



POLICY COMMITTEE MEETING
September 11, 2019
30 East Broad Street, Columbus, OH 43215, Room 336

<p>Members: Robert Giacalone Mark Bechtel, MD Harish Kakarala, MD</p> <p>Other Board Members present: Michael Schottenstein, MD Bruce Saferin, DPM Kim Rothermel, MD Jonathan Feibel, MD Richard Edgin, MD Sherry Johnson, DO</p>	<p>Staff: Kimberly Anderson, Chief Legal 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 9:00 a.m. Dr. Kakarala was appointed to the committee for today's meeting as Dr. Sojin was unable to attend.

Meeting Minutes Review

Mr. Giacalone reported that the draft minutes of the August 14, 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 August 14, 2019 Policy Committee meeting. Dr. Kakarala seconded the motion. Motion carried.

Legislative Update

Ms. Anderson reported that we are working on the operational changes included in the budget bill that will be effective October 16, 2019.

Rules Review Update

Ms. Anderson referred to the report included in the agenda materials. Ms. Anderson said that we continue to be on schedule and continue to make progress with the rules. Ms. Anderson said the schedule for the remainder of the year.

Controlled Substance Prescribing Rules

Ms. Anderson referred to the memorandums included in the agenda materials.

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

Ms. Anderson recommended that we file the rules with CSI as no change rules. Ms. Anderson said that the CSI filing would occur after the PAPC had an opportunity to review the rules as physician assistants would be impacted but the rules. She reported that plans are being made to schedule a PAPC meeting in early October.

Motion was made by Dr. Edgin to recommend filing rules 4731-11-02; 4731-11-03 and 4731-11-7 with CSI as no change rules following review of the rules by the Physician Assistant Policy Committee (PAPC). Dr. Bechtel seconded the motion. Motion carried. The matter will be taken to the full board later today.

Ms. Anderson reported that 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. She supported this change.

Motion was made by Dr. Bechtel to make the suggested amendment to Rule 47321-11-11 and to file with rule with CSI following PAPC review. Dr. Kakarala seconded the motion. Motion carried. The matter will be taken to the full board later today.

Ms. Anderson reported that numerous comments were received on Rules 4731-11-04 and .041, which address prescribing weight loss drugs. The comments were included in the agenda materials. Ms. Anderson indicated that she wanted to give the committee time for review of the comments since they are substantive. Ms. Anderson said that the PAPC will also need to review the information.

The materials received regarding Rules 4731-11-04 and .041 will be and discussed at the October 16th Policy Committee meeting.

Adjourn

Dr. Bechtel moved to adjourn the meeting. Motion seconded by Dr. Kakarala. Motion carried. The meeting adjourned at 9:08 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: October 7, 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 10/3/19

For October Board Meeting

4731-1-05 4731-1-24

For October Policy Committee

4731-11-04 4731-11-04.1

For October Licensure Committee

4731-10-01 4731-10-02 4731-10-03
4731-10-04 4731-10-08

For October PAPC Meeting

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

For October Dietetics Advisory Council

4759-4-04 4759-4-08

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

HEARING HELD 10/2/19

4759 Chapter 4731-31-01

Final Filed 9/12/19

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

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4730-1-01	Regulation of Physician Assistants - Definitions		06/12/19							09/30/18	09/30/23
4730-1-05	Quality Assurance System		06/12/19							08/07/18	08/07/23
4730-1-06	Licensure as a physician assistant	03/22/19	06/12/19							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							09/30/15	09/30/20
4730-1-07	Miscellaneous Provisions		06/12/19							09/30/18	09/30/23
4730-1-08	Physician assistant delegation of medical tasks and administration of drugs		06/12/19							07/31/16	07/31/21
4730-2-01	Physician Delegated Prescriptive Authority - Definitions		06/12/19							9/30/18	09/15/19
4730-2-04	Period of on-site supervision of physician-delegated prescriptive authority		06/12/19							11/30/18	11/15/23
4730-2-05	Addition of valid prescriber number after initial licensure		06/12/19							11/30/18	11/15/23
4730-2-06	Physician Assistant Formulary		06/12/19							06/30/14	12/27/19
4730-2-07	Standards for Prescribing		06/12/19							9/30/18	12/27/19
4730-2-10	Standards and Procedures for use of OARRS		06/12/19							09/30/18	09/30/23
4730-4-01	Definitions									04/30/19	04/30/24
4730-4-03	Office Based Treatment for Opioid addiction									04/30/19	04/30/24
4730-4-04	Medication assisted treatment using naltrexone									04/30/19	04/30/24
4731-1-01	Limited Practitioners - Definition of Terms									03/30/20	03/30/25
4731-1-02	Application of Rules Governing Limited Branches of Medicine or Surgery									07/31/19	07/31/24
4731-1-03	General Prohibitions										08/31/23
4731-1-04	Scope of Practice: Mechanotherapy									12/31/18	12/31/23

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-1-05	Scope of Practice: Massage Therapy				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									08/31/18	08/31/23
4731-1-07	Eligibility of Electrologists Licensed by the Ohio State Board of Cosmetology to Obtain Licensure as Cosmetic Therapists Pursuant to Chapter 4731 ORC and Subsequent Limitations									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									09/30/19	09/30/24
4731-1-09	Cosmetic Therapy Curriculum Requirements										08/31/23
4731-1-10	Distance Education									01/31/19	01/31/24
4731-1-11	Application and Certification for certificate to practice cosmetic therapy									03/30/20	03/30/25
4731-1-12	Examination									11/30/16	11/30/21
4731-1-15	Determination of Standing of School, College or Institution									12/31/18	12/31/23
4731-1-16	Massage Therapy curriculum rule (Five year review)									01/31/19	11/30/21
4731-1-17	Instructional Staff									05/31/19	05/31/24
4731-1-18	Grounds for Suspension, Revocation or Denial of Certificate of Good Standing, Hearing Rights									03/30/20	03/30/25
4731-1-19	Probationary Status of a limited branch school									03/30/20	03/30/25
4731-1-24	Massage Therapy Continuing Education	03/09/16		10/26/16	04/24/19	04/29/19	06/05/19				
4731-1-25	Determination of Equiv. Military Educ. For CT/MT	03/22/19	06/12/19							12/31/15	12/31/20
4731-2-01	Public Notice of Rules Procedure									12/07/17	12/07/22
4731-4-01	Criminal Records Checks - Definitions									09/30/19	09/30/24
4731-4-02	Criminal Records Checks									09/30/19	09/30/24
4731-5-01	Admission to Examinations									06/09/17	06/09/22
4731-5-02	Examination Failure; Inspection and Regrading									06/09/17	06/09/22
4731-5-03	Conduct During Examinations									06/09/17	06/09/22

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-5-04	Termination of Examinations									06/09/17	06/09/22
4731-6-01	Medical or Osteopathic Licensure: Definitions									07/31/19	07/31/24
4731-6-02	Preliminary Education for Medical and Osteopathic Licensure									07/31/19	07/31/24
4731-6-04	Demonstration of proficiency in spoken English									06/09/17	06/09/22
4731-6-05	Format of Medical and Osteopathic Examination									07/31/19	07/31/24
4731-6-14	Examination for physician licensure									07/31/19	07/31/24
4731-6-15	Eligibility for Licensure of National Board Diplomats and Medical Council of Canada Licentiates									07/31/19	07/31/24
4731-6-21	Application Procedures for Certificate Issuance; Investigation; Notice of Hearing Rights									07/31/19	07/31/24
4731-6-22	Abandonment and Withdrawal of Medical and Osteopathic Licensure Applications									07/31/19	07/31/24
4731-6-30	Training Certificates									07/31/19	07/31/24
4731-6-31	Limited Preexamination Registration and Limited Certification									07/31/19	07/31/24
4731-6-33	Special Activity Certificates									07/31/19	07/31/24
4731-6-34	Volunteer's Certificates									07/31/19	07/31/24
4731-6-35	Processing applications from service members, veterans, or spouses of service members or veterans.									07/31/19	07/31/24
4731-7-01	Method of Notice of Meetings									07/31/19	07/31/24
4731-8-01	Personal Information Systems	02/20/19								04/21/16	04/21/21
4731-8-02	Definitions									04/21/16	04/21/21
4731-8-03	Procedures for accessing confidential personal information									04/21/16	04/21/21
4731-8-04	Valid reasons for accessing confidential personal information									04/21/16	04/21/21
4731-8-05	Confidentiality Statutes									07/31/16	07/31/21
4731-8-06	Restricting & Logging access to confidential personal information									04/21/16	04/21/21

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-9-01	Record of Board Meetings; Recording, Filming, and Photographing of Meetings									09/15/19	06/17/24
4731-10-01	Definitions									02/02/18	02/02/23
4731-10-02	Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement									05/31/18	05/31/23
4731-10-03	CME Waiver									05/31/18	05/31/23
4731-10-04	Continuing Medical Education Requirements for Restoration of a License									05/31/18	05/31/23
4731-10-05	Out-of-State Licensees									05/31/18	05/31/23
4731-10-06	Licensure After Cutoff for Preparation of Registration Notices									05/31/18	05/31/23
4371-10-07	Internships, Residencies and Fellowships									05/31/18	05/31/23
4371-10-08	Evidence of Continuing Medical Education									05/31/18	05/31/23
4731-10-09	Continuing Medical Education Requirement for Mid-term Licensees									05/31/18	05/31/23
4731-10-10	Continuing Medical Education Requirements Following License Restoration									05/31/18	05/31/23
4731-10-11	Telemedicine Certificates									05/31/18	05/31/23
4731-11-01	Controlled substances; General Provisions Definitions									12/23/18	12/07/22
4731-11-02	Controlled Substances - General Provisions	07/26/19								04/30/19	12/31/20
4731-11-03	Schedule II Controlled Substance Stimulants	07/26/19								12/31/15	12/31/20
4731-11-04	Controlled Substances: Utilization for Weight Reduction	07/26/19								02/29/16	02/28/21
4731-11-04.1	Controlled substances: Utilization for chronic weight management	07/26/19								12/31/15	12/31/20
4731-11-07	Research Utilizing Controlled Substances	07/26/19								09/30/15	09/30/20
4731-11-08	Utilizing Controlled Substances for Self and Family Members									08/17/16	08/17/21

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-11-09	Prescribing to persons the physician has never personally examined.									03/23/17	03/23/22
4731-11-11	Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).	07/26/19								12/31/15	12/31/20
4731-11-13	Prescribing of Opioid Analgesics for Acute Pain									08/31/17	08/31/22
4731-11-14	Prescribing for subacute and chronic pain			3/21/19						12/23/18	12/23/23
4731-12-01	Preliminary Education for Licensure in Podiatric Medicine and Surgery									06/30/17	06/30/22
4731-12-02	Standing of Colleges of Podiatric Surgery and Medicine									06/30/17	06/30/22
4731-12-03	Eligibility for the Examination in Podiatric Surgery and Medicine (see note below)									04/19/17	04/19/22
4731-12-04	Eligibility of Licensure in Podiatric Medicine and Surgery by Endorsement from Another State									06/30/17	06/30/22
4731-12-05	Application Procedures for Licensure in Podiatric Medicine and Surgery, Investigation, Notice of Hearing Rights.									06/30/17	06/30/22
4731-12-06	Visiting Podiatric Faculty Certificates									06/30/17	06/30/22
4731-12-07	Podiatric Training Certificates									06/30/17	06/30/22
4731-13-01	Conduct of Hearings - Representative; Appearances									07/31/16	07/31/21
4731-13-02	Filing Request for Hearing									07/31/16	07/31/21
4731-13-03	Authority and Duties of Hearing Examiners									09/30/18	07/31/21
4731-13-04	Consolidation										04/21/21
4731-13-05	Intervention										04/21/21
4731-13-06	Continuance of Hearing									09/30/16	09/30/21
4731-13-07	Motions									09/30/18	04/21/21
4731-13-07.1	Form and page limitations for briefs and memoranda									09/30/18	09/30/23
4731-13-08	Filing									07/31/16	07/31/21
4731-13-09	Service									07/31/16	07/31/21
4731-13-10	Computation and Extension of Time									07/31/16	07/31/21
4731-13-11	Notice of Hearings									07/31/16	07/31/21

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-13-12	Transcripts									07/31/16	07/31/21
4731-13-13	Subpoenas for Purposes of Hearing	05/09/19	06/12/19							07/31/16	07/31/21
4731-13-14	Mileage Reimbursement and Witness Fees										04/21/21
4731-13-15	Reports and Recommendations									07/31/16	07/31/21
4731-13-16	Reinstatement or Restoration of Certificate									07/31/16	07/31/21
4731-13-17	Settlements, Dismissals, and Voluntary Surrenders									04/21/16	04/21/21
4731-13-18	Exchange of Documents and Witness Lists									07/31/16	07/31/21
4731-13-20	Depositions in Lieu of Live Testimony and Transcripts in place of Prior Testimony									07/31/16	07/31/21
4731-13-20.1	Electronic Testimony									07/31/16	07/31/21
4731-13-21	Prior Action by the State Medical Board									04/21/16	04/21/21
4731-13-22	Stipulation of Facts									04/21/16	04/21/21
4731-13-23	Witnesses									09/14/16	09/30/21
4731-13-24	Conviction of a Crime									04/21/16	04/21/21
4731-13-25	Evidence									07/31/16	07/31/21
4731-13-26	Broadcasting and Photographing Administrative Hearings									04/21/16	04/21/21
4731-13-27	Sexual Misconduct Evidence									04/21/16	04/21/21
4731-13-28	Supervision of Hearing Examiners									04/21/16	04/21/21
4731-13-30	Prehearing Conference									04/21/16	04/21/21
4731-13-31	Transcripts of Prior Testimony									04/21/16	04/21/21
4731-13-32	Prior Statements of the Respondent									04/21/16	04/21/21
4731-13-33	Physician's Desk Physician									04/21/16	04/21/21
4731-13-34	Ex Parte Communication									07/31/16	07/31/21
4731-13-35	Severability									04/21/16	04/21/21
4731-13-36	Disciplinary Actions									07/31/16	07/31/21
4731-14-01	Pronouncement of Death									06/30/16	06/30/21
4731-15-01	Licensee Reporting Requirement; Exceptions									11/17/17	11/17/22
4731-15-02	Healthcare Facility Reporting Requirement									11/17/17	11/17/22
4731-15-03	Malpractice Reporting Requirement									11/17/17	11/17/22
4731-15-04	Professional Society Reporting									11/17/17	11/17/22

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-17-06	Barrier Techniques										08/17/21
4731-17-07	Violations									11/09/16	11/30/21
4731-18-02	Use of Light Based Medical Devices	01/17/18	03/14/18							05/31/02	06/30/05
4731-18-03	Delegation of the Use of Light Based Medical Devices	01/17/18	03/14/18							06/30/00	06/30/05
4731-18-04	Delegation of the Use of Light Based Medical Devices; Exceptions	01/17/18	03/14/18							05/31/02	05/31/07
4731-20-01	Surgery Privileges of Podiatrist - Definition of Foot									05/31/18	05/31/23
4731-20-02	Surgery: Ankle Joint									05/31/18	05/31/23
4731-22-01	Emeritus Registration - Definitions									08/31/17	08/31/22
4731-22-02	Application									08/31/17	08/31/22
4731-22-03	Status of Registrant									05/12/17	05/12/22
4731-22-04	Continuing Education Requirements									05/12/17	05/12/22
4731-22-06	Renewal of Cycle of Fees									05/12/17	05/12/22
4731-22-07	Change to Active Status									08/31/17	08/31/22
4731-22-08	Cancellation of or Refusal to Issue an Emeritus Registration									05/12/17	05/12/22
4731-23-01	Delegation of Medical Tasks - Definitions									11/30/16	11/30/21
4731-23-02	Delegation of Medical Tasks									11/30/16	11/30/21
4731-23-03	Delegation of Medical Tasks: Prohibitions									08/17/16	08/17/21
4731-23-04	Violations									08/17/16	08/17/21
4731-24-01	Anesthesiologist Assistants - Definitions									07/31/19	07/31/24
4731-24-02	Anesthesiologist Assistants; Supervision									07/31/19	07/31/24
4731-24-03	Anesthesiologist Assistants; Enhanced Supervision									07/31/19	07/31/24
4731-24-05	Military Provisions Related to Certificate to Practice as an Anesthesiologist Assistant									07/31/19	07/31/24
4731-25-01	Office-Based Surgery - Definition of Terms										03/01/23
4731-25-02	General Provisions									05/31/18	05/31/23
4731-25-03	Standards for Surgery Using Moderate Sedation/Analgesia									05/31/18	08/31/23

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4731-25-04	Standards for Surgery Using Anesthesia Services									05/31/18	05/31/23
4731-25-05	Liposuction in the Office Setting									03/01/18	03/01/23
4731-25-07	Accreditation of Office Settings									05/31/18	05/31/23
4731-25-08	Standards for Surgery									09/30/19	09/30/24
4731-26-01	Sexual Misconduct - Definitions									06/30/16	06/30/21
4731-26-02	Prohibitions									06/14/16	06/14/21
4731-26-03	Violations; Miscellaneous									06/30/16	06/30/21
4731-27-01	Definitions									02/04/19	02/02/24
4731-27-02	Dismissing a patient from the medical practice									05/31/19	05/31/24
4731-27-03	Notice of termination of physician employment or physician leaving a practice, selling a practice, or retiring from the practice of medicine									05/31/19	05/31/24
4731-28-01	Mental or Physical Impairment									08/31/17	08/31/22
4731-28-02	Eligibility for confidential monitoring program									08/31/18	08/31/23
4731-28-03	Participation in the confidential monitoring program									08/31/18	08/31/23
4731-28-04	Disqualification from continued participation in the confidential monitoring program									08/31/18	08/31/23
4731-28-05	Termination of the participation agreement for the confidential monitoring program									08/31/18	08/31/23
4731-29-01	Standards and procedures for operation of a pain management clinic.									06/30/17	06/30/22
4731-30-01	Internal Management Definitions									09/23/18	09/23/23
4731-30-02	Internal Management Board Metrics	07/26/19								09/23/18	09/23/23
4731-30-03	Approval of Licensure Applications									10/17/19	10/17/24
4731-31-01	Requirements for assessing and granting clearance for return to practice or competition. (concussion rule)					04/10/19	05/13/19			09/18/15	09/18/20
4731-32-01	Definition of Terms									09/08/17	09/08/22
4731-32-02	Certificate to Recommend Medical Marijuana									09/08/17	09/08/22
4731-32-03	Standard of Care									09/08/17	09/08/22

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4759-8-11	<i>Computation and Extension of Time</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-12	<i>Transcripts</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-13	<i>Subpoenas for Purposes of Hearing</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-14	<i>Mileage Reimbursement and Witness Fees</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-15	<i>Reports and Recommendations</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-16	<i>Exchange of Documents and Witness Lists</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-17	<i>Pre-hearing conference</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-18	<i>Requirements for pre-hearing exchange of information</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-19	<i>Status conference</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-20	<i>Depositions and transcripts of prior testimony</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-21	<i>Prior action by the board</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-22	<i>Stipulation of Facts</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-23	<i>Witnesses</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-24	<i>Conviction of a Crime</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-25	<i>Rules of evidence</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-26	<i>Broadcasting and Photographing Administrative Hearings</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-27	<i>Sexual misconduct evidence</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-28	<i>Reinstatement of license</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-8-29	<i>Settlements, Dismissals, and Voluntary Surrenders</i>	04/19/18	07/11/18	09/25/18							12/20/17
4759-9-01	<i>Severability</i>	04/19/18	07/11/18	09/25/18							12/18/17
4759-10-01	<i>Definitions</i>	04/19/18	07/11/18	09/25/18							12/18/17
4759-10-02	<i>Procedures for accessing confidential personal information</i>	04/19/18	07/11/18	09/25/18							12/18/17
4759-10-03	<i>Valid reasons for accessing confidential personal information</i>	04/19/18	07/11/18	09/25/18							12/18/17
4759-10-04	<i>Confidentiality Statutes</i>	04/19/18	07/11/18	09/25/18							12/18/17
4759-10-05	<i>Restricting & Logging access to confidential personal information in computerized personal information systems</i>	04/19/18	07/11/18	09/25/18							12/18/17
4759-11-01	<i>Miscellaneous Provisions</i>	04/19/18	07/11/18	09/25/18							
4761-2-03	<i>Board Records</i>									02/28/19	02/28/24
4761-3-01	<i>Definition of terms</i>									02/28/19	02/28/24

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date
4761-4-01	Approval of educational programs									02/28/19	02/28/24
4761-4-02	Monitoring of Ohio respiratory care educational programs									02/28/19	02/28/24
4761-4-03	Recognition of military educational programs for active duty military members and/or military veterans									11/15/18	11/15/23
4761-5-01	Waiver of licensing requirements pursuant to division (B) of section 4761.04 or the Revised Code	04/23/19	06/12/19							04/24/13	04/24/18
4761-5-02	Admission to the Ohio credentialing examination	04/23/19	06/12/19							05/06/10	05/06/15
4761-5-04	License application procedure	04/23/19	06/12/19							08/12/13	08/15/18
4761-5-06	Respiratory care practice by polysomnographic technologists	04/23/19	06/12/19							12/31/16	12/31/17
4761-6-01	Limited permit application procedure	04/23/19	06/12/19							02/28/19	02/28/24
4761-7-01	Original license or permit, identification card or electronic license verification									02/28/19	02/28/24
4761-7-03	Scope of respiratory care defined										11/15/23
4761-7-04	Supervision										11/15/23
4761-7-05	Administration of medicines										11/15/23
4761-8-01	Renewal of license or permits	03/22/19	06/12/19								08/15/18
4761-9-01	Definition of respiratory care continuing education										02/28/24
4761-9-02	General RCCE requirements and reporting mechanism	03/22/19	06/12/19								05/06/15
4761-9-03	Activities which do not meet the Ohio RCCE requirements									02/28/19	02/28/24
4761-9-04	Ohio respiratory care law and professional ethics course criteria										02/28/24
4761-9-05	Approved sources of RCCE										02/28/24
4761-9-07	Auditing for compliance with RCCE requirements										05/06/15
4761-10-01	Ethical and professional conduct									02/28/19	02/28/24
4761-10-02	Proper use of credentials										11/15/23
4761-10-03	Providing information to the Board	04/23/19	06/12/19								05/06/15
4761-12-01	Initial application fee									06/04/14	05/06/15
4761-15-01	Miscellaneous Provisions									02/28/19	02/28/24



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: October 7, 2019

Rules related to controlled substances prescribed for weight loss are due for the five-year rule review on 12/31/2020 and were circulated for comment. Several comments were received and provided to the Policy Committee at the September 11, 2019 meeting.

The following is a short description of the comments received:

Trace Curry, M.D. Eliminate the 12-week limit:

Derrick Cetin, D.O. 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

Luke Selby, M.D., Chris Gallagher, Megan Skinner, APRN and Maria Schroff, M.D.

Urges 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.

Neal Nesbett, M.D. 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

Beth Adamson, OAPA: Comments are applicable to 4731-11-04 and 4731-11-04.1. Supervising physician should be authorize PA to prescribe any drug within physician's normal practice and without requiring physician to review each chart after the PA sees the patient. Recommends use of a more inclusive term such as "practitioner" or "prescriber"

Donna Leitzel, patient Rule imposes extraordinary restrictions on use of weight loss drugs

Ross Henchen, M.D., Cheryl Milani, MMS, PA-C, Alana Mercer, MSHS, PA-C:

The rules are overly restrictive. Let PAs prescribe weight loss drugs; consider rescinding the rules completely and let physicians use medical judgment.

Latyonya Fore, NP: Recommends removal of the verbiage “short term anorexiant for purposes of weight reduction” and replacing it 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.

Barto Burguera M.D., Ph.D.: The rule 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 loose weight. Medical Board should designate phentermine to be a chronic weight loss drug. The letter Incudes references to several studies.

Karen Schultz, CNS: Should amend both 4731-11-04 and 4731-11-04.1 to allow continuous treatment as phentermine is safe.

Scott W. Butsch, M.D. Obesity is a chronic disease and the rules prevent appropriate treatment.

Kay Mavko, R.D. 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.

Stan Anderson, M.D. 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

Sandra Thornhill, P.A. Should rescind the rule, have a rule for obesity treatment instead. Limits patient's abilty to lose any significant amount of weight. Rule limits PA practice and is contradictive to "new process of prescribing."

Ethan Lazarus, M.D. Should allow long-term use of phentermine. Ohio physician who treats obesity according to standard of care violates the Ohio rule.

Steven Schierholt, Executive Director, Board of Pharmacy:

Supports continuing the rules are currently written.

The comments and the applicable rules are attached.

Action Needed: **Review comments and determine if amendments to the rules are needed. Refer to the full Board for filing with CSI.**



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

4700 Reed Road, Suite N • Columbus, OH 43220 • PH: 600.292.4997 • FX: 614.624.2103 • oapa@ohiopa.com • www.ohiopa.com

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.*

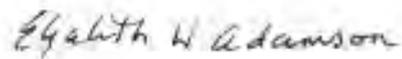
The passage of Senate Bill 259 has greatly expanded Physician Assistant scope of practice and prescriptive authority to be equivalent to and consistent with their supervising physician scope of practice. There are no citation in either ORC 4730 or OAC 4730 that specifically requires a supervising physician 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.

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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.

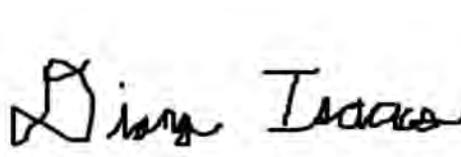
Sincerely,



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**

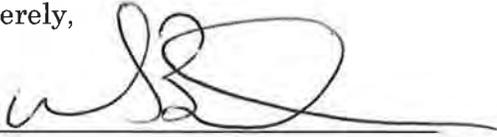
We need to recognize that our knowledge of obesity and therefore the practice of using obesity pharmacotherapy has changed. No longer do we think that a higher dose of a drug is necessarily more effective. Instead we may think of using combinations of medications with the understanding of the complex 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
latfore@yahoo.com

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
Washington Policy Consultant
Obesity Action Coalition
www.obesityaction.org
chris@potomaccurrents.com
571-235-6475



August 9, 2019

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

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'.

2211 Crocker Rd Suite 170 Westlake, Ohio 44145

440-250-0822

www.getvitalityhealth.com

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 weeks, 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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Contact Information for Doctor Lazarus:

5995 Greenwood Plaza Blvd, Ste 150
Greenwood Village, CO 80111

EthanLazarus@gmail.com

303-750-9454

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,

A handwritten signature in blue ink, appearing to read "Steven W. Schierholt".

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
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Sincerely,

A handwritten signature in blue ink, appearing to read "Steven W. Schierholt".

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
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