				01/24/17
4731-1-23	<i>Home Study Schools</i>														<i>rescinded</i>
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	<i>Determination of Equiv. Military Educ. For CT/MT</i>		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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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		07/05/19	08/09/19				06/29/19
4731-4-02	Criminal Records Checks			02/20/19			04/23/19	05/31/19		07/05/19	08/09/19				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
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		07/10/19	07/31/19	07/31/24
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		07/10/19	07/31/19	07/31/24
4731-6-03	<i>Eligibility for the Medical and Osteopathic Examination</i>			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19		07/10/19	07/31/19	<i>rescinded</i>
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		07/10/19	07/31/19	07/31/24
4731-6-07	<i>Passing Average on Examination</i>			2/26/18 2/8/17 5/13/2016		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19		07/10/19	07/31/19	<i>rescinded</i>
4731-6-10	<i>Clinical Competency Examination</i>			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		07/10/19	07/31/19	<i>rescinded</i>
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		07/10/19	07/31/19	07/31/24

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-6-15	Eligibility for Licensure of National Board Diplomats and Medical Council of Canada 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		07/10/19	07/31/19	07/31/24
4731-6-16	<i>Eligibility for Medical or Osteopathic Licensure by Endorsement of Licenses Granted by Other States</i>			2/26/18 2/8/2017		07/13/16	09/25/18			4/10/19 6/9/2017	05/13/19		07/10/19	07/31/19	rescinded
4731-6-20	<i>Requests for medical or osteopathic licensure application</i>														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		07/10/19	07/31/19	07/31/24
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		07/10/19	07/31/19	07/31/24
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		07/10/19	07/31/19	07/31/24
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		07/10/19	07/31/19	07/31/24
4731-6-32	<i>Visiting Faculty Certificates</i>			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		07/10/19	07/31/19	rescinded
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		07/10/19	07/31/19	07/31/24
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		07/10/19	07/31/19	07/31/24
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		07/10/19	07/31/19	07/31/24
4731-7-01	Method of Notice of Meetings								04/08/19	04/29/19	06/05/19		07/10/19	07/31/19	07/31/24

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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
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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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			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
4731-11-02	Controlled Substances - General Provisions	7/10/2019	7/10/19 10/8/14 05/13/15	7/26/19 5/11/18 Revision 4/13/17		6/14/18 05/11/17 1/8/2015 06/13/18				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	7/10/2019	7/10/19 10/8/14 05/13/15	07/26/19			01/08/15			8/24/15 7/1/2015	11/02/15		10/14/2015	12/31/15	12/31/20
4731-11-04	Controlled Substances: Utilization for Weight Reduction	7/10/2019	7/10/19 10/8/14 05/13/15	07/26/19			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	7/10/2019	7/10/19 10/8/14 05/13/15	07/26/19			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	7/10/2019	7/10/19 10/8/14 05/13/15	07/26/19			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

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4731-11-11	Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).	7/10/2019	7/10/19 10/8/14 05/13/15	7/26/19 7/23/15 1/22/15			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 Prescribing of Opioid Analgesics for Acute Pain		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 filed 8/21/17	04/30/19	rescinded
4731-11-13	Prescribing for subacute and chronic pain			04/13/17			05/11/17				07/26/17			08/31/17	08/31/22
4731-11-14	Preliminary Education for Licensure in Podiatric Medicine and Surgery			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
4731-12-01	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
4731-12-02	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
4731-12-03	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
4731-12-04	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
4731-12-05	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
4731-12-06	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
4731-12-07	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
4731-13-01	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
4731-13-02	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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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
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	<i>Prehearing conference</i>														<i>rescinded</i>
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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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
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; Confidentiality 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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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	<i>Practice Prohibition</i>		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		07/10/19	07/31/19	<i>rescinded</i>
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
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	<i>Standards for Surgery</i>			1/17/18 1/15/2016		03/14/18	06/27/18			7/30/19 4/10/19	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	<i>Duty of License to Report HIV or HBV Infection; Confidentiality</i>		12/09/15	12/11/15		02/10/16	03/07/16	05/11/16		08/16/16	09/19/16		<i>Rescinded</i> 1/9/2016	11/30/16	<i>Rescinded</i> 1/9/2016

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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
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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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
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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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		07/10/19	07/31/19	07/31/24
4731-24-02	Anesthesiologist Assistants; Supervision			10/30/18			1/11/19 11/7/2013			4/10/19 2/19/14	05/13/19		07/10/19	07/31/19	07/31/24
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		07/10/19	07/31/19	07/31/24
4731-24-04	<i>Anesthesiologist Assistants; Prohibitions</i>						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		07/10/19	07/31/19	07/31/24
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			7/30/19 4/10/19	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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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
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		07/10/19	07/26/19									09/12/18	09/23/18	
4731-30-03	Approval of Licensure Applications		07/26/19						8//14/19	08/26/19				10/17/19	10/17/24
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 Condition 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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-33-02	Standards and procedure for withdrawal management for drug or alcohol addiction	5/8/2019	05/08/19	05/09/19	07/10/19										
4731-33-03	Office-Based Treatment for Opioid 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		07/10/19	07/31/19	07/31/24
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

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 recommendation	Standing Authority to File with JCAAR	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
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
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

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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
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

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4761-4-03	<i>Recognition of military educational programs for active duty military members and/or military veterans</i>			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	<i>Non-resident practice of respiratory care</i>									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	<i>Criminal records check</i>													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
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	<i>Licenses not in active practice</i>									01/19/19				02/28/19	Rescinded
4761-9-01	Definition 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

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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
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		07/08/19	09/08/19				08/17/21
4774-2-02	Criminal Records Checks			01/15/16			04/23/19	05/31/19		07/08/19	09/08/19				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



MEMORANDUM

TO: Amol Soin, M.D., Chair, Policy Committee
Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Controlled Substance Prescribing Rules

DATE: September 3, 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 anorexiant 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)

The rules were circulated to interested parties as no change rules in order to obtain feedback. No comments were received for the following rules:

- 4731-11-02;
- 4731-11-03;
- 4731-11-07

Recommendation: File rules with CSI as no change rules.

One comment, from the Board of Pharmacy, was received for Rule 4731-11-11. The Pharmacy Board recommends that Section (A)(5) defining “reported drugs” should be updated to Rule 4729:8-2-01 of the OAC.

Recommendation: Make the suggested amendment and file rule with CSI.

Numerous comments were received on Rules 4731-11-04 and.041, which are attached for your review.

Recommendation: Review the comments and discuss at the October Policy Committee meeting.

Note: The rules must be reviewed by PAPC, and we are looking to schedule a meeting for October. Any CSI filing will occur after PAPC review and any comments provided to the Policy Committee and full Board prior to filing.

Action Requested: For Rules 4731-11-02, 4731-11-03, 4731-11-07, refer to full Board for filing with CSI as no change rules. For Rule 4731-11-11, refer to full Board with suggested amendments, and for filing with CSI. No action requested at this time for Rules 4731-11-04 and 4731-11-041.

Name	Email	Organization	Comments	Attachments
Rule 4731-11-04 Curry, Trace, M.D.	trace.curry@gmail.com	Medical Board JouneyLite Physicians	Short term anorexiant for weight reduction Get rid of the 12 week limit Current rule emphasizes when NOT to use rather than when to use. If patient just 1 day late for filling script, must be off for 6 months, they gain back weight. Should be able to use the short acting medications such as phentermine long term to treat obesity as it should be as a chronic disease	pdf or Word document (link)
Cetin, Derrick, D.O.	CETIND@ccf.org		I urge the Board to work with both patients and the healthcare community to better understand how Ohio's overly restrictive and dated prescribing restrictions are impeding so many Ohioans from accessing the full continuum of care for obesity — in the same fashion that others currently enjoy who struggle with chronic disease such as high cholesterol, heart disease or diabetes.	
Selby, Luke, M.D.	Luke.Selby@osumc.edu		Re-submission of 2013 letter as OSMA position has not changed. Rule is out-dated, particularly 3 months limitation and having see patient every 3 months	
Nesbett, Neal, M.D. Gallagher, Chris	hayhurst@osma.org chris@potomaccurrents.com	OSMA Obesity Action Coalition	Same as Dr. Selby Comments applicable to 4731-11-04 and 4731-11-04.1. Supervising physician should be authorized to prescribe any drug within physician's normal practice and without requiring physician to review each chart after the PA sees the patient. Use a more inclusive term such as "practitioner" or "prescriber"	
Adamson, Beth, Exec Dir. Leitzel, Donna, patient	oapa@ohiopa.com leitzel@wowway.com	OAPA	Extraordinary restrictions on use of weight loss drugs Overly restrictive rules. Let PAs prescribe weight loss drugs; consider rescinding the rules completely and let physicians use medical judgment.	
Henchen, Ross, M.D. and 2 PAs Skinner, Megan, APRN	alana@getvitalityhealth.com t_m_skinner5@yahoo.com		Same as Dr. Selby remove this verbiage "short term anorexiatic for purposes of weight reduction" and replacing with "anti-obesity medication for the purpose of treating overweight and obesity. Allow long-term use of "short-term" drugs. In 4731-11-04.1, allow PAs to prescribe and change medications as do APRNs.	
Fore, Latyonya, NP	latfore@yahoo.com		Should allow telemedicine visits for both 4731-11-04 and 4731-11-04.1. For 4731-11-04, drop the 12 weeks maximum, require closer monitoring for 12 weeks, but allow long term use. Should not require discontinuation based on failure to lose weight. Medical Board should designate phentermine to be a chronic weight loss drug. Includes references to several studies.	
Burguera, Barto, M.D., PhD Schultz, Karen, CNS Schroff, Maria, MD	barnhab@ccf.org SCHULZK@ccf.org dr.mara2007@gmail.com	Cleveland Clinic	Should amend both 4731-11-04 and 4731-11-04.1 to allow continuous treatment as phentermine is safe. Same as Dr. Selby	
Butsch, W. Scott, MD, Director of Obesity Medicine	BUTSCHW@ccf.org	Cleveland Clinic	Obesity is a chronic disease and the rules prevent appropriate treatment.	
Mavko, Kay, RD		OH Academy of Nutrition and Dietetics	Please correct spelling of dietitian. For both 4731-11-04 and 4731-11-04.1, add requirements for "nutritionally adequate calorie restricted diet", "nutritional counseling and intensive behavioral therapy" and exercise program for weight loss.	
Anderson, Stan, M.D.	ASpicer@ohioafp.org		Obesity needs on-going treatment, OARRS should take care of "doctor shopping" concerns, easier to prescribe morphine than Schedule 4 weight loss drug, chronic weight management drugs too expensive for many patients Should rescind the rule, have a rule for obesity treatment instead. Limits patient's ability to lose any significant amount of weight. Rule limits PA practice and is contradictory to "new process of prescribing."	
Thornhill, Sandra, PA Schierholt, Steven, Exec. Director	Sandra.Thornhill@Uhhospitals.org Cameron.McNamee@pharmacy.ohio.gov	Ohio Board of Pharmacy Obesity Medicine Association	Supports continuing the rules as currently written. Should allow long-term use of phentermine. OH physician who treats obesity according to standard of care violates the Ohio rule.	
Lazarus, Ethan, M.D., VP	chris@potomaccurrents.com			



August 9, 2019

Sallie Debolt, General Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 4715

Dear Ms. Debolt:

The Ohio Association of Physician Assistants (OAPA) would like to address rules OAC 4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-07 and 4731-11-11 which the Medical Board is proposing to continue without any changes; and further OAPA would like to submit suggested amendments to 4731-11-04.1.

In 2018, the 132nd General Assembly passed Senate Bill 259 which expands the authority of physician assistants to prescribe drugs and therapeutic devices by eliminating the State Medical Board's authority to adopt a physician assistant formulary, which in turn expands the supervising physician's authority and decision-making process in granting physician-delegated prescriptive privileges to physician assistants. OAPA recognizes Senate Bill 259 does not eliminate the Board's statutory authority to adopt rules in accordance with ORC 4730.39 governing physician-delegated prescriptive authority, provided any rules adopted are consistent with the intent and spirit of the statutes. OAPA believes a physician assistant has the authority to prescribe any drugs or therapeutic devices that are within the supervising physician scope of practice in accordance with ORC 4730.41 and 4730.42. Further, OAPA believes the Board should not have authority to promulgate rules that would restrict a supervising physician from delegating to a physician assistant the responsibility of **prescribing, administering and/or monitoring the therapeutic efficacy of** any drug or therapeutic device the supervising physician is authorized to prescribe within their scope of practice that have not been specifically restricted by federal law.

OAPA could not find any federal rules and regulations that restricts a physician assistant from prescribing stimulants or anorexiant for either short-term weight reduction or chronic weight management. Nor could OAPA find any pharmaceutical manufacturers suggestion that only a physician shall be allowed to prescribe anorexiant for the same.

OAC 4730-2-07 (A)(3) currently states that physician assistants and supervising physicians must follow the requirements set in all sections of OAC 4731-11. OAPA understands that multiple sections of OAC 4730 of the physician assistant rules have been proposed to be amended to comply with the recent changes made in Senate Bill 259 and are currently being reviewed by the Common Sense Initiative Office, however; the requirements set forth in OAC 4730-2-07 to comply with OAC 4731-11 have not been proposed to be either amended or eliminated.

Constituent Chapter of the American Academy of Physician Assistants

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Therefore, OAPA is suggesting the following amendments to OAC 4731-11-04.1:

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 anorexiant. 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 anorexiant. 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) (2) 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 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.

*Note: OAPA has not suggested inserting the terms "physician assistant" in every section of OAC 4731-11 because the requirements set forth in OAC 4730-2-07 clearly imply that every standard of care a physician shall be held to when prescribing controlled substances, a physician assistant should be held to the same standards. And, as physician assistant is currently included in OAC 4731-11-04.1 (A) (2) (a) and (5), (B)(2)(a)(b) and (3)(a)(b); OAPA believes it is necessary to **amend by deleting** these subsections as to keep the language consistent throughout all sections of OAC 4731-11.*

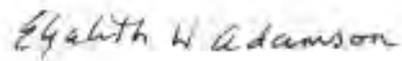
The passage of Senate Bill 259 has greatly expanded Physician Assistant scope of practice and prescriptive authority to be equivalent to and consistent with their supervising physician scope of practice. There are no citation in either ORC 4730 or OAC 4730 that specifically requires a supervising physician to "**personally review the medical records of each patient to whom the physician assistant has prescribed a controlled substance anorexiant following each visit**", or for any other particular type of patient care service, condition, diagnosis, drugs and therapeutic devices or treatment. The responsibilities of the supervising physician are clearly delineated in ORC 4730.21. OAPA believes the language in OAC 4731-11-04.1 requiring a physician to "personally review each medical record for each visit" is overly restrictive and inconsistent with the intent of ORC 4730.21. OAPA also believes the current language in OAC 4731-11-04.1 has already caused confusion amongst some physicians and administrators that have questioned if physician assistants are not mentioned in the other sections of OAC 4731-11 are they excluded from being able to be delegated the authority to prescribe stimulants and/or anorexiant as described in OAC 4731-11-03 and OAC 4731-11-04.

In conclusion, OAPA believes to achieve clarity with our regulatory terminology in Ohio, future consideration should be the utilization of more generic term such as practitioner, prescriber, provider or prescribing provider when crafting new language for Ohio statutes or rules governing the prescriptive authority and/or scope of practice for physicians, physician assistants and advanced practice registered nurses. The Medical Board's request for review OAC 4731-11 has clearly evoked the need to consider making these changes.

Page 5

If it has not been done already, OAPA respectfully requests this proposed rule be reviewed by the Physician Assistant Policy Committee of the Medical Board so they may make recommendations to the board in accordance with ORC 4730.06 (A) (2). OAPA greatly appreciate the opportunity to comment on these proposed rules. If you have any questions or need further information, please do not hesitate to contact us.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth W. Adamson".

Elizabeth W. Adamson
Executive Director

Debolt, Sallie

From: Ann Spicer <ASpicer@ohioafp.org>
Sent: Monday, August 12, 2019 9:49 AM
To: Debolt, Sallie
Subject: FW: obesity rules

Sallie - I realize that the deadline for comments on the obesity rules has passed but I just received these comments from our immediate past president who is double-boarded in obesity medicine and family medicine. I hope that you will accept these comments for consideration.

Ann

Ann M. Spicer | Executive Vice President Ohio Academy of Family Physicians
4075 N. High St. | Columbus, OH 43214
Direct: 614.914.5625 | Main: 614.267.7867 | Fax: 614.267.9191 aspicer@ohioafp.org |
<https://gcc01.safelinks.protection.outlook.com/?url=www.ohioafp.org&data=02%7C01%7CSallie.Debolt%40med.ohio.gov%7Ca37bea8fb9414999468c08d71f2bc94f%7C50f8fcc494d84f0784eb36ed57c7c8a2%7C0%7C0%7C637012145226036809&sdata=Xhoh9xrBuLkqfQFEJrukkf7uKzY05PXfLi%2BsCrU2XX0%3D&reserved=0>

-----Original Message-----

From: Stan Anderson [mailto:stanand1@sbcglobal.net]
Sent: Sunday, August 11, 2019 8:38 AM
To: Ann Spicer <ASpicer@ohioafp.org>
Cc: Jennifer Hayhurst <jhayhurst@osma.org>
Subject: Re: obesity rules

1. People with high BMI do not normalize in 3 months
2. Obesity is a disease. It needs ongoing treatment.
3. If a person is delayed by 38 days from the first prescription they can not get it filled for 6 months. Really?!
4. It is easier to prescribe morphine than a schedule 4 medicine.
5. Across the country there are more abuses for Tylenol than for phentermine.
6. Because of the Board's restrictions there are the fewest number of obesity specialists in Ohio.
7. The board is prejudicial and biased in that we have to use the most expensive medicines (branded) and more surgeries.
8. The approach that the board takes is outdated and not scientifically valid.
9. Poverty is a risk factor for obesity. People cannot afford branded meds. This is a disease that affects African Americans and Latinos disproportionately.
10. The emotional impact on patients that begin to lose weight and feel great, only to be told we have to stop it is devastating. Devastating! The number of people that come back in crying is overwhelming.
11. The original reason that the 3 month restriction was put in place was because of several deaths caused by inappropriate use due to doctor shopping. So with OARRS in place and better awareness that will never happen again.
12. It does not make any sense that this has been made into an extremely highly regulated fiasco.

Stan Anderson, MD



August 9, 2019

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

RE: Rules: 4731-11-04 and 4731-11-04.1

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 rules under the five year review. Below we have proposed either inserting new language or eliminating language to better care for patients.

4731-11-04 Controlled substances: utilization of short term anorexiant for weight reduction

Current Language

4731-11-04(C)(1) The physician shall personally meet face-to-face or via telemedicine 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.

CC comments

We suggest that the Medical Board allow patients to meet with their physicians via telemedicine as patients oftentimes find it difficult to come to the office because they are struggling to get time off of work or they face challenges with transportation. Providing patients with the option of telemedicine will alleviate these concerns and remove a substantial barrier to their success while still maintaining the important patient-physician relationship.

Current Language

4731-11-04(C)(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 be closely monitored for the first three

months of treatment ~~not exceed twelve weeks~~. That time period includes any interruption in treatment that may be permitted under paragraph (C)(3) of this rule.

CC Comments: We suggest the above modifications be made to the current language. There are a number of studies (please see relevant studies cited at the end of this document) that demonstrate that addiction to these medications is low and their efficacy in treatment is high. Further, studies also show that patients who are able to stay on the medications are able to maintain their weight loss. The requirement that patients only use these for short-term treatment is a substantial barrier to care for those patients who are successful as removing them from the medication may derail their progress.

Current Language

~~4731-11-04 (C)(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~~

~~4731-11-04 (C)(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.~~

CC Comments

As mentioned previously, we believe that references to short-term use of the drugs should be modified because studies have demonstrated the safety and efficacy of the medications.

Current Language

~~4731-11-04 (5) The physician shall not initiate or shall discontinue utilizing all controlled substance short term anorexiant for purposes of weight reduction immediately upon ascertaining or having reason to believe:~~

~~(5)(c)~~

~~(e) 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;~~

Cleveland Clinic Comments:

We are concerned that the rule requires patients to be removed from the medication if they are failing to lose weight. We suggest that this language be removed because in our experience, some patients are rapidly gaining weight and the medication helps to stabilize them so that aren't gaining weight but not yet losing it. In this instance, we believe patients should be allowed to remain on the medication

so that they can begin their treatment and move towards weight loss.

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

Current Language:

4731-11-04.1(B)(1) The physician shall meet face-to-face with the patient for the initial visit and at least every thirty days either face-to face or telemedicine 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.

Cleveland Clinic Comments

Similar to our comments above, we believe the Medical Board should include telemedicine as an option for patients to support their weight loss journey.

Other Cleveland Clinic Comments – Phentermine Designation

We believe that the Medical Board should designate phentermine as a chronic weight loss medication. Below we have provided our reasoning and supporting research for our position.

Clinical guidelines support long-term use

The 2015 Endocrine Society has clinical guidelines on the pharmacologic management of obesity stating that there is minimal evidence of any serious, long-term side effects with phentermine and that it is reasonable for clinicians to prescribe phentermine long-term. The guidelines include safety recommendations for long-term prescribing. The review article below also describes the off-label use of phentermine in clinical practice.

References

Apovian CM, Aronne LJ, Bessen DH et al. **Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline.** J Clin Endocrinol Metab, February 2015, 100(2):342–362 Available at: <https://academic.oup.com/jcem/article/100/2/342/2813109>

Hendricks EJ. Off-label drugs for weight management. <https://www.dovepress.com/off-label-drugs-for-weight-management-peer-reviewed-article-DMSO>

Available at: <https://www.dovepress.com/off-label-drugs-for-weight-management-peer-reviewed-article-DMSO>

Phentermine has demonstrated safety in long-term use

In a 28 week, randomized, controlled trial comparing phentermine/topiramate extended release (Qsymia® compared to phentermine 15mg daily or topiramate, the 15mg phentermine for 6 months led to 7% weight loss and was safe. This is the same dose available in Qsymia® formulation with is FDA approved for long-term use. Due to the high cost of Qsymia®, it would benefit patients to have phentermine available for long-term use.

References

Aronne LJ, Wadden TA, Peterson C et al. Evaluation of Phentermine and Topiramate versus Phentermine/Topiramate Extended-Release in Obese Adults. Obesity (2013) 21, 2163–2171. doi:10.1002/oby.20584 Available at: <https://onlinelibrary.wiley.com/doi/full/10.1002/oby.20584>

Qsymia® prescribing information Available at:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=40dd5602-53da-45ac-bb4b->

Studies demonstrate long-term safety and efficacy

A retrospective study from an electronic medical record of 13,972 adults comparing those with longer term use to those with short-term use (<3 months) demonstrated that long-term users of phentermine experienced more weight loss: patients using continuously for >12 months experienced 7.4% weight loss, and at 24 months it was much greater than the short-term group. Composite cardiovascular death (CVD) or death outcome was rare (0.3%, 41 deaths) with no significant difference between groups comparing short term, vs long-term use. Patients using phentermine for longer periods experienced greater weight loss that was sustained while staying on the medication.

Reference

Lewis KH, Fischer H, Ard J. et al. Safety and Effectiveness of Longer-Term Phentermine Use: Clinical Outcomes from an Electronic Health Record Cohort. *Obesity* (2019) 27, 591-602. doi:10.1002/oby.22430. Available at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/oby.22430>

Phentermine has demonstrated that it has very low addictive potential

In the rule, one of the current parameters is usage beyond 12 weeks. In the following study, 269 patients were treated for 1.1-21.1 years and the study showed that phentermine did not induce drug cravings or withdrawal symptoms.

Reference

Hendricks EJ, Srisurapanont M, Schmidt SL et al. Addiction potential of phentermine prescribed during long-term treatment of obesity. *International Journal of Obesity*

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 us if you need additional information.

Sincerely,



Barto Burguera, M.D. Ph.D
Chairman Endocrinology & Metabolism Institute
Professor of Medicine, Cleveland Clinic Lerner College of Medicine



Marcio L. Griebeler, M.D.
Director, Obesity EMI Programs

Diana Isaacs, PharmD, BCPS, BCACP, BC-ADM, CDE
Clinical Pharmacy Specialist

AUGUST 8, 2019

TO MEMBERS OF THE STATE MEDICAL BOARD OF OHIO:

I am a physician in the Bariatric and Metabolic Institute at the Cleveland Clinic, whose professional career has focused on the care of patients who are overweight and have obesity. I was the first physician in the U.S. to complete a subspecialty in obesity medicine in 2008 and have practiced obesity medicine in three states. My clinical experience has mostly come from my work at the Massachusetts General Hospital in Boston, MA and, over this past year, at the Cleveland Clinic.

I am in strong favor of amending Rules 4731-11-04 and 4731-11-04.1 .

I want to make three points to support the need to amend these Rules.

- 1. Obesity is a failure of normal weight and energy regulation.**
- 2. Obesity is a heterogeneous chronic disease that requires long term treatment.**
- 3. Anti-obesity medications like phentermine are safe and effective.**

- Obesity is a failure of normal weight and energy regulation**

I believe rules like 4731-11-04 and 4731-11-04.1 in part stem from a common belief that obesity is a character flaw, a behavior problem that exists in weak individuals who don't have the coping mechanisms or willpower to resist high calorie foods and are too lazy to pursue routine exercise.

In the scientific world, this belief is not commonly accepted. We understand the disease of obesity as the failure of normal weight and energy regulatory mechanisms. Our weight (fat mass) is tightly regulated by numerous physiological pathways that connect the brain, digestive tract, fat cells and muscle.¹ The physiology of weight regulation is complex with robust and redundant systems to ensure sufficient, but not excessive, energy stores. Several studies have shown that the body adapts to changes in caloric intake by altering the metabolism and appetite signals.³ So when an individual loses weight on a restricted diet, the body responds by slowing the metabolism and changing intestinal hormones that increase our appetite and make us feel less full. This creates an environment making it difficult to sustain body weight loss.

I see patients with obesity everyday and I believe it is important to recognize that obesity is a failure of normal regulatory mechanisms in the body. We need to

recognize that obesity is not a lifestyle choice or a character flaw, but in fact a disease. ²

- **Anti-obesity medications like phentermine are a safe and effective.**

Anti-obesity medications similarly have been misunderstood and commonly described as appetite suppressants or anorexiant. When medications like phentermine were first developed, it made sense that medications need only to be used for a short period of time, because obesity was thought to be easily resolved just by decreasing our food intake. Short term studies of these medications were effective and safe and no further long term studies were needed, in part due to our incomplete knowledge of obesity at the time. Phentermine is often misclassified as an amphetamine and I think arcane laws like Rules 4731-11-04 and 4731-11-04.1 are a result of this typical historical belief about phentermine and similar class of anti-obesity medications. Historically, the results of other anti-obesity medications like Fenfluramine, co-prescribed with phentermine did not help justify phentermine as an effective and safe medication. However, this was “guilt by association” and phentermine has not been implicated in causing heart failure and death that were described with the “Fen-Phen”. The more than 50 year history of phentermine use in the treatment of obesity and current ranking as the most heavily prescribed anti-obesity medication should be supportive.

- **Obesity is a heterogeneous chronic disease that requires long term treatment**

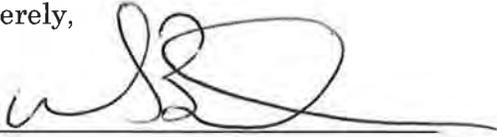
We need to recognize that our knowledge of obesity and therefore the practice of using obesity pharmacotherapy has changed. No longer do we think that a higher dose of a drug is necessarily more effective. Instead we may think of using combinations of medications with the understanding of the complex biology of energy regulation when treating obesity. We need to embrace the heterogeneity of the disease and understand the great variation of response to medications like phentermine. I have noticed an impressive response with some patients with just a quarter of a 37.5mg per day tablet of phentermine. I have seen too many people just within the last year because of these Rules who have regained weight after the phentermine was stopped. If a drug is effective why do we stop it? We don't practice this way in other disease states like hypertension or hyperlipidemia, so why is obesity the exception?

Please realize our knowledge of obesity has evolved and we understand obesity is not just one disease. There are more than 10 types of genetic obesity and more than 200 related comorbidities. Our knowledge of the treatments for obesity has evolved and we no longer have a “one size fits all” approach. We no longer consider medications appetite suppressants as our knowledge of their mechanisms of actions in the complex biological pathways of energy regulation has evolved.

In conclusion, it is important to know these laws are preventing APPROPRIATE treatment of obesity. Many individuals that I have treated in the last year, respond well to the medication, however I'm unable to actually treat this chronic disease. We need to start treating people with obesity appropriately and with respect. That begins, in the State of Ohio, by amending these Rules.

Thank you for considering this matter,

Sincerely,

A handwritten signature in black ink, appearing to read 'W. Butsch', written over a horizontal line.

W. Scott Butsch, MD, MSc.
Director of Obesity Medicine
Bariatric and Metabolic Institute
Cleveland Clinic

References

1. Friedman, JM. A War on Obesity, Not the Obese. *Science*, 2003;299:856-8.
2. Obesity as a Disease: A White Paper on Evidence and Arguments
Commissioned by the Council of The Obesity Society. *Obesity*, 2008;16:1161.
3. Sumithran P et al. Long term persistence of hormonal adaptations to weight loss.
New England Journal of Medicine. 2011; 365:1597-604.

From: [Cetin, D.O., Derrick](#)
To: [Debolt, Sallie](#); [Butsch, Winfield](#)
Subject: RE: Advocating for anti-obesity medications
Date: Wednesday, August 7, 2019 6:54:52 PM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)

Hi Ms Debolt,

I wanted to add my comments on the proposed changes in rule 4731-1104 regarding the guidelines on anti-obesity medications. Thank you for taking the initiative to facilitate such changes. The current guidelines have always been anti-guidelines as the emphasis is on when not to use the medication rather than when to use the medications. Over the years of practicing obesity medicine at the Cleveland Clinic, I have noticed the barriers put by our pharmacists in informing patients that anti-obesity medications should not be continued after the patient has reached a normal BMI or under the anti-guidelines of 27. There is complete lack of understanding of the use of these medications for long term treatment of obesity which is now recognized as a chronic disease. For instance, if a patient is one day late for a refill beyond the 7 day window, the patients are told that phentermine cannot be used again for another 6 months. Insulin, anti-seizure medications, etc. would never be held or stopped, nor should they be stopped, if a patient brought the script in late. Phentermine is the only medication I know of where there is such tight regulation on a controlled substance that does not have any abuse potential. I am keeping an excel spread sheet on all the phentermine responders that when the medication is no longer continued after 12 weeks, the patients gain all the weight back to baseline! It is for this reason that the guidelines should be changed to allow those of us in obesity medicine and others to be able to use the short acting medications such as phentermine long term to treat obesity as it should be as a chronic disease!

Sincerely,

Derrick Cetin, DO

From: Sallie.Debolt@med.ohio.gov [mailto:Sallie.Debolt@med.ohio.gov]
Sent: Wednesday, August 07, 2019 3:06 PM
To: Butsch, Winfield <BUTSCHW@ccf.org>
Subject: [EXT] RE: Advocating for anti-obesity medications

Dear Dr. Butsch:

Rule 4731-11-04 must be reviewed and either continued without change or with amendments with the action finalized no later than 2/28/2021. However, the review can occur at any time. The Medical Board is starting its review now in anticipation of interest in the rule and to ensure all of the rulemaking steps are completed before the deadline.

The email sent recently is the first step in gathering input. The deadline for comments is August 9th.

While the Medical Board will accept comments received after August 9th, comments should be submitted soon thereafter to ensure that they are available for review as the Medical Board determines the proposed action on the rule. Comments should be sent to me at the address below (email is appropriate) prior to August 29, 2019.

From: [Trace Curry](#)
To: [Debolt, Sallie](#)
Subject: Re: Ohio Medical Board seeks input on specified controlled substance rules and an internal management rule applicable to approval of license applications
Date: Friday, July 26, 2019 3:42:04 PM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)

Hi Sallie,

It would greatly benefit residents of Ohio if the 12 week restriction on short term anorectics (such as phentermine) were lifted. As far as I know there are no other states that still have this, and it forces us to have to use chronic weight management medications which are less effective and over 10x more expensive.

Thanks,
Dr. Trace Curry
JourneyLite Physicians

On Fri, Jul 26, 2019 at 3:28 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, public comment is being sought on the proposed language for the following two sets of rules. The rules can be obtained from the Medical Board's website at the following link: <https://www.med.ohio.gov/Laws-Rules/Newly-Adopted-and-Proposed-Rules>. Scroll to "PROPOSED RULES UNDER INITIAL REVIEW." The information for each set of rules contains a memo of explanation and the rules.

Controlled substance prescribing rules:

- 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 anorexiant 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)

4731-30-02: A proposed internal management rule for approval of licensure applications

Deadline for submitting comments: **August 9, 2019**

Comments to: Sallie Debolt, Senior Counsel

State Medical Board of Ohio

Sallie.Debolt@med.ohio.gov



State Medical Board of
Ohio



From: [Latonya Fore](#)
To: [Debolt, Sallie](#)
Subject: Re. controlled substances for utilization of short term anorexiant for weight reduction and for chronic weight management.
Date: Friday, August 9, 2019 2:23:34 PM

August 9, 2019

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

Re. controlled substances for utilization of short term anorexiant for weight reduction and for chronic weight management.

Dear Ms. Debolt:

Thank you for the opportunity to provide comments to the State Medical Board of Ohio on 4731-11-04, OAC, Controlled Substances: Utilization of short term anorexiant for weight reduction and 4731-11-04.1, OAC, Controlled substances: utilization for chronic weight management

I'm Latonya Fore, NP-C, a certified nurse practitioner at University Hospitals of Cleveland and a member of the Obesity Medicine Association. As a healthcare professional who treats those affected by overweight and obesity, I'm so pleased that the Board will be reviewing these regulations as so much has changed surrounding the disease of obesity.

Obesity is recognized as a chronic disease deserving of consistent, long-term medical treatment, which can include pharmacotherapy. Since 1986, the time the law was adopted, the FDA has approved new anti-obesity medications. We are already seeing the profound impact that these new treatment tools are having on those affected by overweight and obesity. Unfortunately, our state's current regulations surrounding the prescribing environment for anti-obesity agents have not kept pace with the environment in which healthcare professionals now treat this disease. Therefore, it is my position that long-term pharmacotherapy may be used for patients affected by obesity, but only in a comprehensive obesity management program that includes a thorough medical evaluation and support for a lifestyle change.

I'm concerned about the state medical board's restrictive regulations, described below, regarding the long-term use of certain anti-obesity drugs such as phentermine, diethylpropion, and phendimetrazine:

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

(A,B) I recommend removing this verbiage “short term anorexiant for purposes of weight reduction” and replacing with “anti-obesity medication for the purpose of treating overweight and obesity”.

(C) (2) The rule limits the duration of antiobesity medications. I recommend removing the verbiage “ 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”. This does not support what we know about obesity and overweight; a chronic relapsing disease. It is my position that anti-obesity medications, both of the older and newer generations, may be used for long-term weight control, similar to the use of anti-hypertensives, anti-diabetics, and lipid-lowering treatments. Approximately 80% of patients with obesity who lose weight return to their previous weight due to metabolic changes. These adaptations may include increases in appetite, as well as decreased energy expenditure. This biologic propensity for weight regain explains the necessity of persistent treatment to prevent relapse.

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

(3)(B)(a) The rule limits physician assistants in the treatment of overweight and obesity. A physician must initiate the prescription and complete two follow up visits for Qsymia or Belviq before allowing a physician assistant to refill. Also, a physician assistant cannot change the drug or the dosing at the visit. I recommend removing this limitation to allow physician assistants to treat overweight and obesity like nurse practitioners.

According to the Ohio Board of Nursing:

A Certified Nurse Practitioner, Clinical Nurse Specialist, and Certified Nurse Midwife shall not prescribe or furnish any drug or device in violation of federal or Ohio law, or rules adopted by the Board.

The prescriptive authority of a Certified Nurse Practitioner, Clinical Nurse Specialist or Certified Nurse Midwife shall not exceed the prescriptive authority of the collaborating physician or podiatrist.

These medications, when added to a properly supervised intensive behavioral program, significantly improve the odds of achieving a 5-10% weight loss (or more), which has been recognized by the National Institutes of Health and the Institute of Medicine as reducing the health risks of associated with overweight and obesity, such as hypertension, hyperlipidemia and Type 2 diabetes to name a few.

In closing, I appreciate the opportunity to comment on the proposed changes. I urge the State Medical Board of Ohio to afford patients with overweight and obesity the same long-term treatment options enjoyed by other chronic disease conditions. Allowing obesity medicine specialists to utilize phentermine and other short-term obesity drugs for long-term treatment of this chronic disease would be an important first step toward this goal.

Latonya Fore, MSN, NP-C, CSOWM, CCM, CBN
Adult-Gerontology Primary Care Nurse Practitioner
Certified Obesity and Weight Management Specialist
Certified Bariatric Nurse
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From: [Chris Gallagher](#)
To: [Debolt, Sallie](#)
Cc: [Joe Nadglowski](#)
Subject: OAC Public Comments re SMBO review of Anti-Obesity Agents
Date: Friday, August 9, 2019 9:47:25 AM

Ms. Debolt,

On behalf of the more than 64,000 members of the Obesity Action Coalition (OAC), a National non-profit organization dedicated to giving a voice to the individual affected by the disease of obesity, we are pleased to provide the following comments regarding the State Medical Board of Ohio's review of the prescribing restrictions for anti-obesity agents outlined under rule:

4731-11-04, OAC, Controlled Substances: Utilization of short term anorexiant for weight reduction

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

The OAC is thankful that the Board will be reviewing these regulations – especially given the tremendous advances that have been made this decade in understanding both the science and physiology surrounding obesity.

Since 2013, the Food and Drug Administration has approved four new anti-obesity medications and many more agents are progressing through the development process. We are already seeing the profound impact that these new treatment tools are having on those affected by overweight and obesity. Despite this progress, patients continue to face discriminatory hurdles to care – barriers that are based more on historical misconceptions than evidence-based science. Preconceptions that those who are affected by obesity came to it through character flaw, lack of willpower, poor lifestyle choices or all of the above.

Those who are affected by obesity deserve both respect and access to the full continuum of care for this complex and chronic disease — in the same fashion that others currently enjoy who struggle with chronic disease states such as high cholesterol, heart disease or diabetes. We are hopeful that the Board will work with both healthcare professionals and patients to better understand the significant changes that have occurred in the obesity treatment landscape since these rules were last substantively amended more than a decade ago.

Again, thank you for this opportunity to provide feedback regarding this issue. We look forward to working with the State Medical Board as part of the review process.

Chris Gallagher
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August 9, 2019

Ms. Sallie Debolt
Senior Counsel
State Medical Board of Ohio
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Thank you for the opportunity to provide comments regarding the controlled substance prescribing rules up for the required-five year rule review by 12/31/2020. Our comments are in regards to the following two laws.

- 4731-11-04, OAC, Controlled Substances: utilization of short term anorexiant for weight reduction
- 4731-11-04.1, OAC, Controlled substances: utilization for chronic weight management

We would like to invite the medical board to reconsider amendment of the aforementioned two rules regarding the pharmacologic treatment of obesity. We believe the current practice barriers that exist in Ohio for obesity medicine providers can be reduced to better improve public health, specifically to help address the national obesity epidemic and improve the lives of those suffering from this disease and associated comorbidities.

This practice hopes the board recognizes obesity as a chronic disease and has considered the implications this disease has on overall patient health and wellbeing, especially when left untreated. Currently available anti-obesity pharmacotherapies have demonstrated safety and efficacy in clinical trials and clinical use. Not only are these medications able to assist patients in losing weight when part of a comprehensive weight loss program, but they have also been associated with significant improvements in lipids, blood pressure, fasting glucose, HgA1C, decreased inflammation markers, decreased waist circumference, and a reduction in the progression to type 2 diabetes.

This practice believes the current weight loss laws in Ohio cause undue burdens on patients and providers. Patients have limited access to anti-obesity medications, and restrictions prevent healthcare providers from adequately treating patients with obesity and assisting them in a comprehensive battle against a host of associated comorbidities. Simply put, patients in Ohio are not able to access adequate care for Obesity.



We would like to advocate for the following:

1. Enabling PAs to write for anti-obesity medications. We know this will increase access to patient care for obesity treatment. PAs have the education necessary to prescribe these medications safely to patients. We believe the ability to write for these medications should be determined at the practice level between the supervising physician and the PA (assuming the PA holds a DEA license, a valid prescriber number issued by the State Medical Board, and has been granted physician-delegated prescriptive authority).
 - a. PAs receive pharmacology training at regular intervals. As a reminder, in order for PAs to be eligible for renewal of prescriptive endorsement, they are required to complete at least twelve hours of continuing education in pharmacology every two years in addition to maintaining certification by the NCCPA, which includes completing not less than one hundred hours of continuing medical education.
 - b. Training in obesity medication is widely available to PAs, one such example is The American Academy of Physician Assistants (AAPA) 10 credit CME course titled Obesity Leadership Edge: A PA-Driven Chronic Care Model for the Management of Overweight and Obesity. This course was developed back in 2017 which per the AAPA, “... is a call to action for PAs to be able to diagnose and treat overweight and obese patients regardless of practice setting and across the spectrum of the disease and patient’s age”
2. We would like the board to consider redacting the weight loss laws and allowing clinicians to use their clinical judgement to responsibly prescribe medications for their patients based on evidence based-guidelines. We urge the Board to work with both patients and the healthcare community to better understand how Ohio’s overly restrictive and dated prescribing restrictions are impeding so many Ohioans from accessing the full continuum of care for obesity.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Ross Henschen MD'.

Ross Henschen, MD

Cheryl Milani MMS, PA-C

A handwritten signature in black ink, appearing to read 'Cheryl Milani PA-C'.

Alana Mercer MSHS, PA-C

A handwritten signature in black ink, appearing to read 'Alana Mercer PA-C'.

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August 16, 2019

To the Honorable Members of the State Medical Board of Ohio,

The Obesity Medicine Association (OMA) represents 3,000 health care providers engaged in treating patients affected by obesity.

We applaud you for taking action in the 1990's to protect your residents from the harmful effects of fenfluramine. At the time your policies around weight management were written, they made a lot of sense. But today, Ohio laws are out-of-date and are overly restrictive. In fact, **Ohio laws currently directly contradict the standard of care with regards to obesity treatment.** A doctor providing the proper care to a patient affected by obesity in Ohio is breaking Ohio law. This needs to change now. As they stand, Ohio laws unfairly target patients affected by obesity and the physicians who treat them.

We are writing to you to encourage you to retire these laws. There are not laws in place to govern how physicians treat other diseases like diabetes or hypertension. Obesity is a disease and having restrictive laws around obesity promulgates weight bias and stigma.

Our American Medical Association recognized obesity as a disease in 2013. In 2018, our AMA resolved to work with state and specialty societies to identify states in which physicians are restricted from providing the current standard of care with regards to obesity treatment, and to actively lobby with state medical societies and other interested stakeholders to remove out-of-date restrictions at the state and federal level prohibiting healthcare providers from providing the current standard of care to patients affected by obesity.

Ohio is one of the few remaining states with such restrictive laws in place.

Ohio rules do not allow physicians to use FDA-approved medications in any way that would be construed as off-label. Even though brand-name Phentermine (marketed as Qsymia) is approved for chronic use, Ohio does not allow physicians to prescribe generic phentermine at the same doses found in Qsymia long-term. Further, Ohio does not allow use of these medications outside of BMI guidelines published in the labels, even though many patients who fall outside of these guidelines might benefit. For example, most physicians will use metformin off-label to prevent diabetes in a patient with pre-diabetes; however, Ohio will only allow treatment of obesity once the disease is full-blown, and does not allow a physician and patient to exercise their best judgment for use in a high-risk patient with pre-obesity.

Since the 1990s when Ohio implemented these rules, obesity rates and complications have doubled to tripled (Hales et al, 2018). Rates are expected to continue to rise, with the Robert Wood Johnson Foundation projecting that by 2030 roughly half the population may be affected by obesity (Levi, Vinter et al, 2014). CDC data from 2017 show the obesity rate in the United States is 39.8%. The Hispanic and non-Hispanic Black populations are particularly affected, with obesity rates of 47% and 46.8% respectively (CDC - Obesity Rates).

Obesity is now recognized as a chronic disease. As early as 1997, the World Health Organization published a document identifying obesity as a disease (WHO, 2000). In 2013, the AMA passed Resolution 420 (A-13) "Recognition of Obesity as a Disease" with a comprehensive recognition of the metabolic and hormonal dysfunction associated with obesity. Also in 2013, the American Heart Association(AHA), the American College of Cardiology(ACC), and The Obesity Society(TOS) published guidelines for the management of overweight and obese utilizing a chronic disease model for the treatment of obesity (Jensen et al, 2014). The American Association of Clinical Endocrinologists argued that the term obesity should be changed to Adiposity Based Chronic Disease in a position statement published in 2016 (Mechanick et al, 2016). Finally, the World Obesity

Federation identified obesity as a chronic, relapsing disease in a position statement published in *Obesity Reviews* in 2017 (Bray et al, 2017). In addition to the organizations above, the ADA, ACC, OMA, WOF, NIH, USDA, FTC, AAFP, IOM, ACP, AACE, ACE, and many others have followed suit.

The revelation of the role of the neuro-endocrine regulatory system influencing hunger and satiety came with the discovery of the adipokine, leptin, in 1994. Since then, an understanding of the complex interplay between adipose tissue, the gut, the pancreas, peripheral nervous system and the central nervous system has led to a better understanding of the complex interplay between peripheral agents and the brain in the regulation of appetite (Schwartz et al, 2017). Appetite control has moved from the common perception of a self-induced behavior to biologically regulated action. Genetics, epigenetics, sedentary lifestyle, food availability, socioeconomic factors, gut microbiome, endocrine disrupting chemicals, and even viruses are additional factors identified as contributors to obesity (Schwartz et al, 2017).

Obesity is identified as a multi-metabolic, hormonal and inflammatory disease state with over 236 health consequences related to metabolic dysfunction, fat mass effect, and psychosocial dysfunction (Kahn 2017). Rates of type 2 diabetes have risen in concert with the rise in obesity rates (CDC - Obesity and Diabetes). Overweight and obesity, especially increased visceral adiposity, is associated with increased risk of coronary heart disease and stroke (Jensen et al., 2014). Obesity is associated with at least 13 different cancers (CDC - Obesity and Cancer) and accounts for approximately 20% of all cancer cases (Wolin et al, 2010). Other well-known obesity-related health conditions include non-alcoholic fatty liver disease, gallbladder disease, infertility, polycystic ovary disease, metabolic syndrome, and chronic kidney disease (Williams et al, 2015).

The mass effect of obesity is associated with immobility, osteoarthritis, gastroesophageal reflux, and obstructive sleep apnea (Bays et al, 2017). The psychosocial impact of obesity includes higher rates of depression, impaired relationships, poor quality-of-life, and loss of productivity related to absenteeism and presenteeism (Bays et al, 2017).

The financial impact of obesity has grown, steadily rising from 6.13% of healthcare costs in 2001 to 7.91% in 2015, translating to a staggering \$253 billion dollars per year (Biener et al, 2017). Lower socioeconomic populations are particularly hard hit by obesity, with 33% of adults with obesity earning <\$15,000 compared to 25.4% for those earning \$50,000 or more per year (Levi et al, 2014).

The medical benefits of weight loss are well recognized (Jensen et al, 2014). The Diabetes Prevention Program found that a 7% weight loss reduced the risk of developing diabetes by 58% (Knowler et al., 2002), with continued benefits seen even after 15 years (DPP, 2015). Recently, the benefits of a 5 to 10 percent weight loss on metabolic health was further substantiated in an NHANES analysis (Knell et al., 2018).

There is a common perception that once a weight loss goal is achieved, the process is over and an individual should be able to easily maintain their new weight. Nothing could be further from the truth, as maintaining weight loss has proven to be one of the most challenging components of obesity treatment. The physiologic response to a negative energy balance includes central and peripheral adaptive mechanisms, such as an increase in the appetite stimulating hormone ghrelin, and a reduction in a number of anorectic agents including leptin, cholecystokinin, amylin, and peptide YY (Heymsfield et al, 2017). In the 2011 landmark article "Long-Term Persistence of Hormonal Adaptations to Weight Loss", hormonal drivers of hunger and satiety remained abnormal 52 weeks after completing a 10 week very-low-calorie diet, resulting in persistent hunger and desire to eat (Sumithran et al, 2011). In addition, weight loss results in reductions in resting metabolic rate (Kerns 2017). Put simply, losing weight causes an adaptive response resulting in increased hunger, decreased fullness, and lower metabolism which may persist for years, even in the face of weight regain returning us to our "set-point". (Schwartz 2017).

The Obesity Medicine Association recommends that the medical management of obesity should revolve around 4 pillars of treatment including nutrition, physical activity, behavioral therapy, and pharmacotherapy. Outlined in the OMA Obesity Algorithm, this comprehensive approach goes beyond the simple "eat less and exercise more" advice that has failed for so many years (Bays et al, 2017). For reasons described above, long-term metabolic adaptation to weight loss requires long-term treatment. There are a variety of nutritional interventions that can be effective for weight loss with no clear preference of one dietary strategy over another (Sachs et al, 2009). Patient preference and adherence to a dietary intervention are key to long-term success (Dansinger et al, 2007). Dietary interventions should be nutritionally balanced to prevent essential macronutrient and micronutrient deficits with appropriate medical monitoring for more extreme calorie restriction (Bays 2017). Limited benefit has been realized with physical activity as a sole means of weight loss (Warburton 2006). However, physical activity has many known cardiovascular benefits (Warburton 2006) and is an essential component of weight maintenance, emphasizing the need to continue regular exercise after weight loss goals are achieved (Thomas et al, 2014). A comprehensive approach to obesity treatment was further endorsed in the AHA/ACC/TOS guidelines (Jensen et al, 2014). In addition to the multifactorial approach to the treatment of obesity, the American College of Endocrinology (ACE)/American Association of Clinical Endocrinologists (AACE) gave a Grade A recommendation for long-term pharmacotherapy for obesity treatment (ACE/AACE Guidelines, 2016).

Long-term pharmacotherapy is recommended as an adjunct to therapeutic lifestyle interventions to improve adherence to behavior modifications and help promote long-term weight maintenance by various mechanisms (decreasing appetite, reducing caloric absorption, increasing metabolic rate, resisting food cues, depending on the specific medication utilized). Currently, the US FDA has approved five anti-obesity medications (AOMs) for long-term treatment of obesity.

Orlistat (Xenical):

Approved in 1999, Orlistat is gastrointestinal lipase inhibitor, which, when ingested with a meal, reduces absorption of dietary fat by approximately 35% (Guerciolini R. 1997).

Reported average weight loss 3.9% at 1 year and 2.3% at 2 years.

Lorcaserin (Belviq):

Lorcaserin is a selective serotonin 2c (5HT2c) receptor agonist approved in 2012, is thought to decrease food intake through the proopiomelanocortin neuronal pathway in the brain. At 1 year, 47% of patients achieved a 5% average weight loss and 22.4% achieved a 10% weight loss in the lorcaserin. Treatment with Lorcaserin was associated with improvements in serum lipid levels, insulin resistance, and blood pressure. (Smith, S.R., et al. 2010).

Phentermine/Topiramate (Qsymia):

Qsymia is a combination of controlled-release Phentermine (norepinephrine releasing agent) and Topiramate (GABA receptor modulator) that was FDA approved in 2012. While head-to-head studies have not been completed between AOMs, the Phentermine/Topiramate combination has been reported to have the highest amounts of weight loss with 67% of patients achieving a 5% weight loss and 47%, a 10 percent weight loss at 1 year. (Allison DB, et al. 2012)

Bupropion/Naltrexone (Contrave):

Approved in 2014, Contrave is a combination of a dopamine reuptake inhibitor (Bupropion) and an opioid antagonist (Naltrexone). Bupropion stimulates hypothalamic pro-opiomelanocortin (POMC) neurons, which reduces food intake and Naltrexone blocks opioid receptor-mediated POMC auto-inhibition. The combination is thought to induce weight loss through sustained modulation of CNS reward pathways. (Apovian CM, Aronne L, Rubino D, et al., 2013) Forty-two percent of patients achieving a 5% weight loss and 21% a 10% weight loss on this combination medication.

Saxenda (Liraglutide):

Saxenda is a Glucagon-like peptide-1 receptor agonist. Its effects on the reduction in food intake are thought to be primarily mediated by GLP-1 receptor presence in several areas of the brain involved in appetite regulation. In study participants followed for 56 week, a 5% weight loss was achieved by 62%, and a 10% weight loss for 34% of participants (Pi-Sunyer, X, et al. 2015).

The Endocrine Society Practice Guidelines recommend if a patient's response to a certain medication is deemed to be effective (generally regarded as a 5% reduction in initial body weight at the three-month mark of initiation of a given dose of medication), the patient continue taking it, barring any adverse effects (Apovian CM et al. 2014).

Phentermine, a component of the FDA approved drug Qsymia, has 60 years of prescribing experience as a stand-alone drug for the treatment of obesity and, for much of that time, has been regarded as the most effective anti-obesity medication available.

Phentermine is a norepinephrine releasing agent that increases satiety and improves metabolism. It is the only AOM known to have an enhancing effect on metabolic rate. A recent study of long-term phentermine use found that 83% of patients had weight loss equal to or greater than 10% of initial baseline weight at 1 year (Hendricks et al., 2011). While increase in heart rate and blood pressure has been reported, weight loss in patients using phentermine has been associated with decreases in blood pressure (Hendricks et al., 2011). In addition, phentermine has not been shown to produce primary pulmonary hypertension (Rich et al., 2000) or valvular heart disease (Bonow et al., 2008, Roth, 2007, Rothman and Baumann, 2009).

Another study of nearly 14,000 individuals showed that phentermine was safe and effective for long-term use (Lewis et al. Obesity, April 2019).

Phentermine is a substituted phenethylamine and is not identical in structure, effects, or adverse effects to amphetamine or methamphetamine. In a PubMed search for "phentermine" of almost 1400 papers, nothing resembling the stimulant use disorder associated with amphetamine and cocaine use was seen with phentermine. In a post-marketing study of phentermine, long-term use did not induce withdrawal cravings, even at doses higher than 37.5 mg/day. Likewise, abrupt cessation of long-term phentermine did not induce symptoms of stimulant withdrawal (Hendricks, 2017).

In the long-term treatment of obesity, the use of phentermine is recognized by medical organizations that specialize in obesity treatment (Apovian et al. 2015, OMA, 2015). Dose titration to effect with phentermine is a common prescribing pattern amongst trained obesity medicine practitioners and appears to be safe and effective for patients (Steelman and Westman, 2016). As mentioned above, four new medications have been approved by the FDA for long-term use in obesity treatment since 2012. Unfortunately, insurance coverage remains limited, or associated with cost-prohibitive co-pays, resulting in only 2% of patients with obesity receiving anti-obesity medications who need them for long term disease treatment For a great majority of patients with obesity, **phentermine remains a safe, effective, non-addicting, and affordable treatment option.** It is the most widely

prescribed anti-obesity medication currently available, with at least 3 million phentermine prescriptions written per year compared to approximately 600,000 of its closest competition (Contrave), and roughly 200,000 for Saxenda.

In summary, as with any other disease, the treatment of obesity is complex, requiring a multidisciplinary approach that includes AOMs. Due to metabolic adaptation driving individuals back to their "set point" weight, maintaining weight loss is a daunting task without anti-obesity medications to help control hunger and increase metabolism. Phentermine is a safe, cost effective option for the treatment of obesity.

Phentermine has NOT been linked to pulmonary hypertension or valvular heart disease and has almost sixty years of proven efficacy and safety. Phentermine is widely prescribed, with at least 3 million prescriptions written annually, and is included on guidelines and algorithms of experts in the field of obesity for long term use.

With a disease that affects 40% of the U.S. population and only 2% receiving appropriate treatment with anti-obesity medications due to cost constraints, the restriction of Phentermine for the treatment obesity (and its 236+ associated medical complications) is at this stage incomprehensible. In fact, with every 5-point increase in body mass index above normal increasing mortality by 30%, (Lancet 2009) not treating patients with long term phentermine as an option could be considered medical malpractice.

Sincerely,



Ethan Lazarus, M.D.

Vice-President, Obesity Medicine Association

Delegate, American Medical Association

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From: [Home](#)
To: [Debolt, Sallie](#)
Subject: Corporate comments regarding Rules 4731-11-04 and 4731-11-04.1
Date: Friday, August 9, 2019 10:37:25 AM

Dear madam,

My name is Donna Leitzel and I have the disease of obesity.

This disease and the treatment of it have been an 18 year long journey for me. I've always hidden myself in my weight out of fear. It wasn't until after having RNY at the weight of 320 that I learned better coping mechanisms. Unfortunately by this period in my life biology & genetics has caught up with me.

I've since become aware of the many and varied treatment options that are available for this disease, surgical, behavioral, pharmaceutical, etc... Due to my weight and comorbidities, my PCP and I decided that the surgical approach would be the best given my health at that time.

I've reached a point now in the treatment of my disease that pharmacotherapy is something I need. I felt relief when my PCP was willing to write a prescription for medications that can assist in the lifelong treatment of obesity. However, that relief turned to dismay when I learned of the extraordinary restrictive rules surrounding these medications in Ohio.

Sincerely,
Donna Leitzel has



Sallie Debolt, Senior Counsel
State Medical Board of Ohio
Sallie.Debolt@med.ohio.gov

August 11, 2019

Dear Ms. Debolt;

On behalf of the Ohio Academy of Nutrition and Dietetics (OAND) I would like to thank you for the opportunity to review the following rules:

4731-11-04, OAC, Controlled Substances: Utilization of short term anorexiant for weight reduction

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

After review by interested members specializing in practice related to weight management we would like to provide the following comments.

4731-11-04 OAC – (B)(1), and (B)(3)(e) – Please correct the spelling of the word “dietician” to “dietitian” which is the preferred spelling for the professional title used by dietitians. “Dietitian” is also consistent with the spelling used throughout Chapter 4759 ORC in the licensure of dietitians in Ohio. The spelling “dietitian” is also used throughout 4759 OAC, including rule 4731-11-04.1 which is up for review at this time.

4731-11-04 OAC – (B)(2)(g) – Weight loss treatment is most effective in achieving sustained weight loss and improved clinical parameters when the treatment plan produces changes in lifestyle behaviors that contribute to both sides of the energy balance equation.¹ Weight loss treatment plans that include the use of weight loss medications (short term anorexiant) should also include calorie restricted diets that maintain nutrient adequacy, exercise, nutritional counseling, and intensive behavioral therapy and counseling delivered by qualified physicians, dietitians, and other qualified practitioners.

OAND suggests that the treatment plan being developed and documented by the physician in **4731-11-04 (B)(2)(g)** should include at minimum a “nutritionally adequate calorie restricted diet” , “nutritional counseling and intensive behavioral therapy” and exercise program for weight loss.

¹ Position of the Academy of Nutrition and Dietetics: Interventions for the Treatment of Overweight and Obesity in Adults *Raynor, Hollie A. et al.*
Journal of the Academy of Nutrition and Dietetics, Volume 116, Issue 1, 129 - 147

4731-11-04 (C)(1) –“ The physician shall personally meet face-to-face with the patient”

Patients utilizing weight loss medications often complain about the burden required by the requirement of meeting with the physician every 30 days.

The OAND suggests that the board consider how various technologies (**telecommunication by videotelephony, e-health interventions, computer based interventions, and smart-phone interventions**) that are now available to consumers may be utilized to decrease the intervention costs of such frequent face-to-face contact required for patients being treated for weight loss and obesity. The current technologies can provide an increased access to physicians and other practitioners who may be providing medical care, intensive behavioral therapy, and nutrition counseling for patients. Internet web-sites, computer tracking systems, discussion boards, chat rooms, smart-phone apps etc. provide the opportunity for frequent interactive feed-back, tailored messaging, and focused education.

4731-11-04.1 (A)(1)(h) – Chronic weight loss (obesity) treatment is most effective in achieving sustained weight loss and improved clinical parameters when the treatment plan produces changes in lifestyle behaviors that contribute to both sides of the energy balance equation.' Weight loss treatment plans that include the use of controlled substance weight loss medications should also include calorie restricted diets that maintain nutrient adequacy, exercise, nutritional counseling, and intensive behavioral therapy and counseling delivered by qualified physicians and other qualified practitioners.

OAND suggests that the treatment plan developed and documented by the physician in **4731-11-04.1(A)(1)(h)** should include at minimum a “nutritionally adequate calorie restricted diet” , “nutritional counseling and intensive behavioral therapy” and exercise program for weight loss.

Thank you for the opportunity to provide input on these rules. OAND looks forward to participating in the process.

Kay Mavko, MS, RDN, LD
State Regulatory Specialist
Ohio Academy of Nutrition and Dietetics



November 7, 2013

Anita M. Steinbergh, DO
President
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Dear Dr. Steinbergh,

The Ohio State Medical Association (OSMA), representing over fifteen thousand Ohio physicians, is writing to state our opposition to Medical Board Rule 4731-11-04, Ohio Administrative Code (OAC), *Controlled substances: Utilization for weight reduction*. Despite previous objections from the OSMA regarding the necessity of this rule, and considering the advances in pharmaceutical obesity practices and the recognition of obesity as a chronic disease, limits set by the board in 1986 to curb abuse have stayed in place.

According to the American Obesity Treatment Association (AOTA), the modern scientific understanding of obesity is that it is a complex disease in its own right. The AOTA defines obesity in the following way:

Obesity means accumulation of excess fat on the body. Obesity is considered a chronic (long-term) disease, like high blood pressure or diabetes. It has many serious long-term consequences for your health, and it is the second leading cause of preventable deaths in the United States (tobacco is the first).

The understanding that obesity is a disease has led many major medical authorities, including the American Medical Association (AMA), the National Institutes of Health, and the World Health Organization, to conclude that obesity should be considered a distinct disease entity. At its 2013 meeting, the AMA adopted policy stating, *"Our AMA recognizes obesity as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention."*¹

Since Rule 4731-11-04 became effective, the weight loss medicine specialty has changed enormously, as has the urgent need for doctors willing to treat obese patients. However, Ohio physicians have been increasingly frustrated by the apparent unwillingness of the State Medical Board of Ohio to recognize these changes. In the wake of the current obesity epidemic, it is necessary for the medical board to perform a comprehensive review of the current regulations that prevent practitioners from treating obese patients efficaciously. The regulations are dismissive of the skills and training of clinicians who specialize in weight loss medicine.

¹ <https://ssl3.ama-assn.org/apps/ecommm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fdoc%2fPolicyFinder%2fpolicyfiles%2fHnE%2fH-440.842.HTM>

The OSMA has recently heard concerns from numerous physicians who specialize in weight loss medicine. These physicians have asserted that, of the few states that place restrictions on prescribing for weight loss, Ohio's rule is among the most restrictive. Particularly onerous are the restrictions on anorectic medications that limit their use to three months, despite years of experience and numerous studies that confirm the safety profile of these medications. The physicians also question the necessity of requiring patients to return to the office every thirty days throughout the course of treatment. These nationally-recognized leaders in bariatric medicine feel that, through this rule, the State Medical Board of Ohio is essentially insinuating that physicians who prescribe weight loss medications are less able to make professional judgments than physicians who prescribe more dangerous substances with greater potential for abuse (narcotics, psychoactive drugs, anxiolytics, etc.).

The OSMA urges the State Medical Board of Ohio to end its discrimination against obesity treatment through its outdated rule and to accept that obesity is a chronic disease which requires long-term treatment that should be determined and managed by the treating physician and not by arbitrary limitations and mandates. The physician weight loss experts who have contacted the OSMA about this issue are willing to provide additional information to the medical board and provide testimony, should the medical board make the prudent decision to review the necessity of such stringent regulations.

Thank you for your consideration of this issue.

Sincerely,



Neal J. Nesbitt, MD
President, Ohio State Medical Association

c: OSMA Council
D. Brent Mulgrew, Executive Director, OSMA



STATE OF
OHIO
BOARD OF PHARMACY

August 15, 2019

Mr. Anthony (A.J.) Groeber
Executive Director
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215-6127

Dear Mr. Groeber,

I am writing to express the State of Ohio Board of Pharmacy's support for controlled substance rules for weight management and weight reduction (OAC 4731-11-04 and 4731-11-04.1). As an agency tasked with preventing the diversion of controlled substances in Ohio, the rules remain a measured approach that will continue efforts to limit the ongoing diversion of controlled substance weight loss medications.

While some have advocated for loosening the restrictions on these highly misused medications, it is the position of the Board that such efforts would only lead to further abuse, diversion, and profiteering. One only has to look at the levels of prescribing in surrounding states where the number of doses is substantially higher than what currently exists in Ohio.

In the 1990's and early 2000's, due to aggressive enforcement by the D.E.A. and the Board of Pharmacy, many prescribers were held accountable for their profiteering from the illegal sales of these drugs. Common threads that ran through most of these cases included financial gain; excessive personal furnishing; the diversion of hundreds of thousands of these drugs; the willingness to sell to customers who did not meet the minimum indicated reasons to prescribing these drugs; and to keep customers on these drugs in excess of F.D.A. package insert daily dosing (often for years). As this enforcement took place, the era of the "diet doc" waned.

However, Ohio has seen a resurgence of these unscrupulous providers. Over the past couple of years, our investigators have witnessed a substantial increase in the number of cases regarding inappropriate prescribing and trafficking of controlled substance stimulants used for weight reduction as well as the prescribing of these medications for financial gain, rather than legitimate medical purposes.

In closing, the State of Ohio Board of Pharmacy supports efforts to retain the current versions of rules 4731-11-04 and 4731-11-04.1 of the Ohio Administrative Code. These rules will continue to ensure that patients are closely monitored to prevent the abuse and diversion of these potentially addictive drugs. On behalf of the Board, I thank you for the opportunity to review the draft rule and provide comments.

Sincerely,

Steven W. Schierholt, Esq.
Executive Director
State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215





STATE OF
OHIO
BOARD OF PHARMACY

August 15, 2019

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Executive Director
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215-6127

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Sincerely,

Steven W. Schierholt, Esq.
Executive Director
State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215



AUGUST 8, 2019

TO MEMBERS OF THE STATE MEDICAL BOARD OF OHIO:

I am a Clinical Nurse Specialist in the Bariatric and Metabolic Institute at the Cleveland Clinic, whose professional career has focused on the care of patients who are overweight and have obesity. I have worked with patients battling the disease of obesity for the last 30 years.

I am in strong favor of amending Rules 4731-11-04 and 4731-11-04.1 .

I want to make three points to support the need to amend these Rules.

- 1. Obesity is a failure of normal weight and energy regulation.**
- 2. Obesity is a chronic disease that requires long term treatment just like hypertension and diabetes.**
- 3. Anti-obesity medications like phentermine are safe and effective.**

I believe rules like 4731-11-04 and 4731-11-04.1 in part stem from a common belief that obesity is a character flaw, a behavior problem that exists in weak individuals who don't have the coping mechanisms or willpower to resist high calorie foods.

In the scientific world, this belief is not commonly accepted. We understand the disease of obesity as the failure of normal weight and energy regulatory mechanisms. Patients with the disease of obesity must take in many fewer calories than those without these issues and it is difficult without the best therapy.

I see patients with obesity every day and I have seen patients have the better weight loss outcomes with Phentermine more than any other non-surgical method of treatment. I have also seen too many people just within the last year because of the current rules who have regained weight after the phentermine has stopped. If a drug is effective why do we stop it? We are not seeing adverse effects and patients are actually getting healthier on the drug. We don't practice this way in other disease states like hypertension or hyperlipidemia. A chronic disease like obesity needs continued therapy.

Our patients appreciate your review and reconsideration.

Sincerely,

Karen Schulz RN, MSN, CBN
Nurse Manager
Bariatric and Metabolic Institute
Cleveland Clinic

From: [Selby, Luke](#)
To: [Debolt, Sallie](#)
Subject: Prescribing of medications for weight loss
Date: Thursday, August 8, 2019 8:21:04 PM

Hello,

I recently learned that the State Medical Board of Ohio has begun the five-year review process surrounding the prescribing restrictions for controlled substances for utilization of short term anorexiant for weight reduction and for chronic weight management. I'm so pleased that the Board will be reviewing these regulations as so much has changed this decade regarding both the science and the understanding surrounding the chronic and complex nature of the disease of obesity.

Since 2013, the FDA has approved four new anti-obesity medications and many more agents are now in the development process. We are already seeing the profound impact that these new treatment tools are having on those affected by overweight and obesity. Unfortunately, our state's current regulations surrounding the prescribing environment for anti-obesity agents have not kept pace with the environment in which healthcare professionals now treat this disease.

As a healthcare professional who treats those affected by overweight and obesity, I urge the Board to work with both patients and the healthcare community to better understand how Ohio's overly restrictive and dated prescribing restrictions are impeding so many Ohioans from accessing the full continuum of care for obesity — in the same fashion that others currently enjoy who struggle with chronic disease such as high cholesterol, heart disease or diabetes.

Luke V. Selby, MD MS
Fellow, Division of Surgical Oncology
The Ohio State University Wexner Medical Center
Arthur G. James Cancer Hospital and Solove Research Institute

Sent from my iPhone

From: [Mara Schroff](#)
To: [Debolt, Sallie](#)
Subject: Obesity Meds
Date: Friday, August 9, 2019 7:06:51 PM

I recently learned that the State Medical Board of Ohio has begun the five-year review process surrounding the prescribing restrictions for controlled substances for utilization of short term anorexiant for weight reduction and for chronic weight management. I'm so pleased that the Board will be reviewing these regulations as so much has changed this decade regarding both the science and the understanding surrounding the chronic and complex nature of the disease of obesity.

Since 2013, the FDA has approved four new anti-obesity medications and many more agents are now in the development process. We are already seeing the profound impact that these new treatment tools are having on those affected by overweight and obesity. Unfortunately, our state's current regulations surrounding the prescribing environment for anti-obesity agents have not kept pace with the environment in which healthcare professionals now treat this disease.

As a physician in Ohio, I urge the Board to work with both patients and the healthcare community to better understand how Ohio's overly restrictive and dated prescribing restrictions are impeding so many Ohioans from accessing the full continuum of care for obesity — in the same fashion that others currently enjoy who struggle with chronic disease such as high cholesterol, heart disease or diabetes.

Mara Schroff, MD

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

I recently learned that the Ohio State Medical Board has begun the five-year review process surrounding the prescribing restrictions for controlled substances for utilization of short term anorexiant for weight reduction (4731-11-04, OAC) and for chronic weight management (4731-11-04.1, OAC). I'm so pleased that the Board will be reviewing these regulations as so much has changed this decade regarding both the science and the understanding surrounding the chronic and complex nature of the disease of obesity.

Since 2013, the FDA has approved four new anti-obesity medications and many more agents are now in the development process. We are already seeing the profound impact that these new treatment tools are having on those affected by overweight and obesity. Unfortunately, our state's current regulations surrounding the prescribing environment for anti-obesity agents have not kept pace with the environment in which healthcare professionals now treat this disease.

As a healthcare professional who treats those affected by overweight and obesity, I urge the Board to work with both patients and the healthcare community to better understand how Ohio's overly restrictive and dated prescribing restrictions are impeding so many Ohioans from accessing the full continuum of care for obesity — in the same fashion that others currently enjoy who struggle with chronic disease such as high cholesterol, heart disease or diabetes.

Respectfully submitted,

Megan M. Skinner APRN-BC

Vitality Health

2211 Crocker Rd. Westlake, Ohio 44145

(440)250-0887

From: [Thornhill, Sandra](#)
To: [Debolt, Sallie](#)
Subject: Comments for short-term anorexics
Date: Thursday, August 15, 2019 10:42:02 AM

Ms. Debolt

I'm writing this letter to make comments about the phentermine and chronic use of anti-anorexic drugs. The use of phentermine/Adipex and what the board considers controlled substances for only 3 months limits the patient's ability to lose any significant amount of weight.

As a physician's assistant in Ohio for over 30 years and working in obesity and bariatric medicine the limitations of the drugs for short term and long-term treatment for obesity limits our scope of practice. As you know physician's assistants in the state of Ohio recently adapted a no formulary drug restriction prescribing. To limit just phentermine and what is presumed as "short-term anorexics" is contradictive of to our new process of prescribing. Consideration changing the use of the medications for obesity/bariatrics should be considered and removing "short-term anorexics".

You may not know this about obesity but it is a significant problem. 70% of all Americans are considered obese or morbidly obese. Bariatric/ obesity medicine is trying to help these patients reach their weight loss goals either with medication or surgery or both. There are very few medications available for obesity treatment and limiting prescribing privileges is limiting our scope of practice as physicians assistants.

I hope that the medical board will take into consideration and rescind the rules prescribing medications for weight loss. Consideration and changing the terms to treatment for obesity instead of the use of short-term anorexics.

Thank you for your time and consideration.

Sandra Thornhill PA-C
Nutritional Health& Bariatric Surgery
UH Digestive Health Institute
6707 Powers Blvd.
Medical Arts Center 2
Suite 303
Parma, Ohio 44129
Phone:
440-743-2295 for Scheduling
440-743-2915
Email Sandra.Thornhill@uHhospitals.org

Visit us at www.UHhospitals.org.

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From: [Mcnamee, Cameron](#)
To: [Debolt, Sallie](#); [Anderson, Kimberly](#)
Subject: Rule Comments
Date: Thursday, August 15, 2019 10:49:04 AM
Attachments: [Scanned from a Xerox Multifunction Printer.pdf](#)

Sallie and Kim,

Attached you will find a letter of support for maintaining the Board's weight loss rules. Additionally, I reviewed all of your OAC 4731-11 rules and had two comments (sorry they're so late!):

Rule 4731-11-14

(I) This rule does not apply to inpatient prescriptions as defined in Chapter 4729. of the Revised Code.

-

Comment: Technically, inpatient prescription is defined in the Board's institutional rules. These rules are currently being moved to a new section of the OAC so it may be beneficial to reference agency 4729 of the Administrative Code (or just keep the Chapter 4729. and include a statement that references rules adopted thereunder).

Rule 4731-11-11

(A)(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.

Comment: The reference should be updated to [rule 4729:8-2-01 of the Administrative Code](#).

Let me know if you have any questions.

Best,
Cameron



**STATE OF
OHIO**
BOARD OF PHARMACY

Cameron J. McNamee

Director of Policy and Communications
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: (614) 466.7322 | C: (614) 581.5203 | F: (614) 752.4836
Cameron.McNamee@pharmacy.ohio.gov
www.pharmacy.ohio.gov

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 [4729:8-2-01](#) 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

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 substance 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 substance 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

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4731-11-04 Controlled substances: Utilization of short term anorexiant 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.

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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 anorexiant. 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 anorexiant. 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.

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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.

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