



Rules & Policies Agenda for Board Meeting April 13, 2022

- A. Rule Review Update
 - B. Light-Based Medical Device Rules
 - C. Podiatric Licensure Rules
 - D. Limited Branch Rules
 - E. Controlled Substance Rules
 - F. Telehealth Rules
 - G. Legislative Update
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MEMORANDUM

TO: Betty Montgomery, President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Update

DATE: April 4, 2022

Attached please find the Rule Schedule and Spreadsheet for April 2022.

Requested Action: No action requested.

Legal Dept. Rules Schedule

As of April 4, 2022

RULES TO APRIL BOARD MEETING

For Final Adoption

None

Filed with JCARR

4731-38-01 (IMLC)-Rule hearing held 3.25.22; JCARR jurisdiction ends 4.24.22. Rule to be adopted at May Board meeting.

Review Draft and Approve for Initial Circulation

Podiatric Licensure Rules

4731-12-01

4731-12-02

4731-12-03

4731-12-04

4731-12-05

4731-12-06

4731-12-07

Review Comments and Approve Filing with CSI

Massage Therapy Rules

4731-1-01 4731-1-02 4731-1-03

4731-1-04 4731-1-05 4731-1-07

4731-1-08 4731-1-09 4731-1-10

4731-1-11 4731-1-12 4731-1-15

4731-1-16 4731-1-17 4731-1-18

4731-1-19

Light Based Medical Device Rules

4731-18-01 4731-18-02

4731-18-03

Telehealth Rules

4731-11-09 4731-37-01

Controlled Substance & Weight Loss Rules

4731-11-03 4731-11-04 4731-11-04.1

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	07/16/19	11/07/19	06/18/20	No change rule			09/16/20	06/18/25
4730-1-05	Quality Assurance System		06/12/19	07/16/19	11/07/19	06/19/20	No change rule			09/17/20	06/19/25
4730-1-06	Licensure as a physician assistant	03/22/19	06/12/19	12/04/19		06/18/20	07/23/20	08/17/20	09/09/20	12/31/20	09/30/23
4730-1-07	Miscellaneous Provisions	02/12/22								12/31/21	09/30/23
4730-2-01	Physician Delegated Prescriptive Authority - Definitions		06/12/19	07/16/19	11/07/19	06/18/20	No change rule			09/18/20	06/18/25
4730-2-04	Period of on-site supervision of physician-delegated prescriptive authority		06/12/19	07/16/19	11/07/19	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	11/15/23
4730-2-05	Addition of valid prescriber number after initial licensure		06/12/19	07/16/19	11/07/19	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/23
4730-2-07	Standards for Prescribing	2/12/822								12/31/21	09/30/25
4730-2-10	Standards and Procedures for use of OARRS		06/12/19	07/16/19	11/07/19	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/23
4730-4-01	Definitions	05/09/19		11/15/19	05/20/20	06/18/20	07/23/20	08/17/20	10/14/20	10/31/20	04/30/24
4730-4-02	Standards and procedures for withdrawal management for drug or alcohol addiction	05/09/19		11/15/19	05/20/20	06/18/20	07/23/20	08/17/20	10/14/20	10/31/20	10/31/25
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
4730-5-01											
4730-5-02											
4731-1-01	Limited Practitioners - Definition of Terms	06/17/21								03/30/20	03/30/25
4731-1-02	Application of Rules Governing Limited Branches of Medicine or Surgery	06/17/21								07/31/19	07/31/24
4731-1-03	General Prohibitions	06/17/21									08/31/23
4731-1-04	Scope of Practice: Mechanotherapy	06/17/21								12/31/18	12/31/23
4731-1-05	Scope of Practice: Massage Therapy	06/17/21								11/05/19	11/05/24
4731-1-06	Scope of Practice: Naprapathy									08/31/18	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
4731-1-07	<i>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</i>	06/17/21								12/31/18	12/31/23
4731-1-08	<i>Continuing Cosmetic Therapy Education Requirements for Registration or Reinstatement of a License to Practice Cosmetic Therapy</i>	06/17/21								09/30/19	09/30/24
4731-1-09	<i>Cosmetic Therapy Curriculum Requirements</i>	06/17/21									08/31/23
4731-1-10	<i>Distance Education</i>	06/17/21								01/31/19	01/31/24
4731-1-11	<i>Application and Certification for certificate to practice cosmetic therapy</i>	06/17/21								03/30/20	03/30/25
4731-1-12	<i>Examination</i>									11/30/16	11/30/21
4731-1-15	<i>Determination of Standing of School, College or Institution</i>	06/17/21								12/31/18	12/31/23
4731-1-16	<i>Massage Therapy curriculum rule (Five year review)</i>	06/17/21								01/31/19	11/30/21
4731-1-17	<i>Instructional Staff</i>	06/17/21								05/31/19	05/31/24
4731-1-18	<i>Grounds for Suspension, Revocation or Denial of Certificate of Good Standing, Hearing Rights</i>	06/17/21								03/30/20	03/30/25
4731-1-19	<i>Probationary Status of a limited branch school</i>	06/17/21								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				
4731-2-01	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
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

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
4731-6-04	Demonstration of proficiency in spoken English									06/09/17	06/09/22
4731-6-05	Format of Medical and Osteopathic Examination		09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	01/31/27
4731-6-14	Examination for physician licensure	09/03/20								07/31/19	07/31/24
4731-6-15	Eligibility for Licensure of National Board Diplomats and Medical Council of Canada Licentiates									07/31/19	07/31/24
4731-6-21	Application Procedures for Certificate Issuance; Investigation; Notice of Hearing Rights									07/31/19	07/31/24
4731-6-22	Abandonment and Withdrawal of Medical and Osteopathic Licensure Applications									07/31/19	07/31/24
4731-6-30	Training Certificates									07/31/19	07/31/24
4731-6-31	Limited Preexamination Registration and Limited Certification									07/31/19	07/31/24
4731-6-33	Special Activity Certificates									07/31/19	07/31/24
4731-6-34	Volunteer's Certificates									07/31/19	07/31/24
4731-7-01	Method of Notice of Meetings									07/31/19	07/31/24
4731-8-01	Personal Information Systems	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26
4731-8-02	Definitions	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26
4731-8-03	Procedures for accessing confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26
4731-8-04	Valid reasons for accessing confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-8-05	Confidentiality Statutes	04/29/20		10/05/20	11/18/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-8-06	Restricting & Logging access to confidential personal information	04/29/20		10/05/20	11/18/20	02/11/21			no change	02/11/21	02/11/26
4731-9-01	Record of Board Meetings; Recording, Filming, and Photographing of Meetings									09/15/19	06/17/24
4731-10-01	Definitions	10/25/19		05/26/20		Revised filing 11/3/20 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26

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
4731-10-02	Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement	10/25/19		05/26/20		Revised filing 11/3/20 10/30/20	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-10-03	CME Waiver	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26
4731-10-04	Continuing Medical Education Requirements for Restoration of a License	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	12/04/20	12/07/20	05/12/21	05/31/21	05/31/26
4371-10-08	Evidence of Continuing Medical Education	10/25/19		05/26/20		Revised filings 11/24 & 11/3 - orig 10/30/20	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-11-01	Controlled substances; General Provisions Definitions	02/12/22								10/31/20	10/31/25
4731-11-02	Controlled Substances - General Provisions	07/26/19	11/13/19	10/05/20		05/27/21			no change		05/27/26
4731-11-03	Schedule II Controlled Substance Stimulants	07/26/19	11/13/19	10/05/20						12/31/15	12/31/20
4731-11-04	Controlled Substances: Utilization for Weight Reduction	07/26/19	11/13/19	10/05/20						02/29/16	02/28/21
4731-11-04.1	Controlled substances: Utilization for chronic weight management	07/26/19	11/13/19	10/05/20						12/31/15	12/31/20
4731-11-07	Research Utilizing Controlled Substances	07/26/19	11/13/19	10/05/20		05/27/21			no change		05/27/26
4731-11-08	Utilizing Controlled Substances for Self and Family Members	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26
4731-11-09	Prescribing to persons the physician has never personally examined.	02/12/22								03/23/17	09/19/22

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
4731-11-11	Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).	07/26/19	11/13/19	10/05/20		05/27/21	06/28/21		09/08/21	09/30/21	09/30/26
4731-11-13	Prescribing of Opioid Analgesics for Acute Pain									08/31/17	08/31/22
4731-11-14	Prescribing for subacute and chronic pain			3/21/19	11/14/19	corrected-7/16/20 6/18/2020	07/23/20	08/17/20	10/14/20	10/31/20	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	10/16/22
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	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-02	Filing Request for Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	No change				04/12/26
4731-13-03	Authority and Duties of Hearing Examiners	08/26/20	10/14/20	amended filing 1/6/21 10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-04	Consolidation	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-05	Intervention	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-06	Continuance of Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-07	Motions	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26

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
4731-13-07.1	Form and page limitations for briefs and memoranda	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-08	Filing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-09	Service	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-10	Computation and Extension of Time	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-11	Notice of Hearings	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-12	Transcripts	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-13	Subpoenas for Purposes of Hearing	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-14	Mileage Reimbursement and Witness Fees	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-15	Reports and Recommendations	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-16	Reinstatement or Restoration of Certificate	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-17	Settlements, Dismissals, and Voluntary Surrenders	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-18	Exchange of Documents and Witness Lists	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-20	Depositions in Lieu of Live Testimony and Transcripts in place of Prior Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-20.1	Electronic Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-21	Prior Action by the State Medical Board	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-22	Stipulation of Facts	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-23	Witnesses	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-24	Conviction of a Crime	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-25	Evidence	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-26	Broadcasting and Photographing Administrative Hearings	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-27	Sexual Misconduct Evidence	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26

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4731-13-28	Supervision of Hearing Examiners	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-30	Prehearing Conference	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-31	Transcripts of Prior Testimony	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-32	Prior Statements of the Respondent	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-33	Physician's Desk Physician	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-13-34	Ex Parte Communication	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-35	Severability	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	no change				04/12/26
4731-13-36	Disciplinary Actions	08/26/20	10/14/20	10/23/20	04/02/21	04/12/21	05/17/21	06/07/21	07/14/21	07/31/21	07/31/26
4731-14-01	Pronouncement of Death	01/25/21	03/10/21	03/18/21		05/27/21	06/28/21		09/08/21	09/30/21	09/30/26
4731-15-01	Licensee Reporting Requirement; Exceptions									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
4731-15-05	Liability; Reporting Forms; Confidentially and Disclosure									11/17/17	11/17/22
4731-16-01	Rules governing impaired physicians and approval of treatments programs - Definitions									11/17/17	11/17/22
4731-16-02	General Procedures in Impairment Cases	06/17/21	09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	11/17/22
4731-16-04	Other Violations									11/17/17	11/17/22
4731-16-05	Examinations	06/17/21	09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	11/17/22
4731-16-06	Consent Agreements and Orders for Reinstatement of Impaired Practitioners								01/12/22	01/31/22	11/17/22
4731-16-07	Treatment Provider Program Obligations									11/17/17	11/17/22
4731-16-08	Criteria for Approval	06/17/21	09/08/21	09/24/21	10/27/21	10/29/21	12/03/21			11/17/17	11/17/22
4731-16-09	Procedures for Approval									11/17/17	11/17/22
4731-16-10	Aftercare Contracts									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
4731-16-11	Revocation, Suspension, or Denial of Certificate of Good Standing									11/17/17	11/17/22
4731-16-12	Out-of-State Impairment Cases									11/17/17	11/17/22
4731-16-13	Patient Consent; Revocation of Consent									11/17/17	11/17/22
4731-16-14	Caffeine, Nicotine, and Over-The Counter Drugs									11/17/17	11/17/22
4731-16-15	Patient Rights									11/17/17	11/17/22
4731-16-17	Requirements for the one-bite program									01/31/19	01/31/24
4731-16-18	Eligibility for the one-bite program									01/31/19	01/31/24
4731-16-19	Monitoring organization for one-bite program									01/31/19	01/31/24
4731-16-20	Treatment providers in the one-bite program									01/31/19	01/31/24
4731-16-21	Continuing care for the one-bite program									01/31/19	01/31/24
4731-17-01	Exposure-Prone Invasive Procedure Precautions - Definitions	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-17-02	Universal Precautions	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26
4731-17-03	Hand Washing	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26
4731-17-04	Disinfection and Sterilization	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-17-05	Handling and Disposal of Sharps and Wastes	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-17-06	Barrier Techniques	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21			no change		02/11/26
4731-17-07	Violations	08/26/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-18-01	Definitions	01/10/18	01/20/20	05/12/20	04/05/21	04/09/21	refiled 6-9-21 5/17/2021	06/25/21	07/14/21	07/31/21	07/31/26
4731-18-02	Use of Light Based Medical Devices	01/10/18	01/20/20	05/12/20	04/05/21	04/09/21	refiled 6-9-21 5/17/2021	06/25/21	07/14/21	07/31/21	07/31/26
4731-18-03	Delegation of the Use of Light Based Medical Devices	01/10/18	01/20/20	05/12/20	04/05/21	04/09/21	refiled 6-9-21 5/17/2021	06/25/21	07/14/21	07/31/21	07/31/26

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
4731-18-04	Delegation of phototherapy and photodynamic therapy	01/10/18	01/20/20	05/12/20	04/05/21	04/09/21	refiled 6-9-21 5/17/2021	06/25/21	07/14/21	07/31/21	07/31/26
4731-20-01	Surgery Privileges of Podiatrist - Definition of Foot									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	06/17/21	09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	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	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26
4731-23-02	Delegation of Medical Tasks	01/25/21	03/10/21	03/18/21	04/23/21	refiled 7/14/21 5/27/2021	06/28/21		09/08/21	09/30/21	09/30/26
4731-23-03	Delegation of Medical Tasks: Prohibitions	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26
4731-23-04	Violations	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21			no change		05/27/26
4731-24-01	Anesthesiologist Assistants - Definitions									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
4731-25-01	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
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

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
4731-25-07	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	01/25/21	03/10/21	03/18/21	04/23/21	refiled 7/14/21 5/27/2021	06/28/21		09/08/21	09/30/21	09/30/26
4731-26-02	Prohibitions	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21	06/28/21		09/08/21	09/30/21	09/30/26
4731-26-03	Violations; Miscellaneous	01/25/21	03/10/21	03/18/21	04/23/21	05/27/21	06/28/21		09/08/21	09/30/21	09/30/26
4731-27-01	Definitions									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	06/17/21				refiled 11-4-21 5/7/2020			01/12/22	01/31/22	10/17/24
4731-30-04	Maintenance of List of Disqualifying Criminal Offenses	08/13/21				refiled 11-4-21			09/08/21	12/31/21	12/31/26
4731-31-01	Requirements for assessing and granting clearance for return to practice or competition. (concussion rule)					04/10/19	05/13/19			11/30/19	11/30/24

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
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
4731-32-04	Suspension and Revocation of Certificate to Recommend									09/08/17	09/08/22
4731-32-05	Petition to Request Additional Qualifying Condition or Disease									09/08/17	09/08/22
4731-33-01	Definitions	05/09/19		11/15/19	05/20/20	06/18/20	07/23/20	08/17/20	10/14/20	10/31/20	04/30/24
4731-33-02	Standards and procedures for withdrawal management for drug or alcohol addiction	05/09/19		11/15/19	05/20/20	06/18/20	07/23/20	08/17/20	10/14/20	10/31/20	10/31/25
4731-33-03	Office-Based Treatment for Opioid Addiction									04/30/19	04/30/24
4731-33-04	Medication Assisted Treatment Using Naltrexone									04/30/19	04/30/24
4731-34-01	Standards and Procedures to be followed by physicians when prescribing a dangerous drug that may be administered by a pharmacist by injection.									07/31/19	07/31/24
4731-35-01	Consult Agreements	01/25/21	04/14/21	04/26/21	06/04/21	09/22/21	10/29/21	11/08/21	12/08/21	12/31/21	10/31/25
4731-35-02	Standards for managing drug therapy	01/25/21	04/14/21	04/26/21	06/04/21	09/22/21	10/29/21	11/08/21	12/08/21	12/31/21	10/31/25
4731-36-01	Military provisions related to education and experience requirements for licensure	06/17/21	09/08/21	09/24/21	10/27/21	10/29/21	12/03/21		01/12/22	01/31/22	10/29/21
4731-36-02	Military provisions related to renewal of license and continuing education	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25
4731-36-03	Processing applications from service members, veterans, or spouses of service members or veterans.	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25
4731-36-04	Temporary license for military spouse	02/11/20	02/12/20	02/14/20		02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4731-37-01	Telemedicine	02/12/22									
4731-38-01	Licenses Issued or Renewed Under the Interstate Medical Licensure Compact	11/12/21	01/12/22	01/14/22	02/14/22	02/18/22	03/25/22				
4759-2-01	Definitions									11/30/19	11/30/24
4759-4-01	Applications									11/30/19	11/30/24
4759-4-02	Preprofessional experience										08/28/24
4759-4-03	Examination									11/30/19	11/30/24

[illegible]

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
4761-7-04	Supervision			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25
4761-7-05	Administration of medicines										11/15/23
4761-8-01	Renewal of license or permits	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25
4761-9-01	Definition of respiratory care continuing education			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	02/28/24
4761-9-02	General RCCE requirements and reporting mechanism	03/22/19	06/12/19	12/05/19	09/11/20	09/25/20	10/27/20	11/16/20	12/09/20	12/31/20	12/31/25
4761-9-03	Activities which do not meet the Ohio RCCE requirements									02/28/19	02/28/24
4761-9-04	Ohio respiratory care law and professional ethics course criteria			11/06/19	01/10/20	Refiled 8/24/20 6/18/2020	9/24/20 7/23/2020	08/17/20	11/10/20		02/28/24
4761-9-05	Approved sources of RCCE			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	02/28/24
4761-9-07	Auditing for compliance with RCCE requirements			11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25
4761-10-01	Ethical and professional conduct									02/28/19	02/28/24
4761-10-02	Proper use of credentials										11/15/23
4761-10-03	Providing information to the Board	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20	08/17/20	09/09/20	09/30/20	09/30/25
4761-15-01	Miscellaneous Provisions	02/12/22								02/28/19	02/28/24
4774-1-01	Definitions	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21			no change	02/11/21	02/11/26
4774-1-02	Application for Certificate to Practice	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4774-1-03	Renewal of Certificate to Practice	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21	03/15/21	03/29/21	05/12/21	05/31/21	05/31/26
4774-1-04	Miscellaneous Provisions	04/29/20	10/14/20	10/23/20	11/24/20	02/11/21			no change	02/11/21	02/11/26
4778-1-01	Definition									01/29/19	01/24/24
4778-1-02	Application									04/30/19	04/30/24
4778-1-03	Special Activity License									01/24/19	01/24/24
4778-1-05	Collaboration Agreement									04/30/19	04/30/24
4778-1-06	Miscellaneous Provisions	02/12/22								04/30/19	04/30/24



MEMORANDUM

TO: Betty Montgomery, President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Light-Based Medical Device Rules

DATE: April 4, 2022

The amendments to the light-based medical device rules became effective July 31, 2021, prior to the expiration of Emergency Rule 4731-18-03, which allowed cosmetic therapists to continue to be delegated laser hair removal. Section 4731.33 of the Revised Code was part of the biennial budget bill and became effective September 30, 2021. The statute addressed the use of light-based medical devices for laser hair removal and has some provisions which are different from those in Rule 4731-18-03, Ohio Administrative Code. The statutory provisions will take precedence over any conflicting rule provisions.

In order to provide clarity, Rules 4731-18-01, 4731-18-02 and 4731-18-03 are proposed to be amended. The amendments remove any language that conflicts with Section 4731.33 of the Revised Code and references the statute as being applicable for the delegation of light-based medical devices for laser hair removal. The amended rules address general provisions regarding the delegation of light-based medical devices, and the delegation of vascular lasers for non-ablative dermatologic procedures. Rule 4731-18-04 regarding the delegation of light-based medical devices for phototherapy and photodynamic therapy is unchanged and not part of this package.

In November, 2021, the rules were circulated for comments, and four comments were received. Beth Adamson of the Ohio Association of Physician Assistants requested that the definition of “Ablative dermatologic procedure” in 4731-18-01(D) be updated because physician assistants are already performing procedures in office beneath the dermo-epidermal junction to the subcutaneous fat (such as excisions with intermediate and complex closures) without direct supervision. Ms. Adamson requested a change to Rule 4731-18-02(D) to state that a physician may delegate the application of light based medical devices for hair removal, resurfacing and dermatologic purposes because the current language is restrictive to specialty physician practices such as dermatology, ENT, facial plastic surgery and plastic and reconstructive surgery. Ms. Adamson requests the removal of paragraphs (A)(3), (4), and (5) of Rule 4731-18-03 because the requirement for the physician to evaluate the patient creates more work for the provider. Not requiring these evaluations would allow the physician to do more complex visits or procedures. Matthew Ernst and Jo Kelton of Removery, LLC recommended changes to the rules to allow delegation of laser tattoo removal to cosmetic therapists, physician assistants, registered nurses and licensed practical nurses. Amanda Nelson of the Cosmetic Therapy Association of Ohio recommended changes to Rules 4731-18-01 through 4731-18-03 which would allow cosmetic therapists to be delegated the use of light based medical devices for non-ablative vascular treatments.

The rules and comments were discussed at the February meeting of the Physician Assistant Policy Council. The members did not recommend any specific rule changes, but did have questions about what types of procedures are considered to be non-ablative and able to be completed by a physician assistant, which can be addressed in updates to the Frequently Asked Questions document on this topic.

The purpose of this rule review is to correct any discrepancies between the statute and the rules, which were finalized less than one year ago, after a very lengthy rule-making process. Based on this and the feedback from the PAPC, I recommend filing the rules as drafted with the Common Sense Initiative. A two-week comment period will be part of that process.

Requested Action: Approve filing rules with Common Sense Initiative

4731-18-01

Definitions.

As used in this chapter of the Administrative Code:

- (A) “Light based medical device ” means any device that can be made to produce or amplify electromagnetic radiation at wavelengths equal to or greater than one hundred eighty nm but less than or equal to 1.0×10^6 nm [ten to the sixth power] and that is manufactured, designed, intended or promoted for irradiation of any part of the human body for the purpose of affecting the structure or function of the body.
- (B) “Phototherapy” means the following:
- (1) For paragraph (A) of rule 4731-18-04 of the Administrative Code, phototherapy means the application of light for the treatment of hyperbilirubinemia in neonates.
 - (2) For paragraphs (B) and (C) of rule 4731-18-04 of the Administrative Code, phototherapy means the application of ultraviolet light for the treatment of psoriasis and similar skin diseases. This application can occur with any device cleared or approved by the United States food and drug administration for the indicated use that can be made to produce irradiation with broadband ultraviolet B (290-320nm), narrowband ultraviolet B (311-313 nm), excimer light based (308nm), ultraviolet A1 (340-400nm), or UVA (320-400nm) plus oral psoralen called PUVA.
- (C) “Photodynamic therapy” means light therapy involving the activation of a photosensitizer by visible light in the presence of oxygen, resulting in the creation of reactive oxygen species, which selectively destroy the target tissue.
- (D) “Ablative dermatologic procedure” means a dermatologic procedure that is expected to excise, burn, or vaporize the skin below the dermo-epidermal junction.
- (E) “Non-ablative dermatologic procedure” means a dermatologic procedure that is not expected or intended to excise, burn, or vaporize the epidermal surface of the skin.
- (F) “Physician means a person authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery under Chapter 4731. of the Revised Code and acting within the scope of their practice.
- (G) “Delegation” means the assignment of the performance of a service to a person who is not a physician.

(H) "On-site supervision" means the physical presence of the supervising physician is required in the same location (i.e., the physician's office suite) as the delegate of the light based medical device but does not require the physician's presence in the same room.

~~(I) "Off-site supervision" means that the supervising physician shall be continuously available for direct communication with the cosmetic therapist.~~

~~(H)~~(I) "Direct physical oversight" means the physical presence of the supervising physician is required in the same room to directly observe the delegate of the light based medical device.

~~(H)~~(I) "Vascular laser" means light-based medical devices including lasers and intense pulsed light apparatuses whose primary cutaneous target structures are telangiectasia, venulectasia, and superficial cutaneous vascular structures. In general, these lasers have wavelengths that correspond to the hemoglobin absorption spectrum.

4731-18-02

Use of light based medical devices.

- (A) The application of light based medical devices to the human body is the practice of medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.
- (B) A physician shall not delegate the application of light based medical devices for ablative procedures.
- (C) A physician may delegate the application of a vascular laser for non-ablative dermatologic procedures according to the requirements in paragraph (A) of rule 4731-18-03 of the Administrative Code.
- (D) A physician may delegate the application of light based medical devices for the purpose of hair removal according to the ~~respective~~ requirements of section 4731.33 of the Revised Code~~in paragraphs (B) and (C) of rule 4731-18-03 of the Administrative Code.~~
- (E) A physician may delegate the application of phototherapy for the treatment of hyperbilirubinemia in neonates according to the requirements in paragraph (A) of rule 4731-18-04 of the Administrative Code.
- (F) A physician may delegate the application of phototherapy and photodynamic therapy only for dermatologic purposes according to the requirements of paragraphs (B) and (C) of rule 4731-18-04 of the Administrative Code.
- (G) A violation of paragraph (B) of this rule shall constitute "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 and "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in division (B)(20) of section 4731.22 of the Revised Code, to wit: section 4731.41 of the Revised Code.

4731-18-03

Delegation of the use of light based medical devices for specified non-ablative procedures.

(A) A physician may delegate the application of a vascular laser for non-ablative dermatologic procedures only if all the following conditions are met:

(1) The vascular laser has been specifically cleared or approved by the United States food and drug administration for the specific intended non-ablative dermatologic procedure;

(2) The use of the vascular laser for the specific non-ablative dermatologic use is within the physician's normal course of practice and expertise;

(3) The physician has seen and evaluated the patient to determine whether the proposed application of the specific vascular laser is appropriate;

(4) The physician has seen and evaluated the patient following the initial application of the specific vascular laser, but prior to any continuation of treatment in order to determine that the patient responded well to the initial application of the specific vascular laser;

(5) The person to whom the delegation is made is one of the following:

(a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement; or,

(b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code;

(6) For a physician assistant, the authorization must meet the requirements of section 4730.21 of the Revised Code.

(7) For a registered nurse or licensed practical nurse, the physician must ensure that the person to whom the delegation is made has received adequate education and training to provide the level of skill and care required including:

(a) Eight hours of basic education that must include the following topics: light based procedure physics, tissue interaction in light based procedures, light based procedure safety including use of proper safety equipment, clinical application of light based procedures, pre and post-operative care of light based procedure patients, and reporting of adverse events;

(b) Observation of fifteen procedures for each specific type of vascular laser non-ablative procedure delegated. The procedures observed must be performed by a physician for whom the use of this specific vascular laser procedure is within the physicians normal course of practice and expertise; and

- (c) Performance of twenty procedures under the direct physical oversight of the physician on each specific type of vascular laser non-ablative procedure delegated. The physician overseeing the performance of these procedures must use this specific vascular laser procedure within the physicians normal course of practice and expertise;
- (d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in paragraph (A)(7)(a) of this rule must only be completed once by the delegate regardless of the number of types of specific vascular laser procedures delegated and the number of delegating physicians. The training requirements in paragraphs (A)(7)(b) and (A)(7)(c) of this rule must be completed by the delegate once for each specific type of vascular laser procedure delegated regardless of the number of delegating physician;
- (8) For delegation to a registered nurse or licensed practical nurse, the physician provides on-site supervision at all times that the person to whom the delegation is made is applying the vascular laser; and,
- (9) For delegation to a registered nurse or licensed practical nurse, the physician supervises no more than two persons pursuant to this rule at the same time.
- (B) A physician may delegate the application of light based medical devices for the purpose of hair removal in accordance with the requirements of section 4731.33 of the Revised Code.
- (C) The physician assistant, registered nurse or licensed practical nurse shall immediately report to the supervising physician any clinically significant side effect following the application of the light based medical device or any failure of the treatment to progress as was expected at the time the delegation was made. The physician shall see and personally evaluate the patient who has experienced the clinically significant side effect or whose treatment is not progressing as expected as soon as practicable.
- (D) A violation of paragraph (A), (B), or (C) of this rule by a physician shall constitute "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.
- (E) A violation of division (A)(5) of this rule shall constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in division (B)(20) of section 4731.22 of the Revised Code, to wit: section 4731.41 of the Revised Code.

(F) A violation of paragraph (C) of this rule by a physician assistant shall constitute "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 patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code.

*** DRAFT - NOT YET FILED ***

4731-18-03

Delegation of the use of light based medical devices for specified non-ablative procedures.

(A) A physician may delegate the application of a vascular laser for non-ablative dermatologic procedures only if all the following conditions are met:

- (1) The vascular laser has been specifically cleared or approved by the United States food and drug administration for the specific intended non-ablative dermatologic procedure;
- (2) The use of the vascular laser for the specific non-ablative dermatologic use is within the physician's normal course of practice and expertise;
- (3) The physician has seen and evaluated the patient to determine whether the proposed application of the specific vascular laser is appropriate;
- (4) The physician has seen and evaluated the patient following the initial application of the specific vascular laser, but prior to any continuation of treatment in order to determine that the patient responded well to the initial application of the specific vascular laser;
- (5) The person to whom the delegation is made is one of the following:
 - (a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement; or,
 - (b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code;
- (6) For a physician assistant, the authorization must meet the requirements of section 4730.21 of the Revised Code.
- (7) For a registered nurse or licensed practical nurse, the physician must ensure that the person to whom the delegation is made has received adequate education and training to provide the level of skill and care required including:
 - (a) Eight hours of basic education that must include the following topics: light based procedure physics, tissue interaction in light based procedures, light based procedure safety including use of proper safety equipment, clinical application of light based procedures, pre and post-operative care of light based procedure patients, and reporting of adverse events;

- (b) Observation of fifteen procedures for each specific type of vascular laser non-ablative procedure delegated. The procedures observed must be performed by a physician for whom the use of this specific vascular laser procedure is within the physician's normal course of practice and expertise; and
 - (c) Performance of twenty procedures under the direct physical oversight of the physician on each specific type of vascular laser non-ablative procedure delegated. The physician overseeing the performance of these procedures must use this specific vascular laser procedure within the physician's normal course of practice and expertise;
 - (d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in paragraph (A)(7)(a) of this rule must only be completed once by the delegate regardless of the number of types of specific vascular laser procedures delegated and the number of delegating physicians. The training requirements in paragraphs (A)(7)(b) and (A)(7)(c) of this rule must be completed by the delegate once for each specific type of vascular laser procedure delegated regardless of the number of delegating physician;
- (8) For delegation to a registered nurse or licensed practical nurse, the physician provides on-site supervision at all times that the person to whom the delegation is made is applying the vascular laser; and,
- (9) For delegation to a registered nurse or licensed practical nurse, the physician supervises no more than two persons pursuant to this rule at the same time.
- (B) A physician may delegate the application of light based medical devices for the purpose of hair removal only if all the following conditions are met:
 - (1) The light based medical device has been specifically cleared or approved by the United States food and drug administration for the removal of hair from the human body;
 - (2) The use of the light based medical device for the purpose of hair removal is within the physician's normal course of practice and expertise;
 - (3) The physician has seen and evaluated the patient to determine whether the proposed application of the specific light based medical device is appropriate;

- (4) The physician has seen and evaluated the patient following the initial application of the specific light based medical device, but prior to any continuation of treatment in order to determine that the patient responded well to that initial application of the specific light based medical device;
- (5) The person to whom the delegation is made is one of the following:
 - (a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement;
 - (b) A cosmetic therapist who was licensed under Chapter 4731. of the Revised Code on April 11, 2021 or who has completed a cosmetic therapy course of instruction for a minimum of seven hundred fifty clock hours and received a passing score on the “Certified Laser Hair Removal Professional ® Examination” administered by “The Society for Clinical and Medical Hair Removal”; or,
 - (c) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code.
- (6) For a physician assistant, the authorization must meet the requirements of section 4730.21 of the Revised Code.
- (7) For cosmetic therapists, registered nurses and licensed practical nurses, the physician shall ensure the person to whom the delegation is made has received adequate education and training to provide the level of skill and care required including:
 - (a) Eight hours of basic education that must include the following topics: light based procedure physics, tissue interaction in light based procedures, light based procedure safety including use of proper safety equipment, clinical application of light based procedures, pre and post-operative care of light based procedure patients, and reporting of adverse events;
 - (b) Observation of fifteen procedures for each specific type of light based medical device procedure for hair removal delegated. The procedures observed must be performed by a physician for whom the use of this specific light based medical device procedure for hair removal is within the physician’s normal course of practice and expertise; and

- (c) Performance of twenty procedures under the direct physical oversight of the physician on each specific type of light based medical device procedure for hair removal delegated. The physician overseeing the performance of these procedures must use this specific light based medical device procedure for hair removal within the physician's normal course of practice and expertise;
 - (d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in paragraph (A)(7)(a) of this rule must only be completed once by the delegate regardless of the number of types of specific light based medical device procedures for hair removal delegated and the number of delegating physicians. The training requirements of paragraphs (A)(7)(b) and (A)(7)(c) of this rule must be completed by the delegate once for each specific type of light based medical device procedure for hair removal delegated regardless of the number of delegating physicians;
 - (e) Delegates who, prior to the effective date of this rule, have been applying a specific type of light based medical device procedure for hair removal for at least two years through a lawful delegation by a physician, shall be exempted from the education and training requirements of paragraphs (A)(7)(a), (A)(7)(b), and (A)(7)(c) of this rule for that type of procedure provided that they obtain a written certification from one of their current delegating physicians stating that the delegate has received sufficient education and training to competently apply that type of light based medical device procedure. This written certification must be completed no later than sixty days after the effective date of this rule, and a copy of the certification shall be retained by each delegating physician and each delegate.
 - (f) For cosmetic therapists, the education and training requirements of paragraph (A)(7)(a), (A)(7)(b), or (A)(7)(c) of this rule may be satisfied through the cosmetic therapy course of instruction in paragraph (B)(5)(b) of this rule if the program provides written verification to the physician that the cosmetic therapist completed the requirements of paragraph (A)(7)(a), (A)(7)(b), or (A)(7)(c) of this rule as part of the cosmetic therapy course of instruction.
- (8) For cosmetic therapists, registered nurses and licensed practical nurses, the physician provides on-site supervision at all times that the person to whom the delegation is made is applying the light based medical device; and,

- (9) For cosmetic therapists, registered nurses and licensed practical nurses, the physician supervises no more than two persons pursuant to this rule at the same time.
- (C) Notwithstanding paragraph (B)(8) of this rule, the physician may provide off-site supervision when the light based medical device is applied for the purpose of hair removal to an established patient if the person to whom the delegation is made pursuant to paragraph (B) of this rule is a cosmetic therapist who meets all of the following criteria:
- (1) The cosmetic therapist has successfully completed a course in the use of light based medical devices for the purpose of hair removal that has been approved by the delegating physician;
 - (2) The course consisted of at least fifty hours of training, at least thirty hours of which was clinical experience; and
 - (3) The cosmetic therapist has worked under the on-site supervision of the physician making the delegation a sufficient period of time that the physician is satisfied that the cosmetic therapist is capable of competently performing the service with off-site supervision.
- The cosmetic therapist shall maintain documentation of the successful completion of the required training.
- (D) The cosmetic therapist, physician assistant, registered nurse or licensed practical nurse shall immediately report to the supervising physician any clinically significant side effect following the application of the light based medical device or any failure of the treatment to progress as was expected at the time the delegation was made. The physician shall see and personally evaluate the patient who has experienced the clinically significant side effect or whose treatment is not progressing as expected as soon as practicable.
- (E) A violation of paragraph (A), (B), (C), or (D) of this rule by a physician shall constitute "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.
- (F) A violation of division (A)(5) or (B)(5) of this rule shall constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated

by the board," as that clause is used in division (B)(20) of section 4731.22 of the Revised Code, to wit: section 4731.41 of the Revised Code.

(G) A violation of paragraph (C) or (D) of this rule by a cosmetic therapist shall constitute the unauthorized practice of medicine pursuant to section 4731.41 of the Revised Code.

(H) A violation of paragraph (D) of this rule by a physician assistant shall constitute "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 patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code.



Ohio Revised Code

Section 4731.33 Use of light-based medical devices for hair removal.

Effective: September 30, 2021

Legislation: House Bill 110 - 134th General Assembly

(A) As used in this section:

- (1) "Light-based medical device" means any device that can be made to produce or amplify electromagnetic radiation at wavelengths equal to or greater than one hundred eighty nm but less than or equal to 1.0×10^6 nm and that is manufactured, designed, intended, or promoted for irradiation of any part of the human body for the purpose of affecting the structure or function of the body.
- (2) "Physician" means a person authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery under this chapter.
- (3) "On-site supervision" means the supervising physician is physically in the same location as the delegate during the use of a light-based medical device, but does not require the physician to be in the same room. "On-site supervision" includes the supervising physician's presence in the same office suite as the delegate during the use of the device.
- (4) "Off-site supervision" means the supervising physician is continuously available for direct communication with the cosmetic therapist during the use of a light-based medical device.
- (5) "Direct physical oversight" means the supervising physician is in the same room directly observing the delegate's use of the light-based medical device.

(B) A physician may delegate the application of light-based medical devices for the purpose of hair removal only if all of the following conditions are met:

- (1) The light-based medical device has been specifically cleared or approved by the United States food and drug administration for the removal of hair from the human body.



(2) The use of the light-based medical device for the purpose of hair removal is within the physician's normal course of practice and expertise.

(3) The physician has seen and evaluated the patient to determine whether the proposed application of the specific light-based medical device is appropriate.

(4) The physician has seen and evaluated the patient following the initial application of the specific light-based medical device, but before any continuation of treatment, to determine that the patient responded well to that initial application of the specific light-based medical device.

(5) The person to whom the delegation is made is one of the following:

(a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement;

(b) A person who was licensed as a cosmetic therapist under Chapter 4731. of the Revised Code on April 11, 2021;

(c) A person who has completed a cosmetic therapy course of instruction for a minimum of seven hundred fifty clock hours and received a passing score on the certified laser hair removal professional examination administered by the society for clinical and medical hair removal;

(d) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code.

(C) For delegation to a physician assistant, the delegation must meet the requirements of section 4730.21 of the Revised Code.

(D)(1) For delegation to a person described under division (B)(5)(b) or (c) of this section, the physician shall ensure that the person to whom the delegation is made has received adequate education and training to provide the level of skill and care necessary, including all of the following:

(a) The person has completed eight hours of basic education that includes the following topics:



- (i) Light-based procedure physics;
 - (ii) Tissue interaction in light-based procedures;
 - (iii) Light-based procedure safety, including use of proper safety equipment;
 - (iv) Clinical application of light-based procedures;
 - (v) Preoperative and postoperative care of light-based procedure patients;
 - (vi) Reporting of adverse events.
- (b) The person has observed fifteen procedures for each specific type of light-based medical device procedure for hair removal that the person will perform under the delegation.
- (c) The person shall perform at least twenty procedures under the direct physical oversight of the physician on each specific type of light-based medical device procedure for hair removal delegated.
- (2) For purposes of division (D)(1)(b) of this section, the procedures observed shall be performed by a physician who uses the specific light-based medical device procedure for hair removal in the physician's normal course of practice and expertise.
- (3) For purposes of division (D)(1)(c) of this section, the physician overseeing the performance of these procedures shall use this specific light-based medical device procedure for hair removal within the physician's normal course of practice and expertise.
- (4) Each delegating physician and delegate shall document and retain satisfactory completion of training required under division (D) of this section. The education requirement in division (D)(1)(a) of this section shall be completed only once by the delegate regardless of the number of types of specific light-based medical device procedures for hair removal delegated and the number of delegating physicians. The training requirements of divisions (D)(1)(b) and (c) of this section shall be completed by the delegate once for each specific type of light-based medical device procedure for hair removal delegated regardless of the number of delegating physicians.



(E) The following delegates are exempt from the education and training requirements of division (D)(1) of this section:

(1) A person who, before the effective date of this section , has been applying a light-based medical device for hair removal for at least two years through a lawful delegation by a physician;

(2) A person described under division (B)(5)(b) of this section if the person was authorized to use a light-based medical device under the cosmetic therapist license;

(3) A person described in division (B)(5)(a) or (d) of this section.

(F) For delegation to a person under division (B)(5)(b), (c), or (d) of this section, the physician shall provide on-site supervision at all times that the person to whom the delegation is made is applying the light-based medical device.

A physician shall not supervise more than two delegates under division (B)(5)(b), (c), or (d) of this section at the same time.

(G)(1) Notwithstanding division (F) of this section, a physician may provide off-site supervision when the light-based medical device is applied for the purpose of hair removal to an established patient if the person to whom the delegation is made is a cosmetic therapist who meets all of the following criteria:

(a) The cosmetic therapist has successfully completed a course in the use of light-based medical devices for the purpose of hair removal that has been approved by the delegating physician;

(b) The course consisted of at least fifty hours of training, at least thirty hours of which was clinical experience;

(c) The cosmetic therapist has worked under the on-site supervision of the delegating physician for a sufficient period of time that the physician is satisfied that the cosmetic therapist is capable of competently performing the service with off-site supervision.



(2) The cosmetic therapist shall maintain documentation of the successful completion of the required training.

(H) A delegate under this section shall immediately report to the supervising physician any clinically significant side effect following the application of the light-based medical device or any failure of the treatment to progress as was expected at the time the delegation was made. The physician shall see and personally evaluate the patient who has experienced the clinically significant side effect or whose treatment is not progressing as expected as soon as practicable.

(I) No physician shall fail to comply with division (A), (B), (G), or (H) of this section. A violation of this division constitutes 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, under division (B)(6) of section 4731.22 of the Revised Code.

(J) No physician shall delegate the application of light-based medical devices for the purpose of hair removal to a person who is not listed in division (B)(5) of this section. A violation of this division constitutes violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate section 4731.41 of the Revised Code for purposes of division (B)(20) of section 4731.22 of the Revised Code.

(K) No cosmetic therapist to whom a delegation is made under division (B)(5)(b) or (c) of this section shall fail to comply with division (G) or (H) of this section. A violation of this division constitutes the unauthorized practice of medicine pursuant to section 4731.41 of the Revised Code.

(L) No physician assistant shall fail to comply with division (H) of this section. A violation of this division constitutes 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 patient is established, for purposes of division (B)(19) of section 4730.25 of the Revised Code.



November 30, 2021

Kimberly Anderson
State Medical Board of Ohio

Re: Comments on 4731-18 Proposed Rules

Dear Ms. Anderson:

The Ohio Association of Physician Assistants (OAPA) respectfully requests the following changes to proposed rules 4731-18.

OAPA requests that proposed rule 4731-18-01 definition (D) be updated.

(D) "Ablative dermatologic procedure" means a dermatologic procedure that is expected to excise, burn or vaporize the skin below the dermo-epidermal junction.

Rationale:

PAs are already performing procedures in office beneath the dermo-epidermal junction to the subcutaneous fat (i.e., excisions with intermediate and complex closures) without direct supervision.

OAPA requests changes to proposed rule 4731-18-02:

(D) A physician may delegate the application of light based medical devices for the purpose of hair removal, RESURFACING AND DERMATOLOGIC PURPOSES. ~~according to the respective requirements of section 4731.33 of the Revised Code in paragraphs (B) and (C) of rule 4731-18-03 of the Administrative Code.~~

Rationale:

The proposed language is restrictive to specialty PA practices such as dermatology, ENT, facial plastic surgery and plastic and reconstructive surgery. PAs in 48 states are safely performing these procedures. The Medical Board could request proof of training that is in compliance with current Ohio laws and supervisory agreements.

Constituent Chapter of the American Academy of Physician Assistants

4700 Reed Road, Suite N • Columbus, OH 43220 • PH: 800.292.4997 • FX: 614.824.2103 • oapa@ohiopa.com • www.ohiopa.com

OAPA requests removal of proposed rule 4731-18-03 (A) (3),(4),(5):

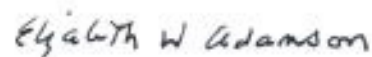
The proposed language requiring a physician to always evaluate the patient first to determine whether the proposed application is appropriate as well as after treatment needs to be removed.

Rationale:

As allowed by ORC 4730-08, PAs are currently seeing and evaluating patients for proposed treatments. Requiring the physician to constantly evaluate the patient creates more work for the provider. Not requiring the evaluations would allow the physician to be available to do more complex visits or procedures.

Thank you for your consideration of our requests and please feel free to contact me if you have any questions.

Elizabeth W. Adamson

A handwritten signature in black ink that reads "Elizabeth W. Adamson". The script is cursive and fluid, with the first letters of the first and last names being capitalized and prominent.

Executive Director

From: [Anderson, Kimberly](#)
To: [Rodriguez, Judith](#)
Subject: FW: New light based devices rules
Date: Monday, November 22, 2021 8:55:39 AM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)

Comment for light based rules

Kimberly Anderson
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From: Matthew Ernst <todmeinerfei@gmail.com>
Sent: Saturday, November 20, 2021 9:52 AM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: New light based devices rules

Hi Kim

After going over these new rules they still seem incredibly ambiguous regarding procedures outside of hair removal. Can you clarify what the rules are for say something like tattoo removal?

CAUTION: This is an external email and may not be safe. If the email looks suspicious, please do not click links or open attachments and forward the email to csc@ohio.gov or click the Phish Alert Button if available.

11/30/2021

By EMAIL: Kimberly.Anderson@med.ohio.gov

To whom it may concern at the Ohio state medical board;

We would like to formally propose changes in the code 4731-18-03 (Delegation of the use of light-based medical devices for specified non-ablative procedures) to allow the delegation of laser tattoo removal to cosmetic therapists, physician assistants, registered nurses, and licensed practical nurses.

This can significantly help those seeking tattoo removal receive treatment in a much more efficient manner. Previously this proposal was deferred due to the higher risk of scarring with tattoo removal and complexity of decision-making regarding selection of the appropriate laser based on tattoo pigment. However, in recent years the combination of better clinical protocols and advancements in laser technology (specifically the picosecond laser) laser tattoo removal is much more effective in removing tattoos with significantly less scarring and post treatment complications. A recent study looked at over 200 subjects receiving laser tattoo removal treatments with a picosecond laser and there was not one that had scarring from the laser treatment [1]. Another study done in 2019 looked at the comparison of the older Q-switch/nanosecond lasers with the new picosecond lasers. The researchers found not only more effective clearing of the pigment using the picosecond lasers, but also less energy and thermal impact on surrounding tissues. Hence much less risk of scarring or other negative side effects [2].

Another consideration for including tattoo removal in this proposal is the lower energy in the picosecond laser for tattoo removal when compared to the lasers used for hair removal. The picosecond lasers specifically target the ink pigment with less energy than in older nanosecond lasers. Hair removal lasers target the melanin in the hair follicle to cause permanent destruction of hair bulge stem cells [3]. With the higher energy and a longer pulse duration used for laser hair removal there is an increased risk of pigmentation changes, especially in darker skin types [4]. Current hair removal lasers use 50 J of energy with fluences of 20 J/cm². The picosecond lasers (Specifically the Picoway) for tattoo removal only deliver up to 0.4 J, with a max fluence around 4 J/cm². If laser hair removal is being considered in this proposed rule so should laser tattoo removal.

We at Removery have over 75 locations in the US, Canada, and Australia and are the world's leader in tattoo removal and fading. We also have an extremely strong and robust laser training program for all of our new and existing employees. We have successfully completed a total of over 100,000 laser tattoo removal sessions so far in 2021 and have completed a total of over 200,000 laser tattoo removal treatments in the past 2 years. All with an extremely low number of adverse events or outcomes (i.e. scarring or complications). Our company has reached it's current size by a combination of organic growth and acquisitions of existing tattoo removal companies. Many of the companies we have acquired have successfully provided over 10,000 laser tattoo removal treatments with similar results.

Removery has a clinical advisory board comprised of physicians, scientists, and skilled clinicians with a combined experience of over 110 years in the laser tattoo removal industry. All our clinic-based laser specialists are trained with 80 hours of traditional education and 80 hours of hands-on clinical training before they treat independently. Not only are the laser specialists thoroughly trained in a comprehensive didactic curriculum, but they also receive monthly ongoing continuing education. The

education process is not complete once they are deemed competent to treat. There is a clinical ladder which we use that has 5 levels of increasing complexity and specialization. Removery is committed to the continual clinical improvement necessary for maintaining our position as the world leader in tattoo removal and fading.

This consideration by the Ohio medical board will help many who reside in Ohio receive proper tattoo removal while not leaving the state for more efficient and cost-effective care.

References

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Picosecond laser versus historical responses to Q-switched lasers for tattoo treatment
JOURNAL OF COSMETIC AND LASER THERAPY
2020, VOL. 22, NOS. 4–5, 210–214
2. Lim SP, Lanigan SW. A review of the adverse effects of laser hair removal. Lasers Med Sci. 2006 Sep;21(3):121-5. doi: 10.1007/s10103-006-0377-y. Epub 2006 Jul 1. PMID: 16816888.
3. Fayne RA, Perper M, Eber AE, Aldahan AS, Nouri K. Laser and Light Treatments for Hair Reduction in Fitzpatrick Skin Types IV-VI: A Comprehensive Review of the Literature. Am J Clin Dermatol. 2018 Apr;19(2):237-252. doi: 10.1007/s40257-017-0316-7. PMID: 28791605.
4. Torbeck RL, Schilling L, Khorasani H, Dover JS, Arndt KA, Saedi N. Evolution of the Picosecond Laser: A Review of Literature. Dermatol Surg. 2019 Feb;45(2):183-194. Doi: 10.1097/DSS.0000000000001697. PMID: 30702447.

We have taken the liberty of drafting a proposed amendment for tattoo removal for your review.

Please do not hesitate to reach out to discuss this proposal in more depth.

Best regards,



Jo Kelton
Chief Operating Officer
B.Sc. (Phty) MPhty, MBA
Removery, LLC
1400 South Congress
Austin, TX, 78704

Final Proposed rule: (DRAFT)

(B) A physician may delegate the application of light-based medical devices for the purpose of tattoo removal only if all the following conditions are met:

- (1) The light-based medical device has been specifically cleared or approved by the United States food and drug administration for the removal of tattoo pigment from the human body;
- (2) The use of the light-based medical device for the purpose of tattoo removal is within the physician's normal course of practice and expertise;
- (3) The physician has approved all protocol for qualification of patients for treatment by the light based medical device for tattoo removal;
- (4) If there is an out of protocol issue that could impact the qualification for treatment or continuation of in process treatment the physician should be consulted prior to continuing with any treatment
- (5) The person to whom the delegation is made is one of the following:
 - (a) A physician assistant licensed under Chapter 4730. of the Revised Code with whom the physician has an effective supervision agreement;
 - (b) A cosmetic therapist who was licensed under Chapter 4731. of the Revised Code on April 11, 2021 or who has completed a cosmetic therapy course for laser tattoo removal for a minimum of one hundred and sixty clock hours and received a passing score on the light-based medical device companies certification test,
 - (c) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code.
- (6) For a physician assistant, the authorization must meet the requirements of section 4730.21 of the Revised Code.
- (7) For cosmetic therapists, registered nurses, and licensed practical nurses, the physician shall ensure the person to whom the delegation is made has received adequate education and training to provide the level of skill and care

required including:

- (a) Eighty hours of basic education that must include the following topics:
light based procedure physics, tissue interaction in light based procedures, light-based procedure safety including use of proper safety equipment, clinical application of light-based procedures, pre and post-operative care of light-based procedure patients, and reporting of adverse events;
- (b) Eighty hours of Observation of fifteen procedures for each specific type of light Based medical device procedure for tattoo removal delegated. The procedures observed must be performed by a physician for whom the use of this specific light-based medical device procedure for tattoo removal is within the physician's normal course of practice and expertise; and
- (c) Performance of five procedures under the direct oversight of the physician on each specific type of light-based medical device procedure for tattoo removal delegated. The physician overseeing the performance of these procedures must use this specific light based medical device procedure for tattoo removal within the physician's normal course of practice and expertise;
- (d) Satisfactory completion of training shall be documented and retained by each physician delegating and the delegate. The education requirement in paragraph (A)(7)(a) of this rule must only be completed once by the delegate regardless of the number of types of specific light based medical device procedures for tattoo removal delegated and the number of delegating physicians. The training requirements of paragraphs (A)(7)(b) and (A)(7)(c) of this rule must be completed by the delegate once for each specific type of light-based medical device procedure for tattoo removal delegated regardless of the number of delegating physicians;
- (e) Delegates who, prior to the effective date of this rule, have been applying

a specific type of light-based medical device procedure for tattoo removal for at least two years through a lawful delegation by a physician, shall be exempted from the education and training requirements of paragraphs (A)(7)(a), (A)(7)(b), and (A)(7)(c) of this rule for that type of procedure provided that they obtain a written certification from one of their current delegating physicians stating that the delegate has received sufficient education and training to competently apply that type of light-based medical device procedure. This written certification must be completed no later than sixty days after the effective date of this rule, and a copy of the certification shall be retained by each delegating physician and each delegate.

(f) For cosmetic therapists, the education and training requirements of paragraph (A)(7)(a), (A)(7)(b), or (A)(7)(c) of this rule may be satisfied through the cosmetic therapy course of instruction in paragraph (B)(5)(b) of this rule if the program provides written verification to the physician that the cosmetic therapist completed the requirements of paragraph (A)(7)(a), (A)(7)(b), or (A)(7)(c) of this rule as part of the cosmetic therapy course of instruction.

(8) For cosmetic therapists, registered nurses, and licensed practical nurses, the physician provides on-site supervision at all times that the person to whom the delegation is made is applying the light-based medical device; and,

(9) For cosmetic therapists, registered nurses, and licensed practical nurses, the physician supervises no more than five persons pursuant to this rule at the same time

(C) Notwithstanding paragraph (B)(8) of this rule, the physician may provide off-site supervision when the light-based medical device is applied for the purpose of tattoo removal to an established patient if the person to whom the delegation is made pursuant to paragraph (B) of this rule is a cosmetic therapist who meets all of the following criteria:

(1) The cosmetic therapist has successfully completed a course in the use of light based medical devices for the purpose of tattoo removal that has been approved by the delegating physician;

(2) The course consisted of at least 160 hours of training, at least eighty hours of which was clinical experience; and

(3) The cosmetic therapist has worked under the supervision of the physician making the delegation a sufficient period of time that the physician is satisfied that the cosmetic therapist is capable of competently performing the service with off-site supervision.

The cosmetic therapist shall maintain documentation of the successful completion of the required training.

(D) The cosmetic therapist, physician assistant, registered nurse or licensed practical nurse shall immediately report to the supervising physician any clinically significant side effect following the application of the light-based medical device or any failure of the treatment to progress as was expected at the time the delegation was made. The physician shall see and personally evaluate the patient who has experienced the clinically significant side effect or whose treatment is not progressing as expected as soon as practicable.

(E) A violation of paragraph (A), (B), (C), or (D) of this rule by a physician shall constitute "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.

(F) A violation of division (A)(5) or (B)(5) of this rule shall constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provisions of this chapter or any rule promulgated by the board," as that clause is used in division (B)(20) of section 4731.22 of the Revised Code, to wit: section 4731.41 of the Revised Code.

(G) A violation of paragraph (C) or (D) of this rule by a cosmetic therapist shall

constitute the unauthorized practice of medicine pursuant to section 4731.41 of the Revised Code.

(H) A violation of paragraph (D) of this rule by a physician assistant shall constitute "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 patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code.

From: [Anderson, Kimberly](#)
To: [Rodriguez, Judith](#)
Subject: FW: CTAO Comments on Light Based Rule 4731-18
Date: Wednesday, December 1, 2021 1:50:32 PM
Attachments: [CTAO Comments on 4731-18 Light Based 2021.pdf](#)
[image001.png](#)
[image003.png](#)
[image004.png](#)

Comments for light based rules.

Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
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Columbus, Ohio 43215
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Kimberly.Anderson@med.ohio.gov



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From: Cosmetic Therapy Association of Ohio <cosmetictherapyohio@gmail.com>
Sent: Wednesday, December 1, 2021 1:24 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>; Reardon, Jill <Jill.Reardon@med.ohio.gov>
Cc: Loucka, Stephanie <Stephanie.Loucka@med.ohio.gov>; Elaine Nelson CT <cosmeticclaser@roadrunner.com>; Amanda Nelson CT <amandanicolenelson@gmail.com>
Subject: CTAO Comments on Light Based Rule 4731-18

Hello Kimberly and Jill,

Attached please see the Cosmetic Therapy Association of Ohio's comments on rule changes regarding light based device delegation. We are asking to be included in delegation for non-ablative

vascular treatments because we receive more laser education hours than any other delegate and vascular treatments use the same machines with the same wavelength and only a few variations to the settings compared to what we've been using for hair removal for over twenty years. If doctor's have been delegating us laser hair removal with ease we anticipate they would welcome our assistance on completing these services for our clients. Cosmetic therapists have been a valuable asset to Medical Directors and can be so much more if provided a path to open new services we are competent to perform.

I additionally would like to inform you that Elaine Nelson, Cosmetic Therapist and Registered Respiratory Therapist, is the new president of CTAO. Amanda has stepped into a trustee role. You are welcome to contact either of us directly at the emails below if needed and our organization's general email inbox, cosmetictherapyohio@gmail.com, will always be monitored by active board members.

Sincerely,

Elaine Nelson, CT, RRT
President
cosmeticclaser@roadrunner.com

Amanda Nelson, CT
Trustee
amandanicolenelson@gmail.com

The Cosmetic Therapy Association of Ohio Board

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November 30, 2021

Kimberly Anderson, Chief Legal Counsel
State Medical Board of Ohio

We appreciate the opportunity to provide public comment from those who own and operate light based medical devices regarding the upcoming changes to rules 4731-18-01 through 4731-18-03. It is our opinion that cosmetic therapists have earned our profession to be added to doctor delegation of the use of light based devices for non-ablative vascular treatments. Our legally required education, rapport with our businesses Medical Directors, and history of laser delegation for hair removal with no incidents of public harm make us more than competent to be added to 4731-18-03 for vascular treatments. We recommend the following be added to 4731-18-03 (A)(5): "(c) A cosmetic therapist who has completed training compliant with Ohio Revised Code 4731-33." We can also be added to 4731-18-03 (A)(7) to have the same education requirements as nurses for vascular treatments as it coincides well with what it takes to work under a delegating Medical Director for laser hair removal compliance.

As the majority of our existing clients are approved for laser hair removal, they have already been assessed by our Medical Directors to be appropriate candidates for use of the site's light based device determined by skin color and verifying no medication/medical contraindications. The same light based devices, being alexandrite, diode, and YAG lasers, using the same wavelengths for hemoglobin absorption as for hair removal, 755nm-1064nm, only require going a little further into the skin depth for a vascular treatment. Laser hair removal destroys the blood supply to the hair to achieve permanent reduction and vascular laser treatments effectively work the same way.

Our education provides the same 8 hours of laser course instructions, the same, if not more, amount of anatomy and physiology of the skin than what nurses and physician assistants (PA) receive and we are legally required to complete 50 hours of laser training. Nurses and PAs only require the 8 education hours and 15 observed/20 supervised treatments which can be completed within days whereas cosmetic therapists spend over a week studying the same material for use on one specialized service for a device that may be capable of other treatments. Our clients want these treatments, our doctors are too busy to provide these one-time remedial services, and we have been working with our Medical Directors by our side for over twenty years who trust us, our education, and our capabilities. The doctor should be able to delegate any non-ablative treatment accordingly that the light based device can perform to their staff who use the machine regularly for other similar services.

We interpret the removal of cosmetic therapy from the rule on laser hair removal is because it is covered by state statute that cannot be changed without legislative effort. We support the removal and understand it is our responsibility to assure we are complying with the Ohio Revised Code 4731-33. If SMBO were to ever have interest in this law being adjusted, we would be happy to partner with you to assure a satisfactory outcome.

Sincerely,

A handwritten signature in cursive script, appearing to read "Amanda Nelson".

Amanda Nelson, CT
Trustee and on behalf of The Cosmetic Therapy Association of Ohio



MEMORANDUM

TO: Betty Montgomery, President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Podiatric Licensure Rules, Chapter 4731-12, Ohio Administrative Code

DATE: April 4, 2022

Rules related to podiatric licensure are due for their five-year rule review in 2022. The proposed changes to the rules are described below and the drafts are attached for your review. Most of the rules have changes that impact more than 50% of the rule language, so they will be filed as new rules with the old rule being rescinded.

4731-12-01 Preliminary Education for Licensure in Podiatric Medicine and Surgery

This rule is proposed to be amended to be a definitions rule for the chapter. The information regarding the preliminary education will be added to Rule 4731-12-02, OAC.

4731-12-02 Standing of Colleges of Podiatric Surgery and Medicine

This rule is proposed to be amended to include information regarding preliminary education and to update the language.

4731-12-03 Eligibility for the Examination in Podiatric Surgery and Medicine

This rule is proposed to be amended to reflect the current designation of the American Podiatric Medical Licensing Examination as the examination of the National Board of Podiatric Medical Examiners.

4731-12-04 Eligibility of Licensure in Podiatric Medicine and Surgery by Endorsement from Another State

This rule is proposed to be amended to reflect the repeal of Section 4731.53 of the Revised Code and to update the examination language.

4731-12-05 Application Procedures for Licensure in Podiatric Medicine and Surgery, Investigation, Notice of Hearing Rights

This rule is proposed to be amended to update the language and be more consistent with rules for MD/DO licensure.

4731-12-06 Visiting Podiatric Faculty Certificates

This rule is proposed to be rescinded as it is inconsistent with and/or redundant of Section 4731.572 of the Revised Code.

4731-12-07 Podiatric Training Certificates

This rule is proposed to be amended to be consistent with the provisions for MD/DO training certificates.

Requested Action: Approve draft rules for initial circulation to interested parties.

4731-12-01

Definitions.

- (A) "APMLE" means the american podiatric medical licensing examination prepared by the national board of podiatric medical examiners.
- (B) "Board" means the state medical board of Ohio.
- (C) "CPME" means the council on podiatric medical education.
- (D) "Examination in podiatric medicine and surgery" means the examination to determine competency to practice podiatric medicine and surgery under section 4731.52 of the Revised Code.
- (E) "License" means a license to practice podiatric medicine and surgery issued under section 4731.56 of the Revised Code.
- (F) "NBPME" means the national board of podiatric medical examiners
- (G) "PMLexis" means the podiatric medical licensing examination prepared by the national board of podiatric medical examiners.
- (H) "Training Program" means an internship, residency, or clinical fellowship program that meets the requirements of division (A)(2) of section 4731.573 of the Revised Code.

TO BE RESCINDED

*** DRAFT - NOT YET FILED ***

4731-12-01

Preliminary education for licensure in podiatric medicine and surgery.

Production of a diploma from a college of podiatric medicine and surgery in good standing as determined by the board at the time the diploma was issued constitutes prima facie evidence that the individual has completed the requisite preliminary education under section 4731.53 of the Revised Code.

4731-12-02

Preliminary education for licensure and standing of colleges of podiatric surgery and medicine.

(A) For the purposes of sections 4731.52 and 4731.572 of the Revised Code, and rule 4731-12-07 of the Administrative Code, a college of podiatric medicine and surgery in the United States shall be defined as being in good standing if, at the time the diploma was issued, the institution was accredited by the CPME or its predecessor accrediting organizations.

(B) Production of a diploma from a college of podiatric medicine and surgery in good standing, at the time the diploma was issued, constitutes prima facie evidence that an applicant for a license has met the requirements of divisions (A)(1)(b) and (A)(1)(c) of section 4731.52 of the Revised Code. An applicant producing a diploma from a college of podiatric medicine and surgery located outside the United States must present evidence sufficient to establish to the board's satisfaction that the educational program met or exceeded the standards established by the CPME.

TO BE RESCINDED

*** DRAFT - NOT YET FILED ***

4731-12-02

Standing of colleges of podiatric surgery and medicine.

- (A) A college of podiatric medicine and surgery in the United States shall be defined as being in good standing at the time the diploma was issued for the purposes of section 4731.53 of the Revised Code if the institution is accredited by the "Council on Podiatric Medical Education," or its predecessor accrediting organizations as determined by the board.
- (B) To meet the requirement of section 4731.53 of the Revised Code that an applicant present a diploma from a college of podiatric medicine and surgery in good standing as defined by the board at the time the diploma was issued, an applicant presenting a diploma from a college located outside the United States must present evidence sufficient to establish to the board's satisfaction that the educational program completed at such school meets or exceeds the standards established by the "Council on Podiatric Medical Education" for colleges of podiatric medicine and surgery in the United States.

*** DRAFT - NOT YET FILED ***

4731-12-03

Podiatric Examination.

(A) The examination in podiatric medicine and surgery shall be all parts of the APMLE. An applicant shall have passed all parts and achieved a recognized passing performance on each part.

TO BE RESCINDED

*** DRAFT - NOT YET FILED ***

4731-12-03

Eligibility for the examination in podiatric medicine and surgery; passing average.

- (A) An applicant for a certificate to practice podiatric medicine and surgery is eligible for consideration to take the examination in podiatric medicine and surgery if, in addition to meeting the other requirements of sections 4731.52 and 4731.53 of the Revised Code, the applicant holds a diploma from a college in good standing as defined in rule 4731-12-02 of the Administrative Code.
- (B) The examination in podiatric medicine and surgery shall consist of parts I, II and III of the national board of podiatric medical examiners examination. . Prior to applying for a certificate to practice podiatric medicine and surgery, and prior to sitting for part III of the national board of podiatric medical examiners examination, an applicant shall have passed parts I and II of the national board of podiatric medical examiners examination.
- (C) An applicant shall obtain diplomate or passing status with the national board of podiatric medical examiners on parts I, II and III of the national board examination in order to be considered as having passed the examination in podiatric medicine and surgery.

4731-12-04

Eligibility for licensure.

The board shall issue a license to each individual who meets all applicable requirements under section 4731.52 of the Revised Code, and who passes the examination in podiatric medicine and surgery in accordance with rule 4731-12-03 of the Administrative Code, or has passed one of the following examinations:

(A) The "PMLexis" administered between June 12, 1990 and December 4, 2000, in addition to the holding of a passing status or diplomate status with the NBPME.

(B) An examination of a state of the United States, United States territory, or district administered before June 12, 1990, that was, in part, a written examination and

(1) Taken without previous or subsequent failure of the examination offered by the NBPME ; and

(2) Taken without previous or subsequent failure of the PMLexis or part III of the APMLE.

TO BE RESCINDED

*** DRAFT - NOT YET FILED ***

4731-12-04

Eligibility for licensure in podiatric medicine and surgery by endorsement from another state.

- (A) An applicant for a license to practice podiatric medicine and surgery who holds a license from another state, United States territory, or the District of Columbia, shall be eligible for licensure consideration without examination if, in addition to any other requirements of sections 4731.51 to 4731.61 of the Revised Code and Chapter 4731-12 of the Administrative Code, the requirements of paragraphs (B) to (E) of this rule are met.
- (B) If the license being endorsed is based upon an examination administered between June 12, 1990 and December 4, 2000, the license shall be based upon the passing of the "PMLexis" in addition to the holding of a passing status or diplomate status with the national board of podiatric medical examiners.
- (C) If the license being endorsed is based upon an examination administered after December 4, 2000, the license shall be based on passing parts I, II and III of the national board of podiatric medical examiners examination.
- (D) If the license being endorsed is based upon an examination administered before June 12, 1990, it shall have been:
 - (1) Administered by the state, United States territory, or district issuing the license, and, have been in part, a written examination;
 - (2) Taken without having failed the national board of podiatric medical examiners examination unless an intervening passing status or diplomate status on that examination has been achieved; and
 - (3) Taken without having failed to achieve a minimum passing score on the PMLexis or part III of the national board of podiatric medical examiners examination unless an intervening passing status on that examination has been achieved. For purposes of this rule, a minimum passing score will be that figure recommended by the national board of podiatric medical examiners/federation of podiatric medical boards.
- (E) An applicant for endorsement licensure shall file an application in the manner provided in section 4731.52 of Revised Code, furnish satisfactory proof that he or she is more than eighteen years of age and of good moral character and provide other facts and materials as the board requires.
- (F) The license being endorsed shall be current and in good standing and shall be a full and unlimited license to practice podiatric medicine and surgery. An exception may

be made by the board in those cases where an applicant cannot renew his or her license in the other jurisdiction for purposes of endorsement due to residency or similar requirements.

4731-12-05

Application procedures for licensure in podiatric medicine and surgery; investigation.

- (A) Pursuant to division (A) of section 4731.52 of the Revised Code, all applicants for a license shall submit to the board an application under oath in the manner determined by the board, and provide such other facts and materials as the board requires. No application shall be considered submitted to the board until the appropriate fee has been received by the board.
- (B) No application shall be considered complete until the applicant has complied with the requirements of paragraph (A) of rule 4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks.
- (C) The board reserves the right to thoroughly investigate all materials submitted as part of an application . The board may contact individual agencies or organizations for recommendations or other information about applicants as the board deems necessary. Applicants may be requested to appear before the board or a representative thereof as part of the application process.
- (D) If an applicant for any license or certificate issued under section 4731.56, 4731.572, or 4731.573, fails to complete the application process within six months of initial application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.
- (E) If the application process extends for a period longer than six months, the board may require updated information as it deems necessary.
- (F) No application being investigated under section 4731.22 of the Revised Code, may be withdrawn without approval of the board.
- (G) Application fees are not refundable.

TO BE RESCINDED

*** DRAFT - NOT YET FILED ***

4731-12-05

Application procedures for licensure in podiatric medicine and surgery; investigation.

- (A) All applicants for licensure in podiatric medicine and surgery shall file an application in the manner provided in section 4731.52 of the Revised Code, and provide such other facts and materials as the board requires including proof of completion of a minimum of one year of postgraduate training in a podiatric internship, residency or clinical fellowship program accredited by the "Council on Podiatric Medical Education."
- (B) No application shall be considered filed until the appropriate fee has been received by the board.
- (C) No application shall be considered complete until the applicant has complied with the requirements of paragraph (A) of rule 4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks and any other forms required to be submitted pursuant to paragraph (A) of rule 4731-4-02 of the Administrative Code.
- (D) All application materials submitted to the board by applicants for licensure in podiatric medicine and surgery will be thoroughly investigated. The board will contact individual agencies or organizations for recommendations or other information about applicants as the board deems necessary. Applicants may be requested to appear before the board or a representative thereof as part of the application process.
- (E) Applications to take the examination for licensure in podiatric medicine and surgery in Ohio shall be filed at the board offices not less than sixty days prior to the first day of the examination. Under special circumstances, later filing may be permitted at the discretion of the board.

TO BE RESCINDED

*** DRAFT - NOT YET FILED ***

4731-12-06

Visiting podiatric faculty certificates.

- (A) For purposes of section 4731.572 of the Revised Code, the following definitions apply:
- (1) "Approved college of podiatric medicine and surgery in good standing" means a college of podiatric medicine and surgery accredited by the "Council on Podiatric Medical Education," or its predecessor accrediting organizations.
 - (2) "A current, unrestricted license" means a license or other authority granted by the appropriate entity or governmental body which lawfully permits the applicant to practice podiatric medicine and surgery without governmental restriction or limitation.
- (B) The duties of the applicant shall be set forth upon the application and approved by the board.
- (C) By signing the application for a visiting podiatric faculty certificate, the dean of the school and the medical director of each affiliated teaching hospital are responsible for assuring that the holder of the certificate does not engage in practice outside its scope. They are further responsible for reporting to the board any belief that practice outside its scope has occurred.
- (D) An individual shall be granted only one visiting podiatric faculty certificate, and shall be ineligible to apply for its renewal .

4731-12-07

Podiatric training certificates.

- (A) A training certificate is mandatory for participation in a training program unless the participant holds a license to practice podiatric medicine and surgery. The participation in the program prior to receiving an acknowledgment letter or a training certificate from the board is the unlicensed practice of medicine pursuant to section 4731.34 of the Revised Code.
- (B) An individual may not begin participation in a training program unless the individual has been issued a diploma from a college of podiatric medicine and surgery in good standing.
- (C) Evidence that the applicant for a training certificate has been accepted or appointed to a training program meeting the requirements of division (A)(2) of section 4731.573 of the Revised Code must include a certification from the training program of both of the following:
- (1) The training program will verify that the applicant has been issued a diploma before permitting the applicant to begin participation in the training program; and
 - (2) The training program will notify the board if a holder of a training certificate has not been issued a diploma before the start date of the training program.
- (D) The holder of a training certificate shall immediately notify the board in writing if the holder has not been issued a diploma before the start date of the training program.
- (E) Upon the board's receipt of an application for a training certificate, or upon the board's receipt of written notice from an applicant for a license that the applicant intends to participate in a training program, and after verifying that the applicant has paid the appropriate fee, the board may issue to the applicant an acknowledgment letter. Fees are neither refundable nor transferable.
- (1) Upon receipt of that acknowledgment letter, the applicant may begin participating in the training program that meets the requirements of section 4731.573 of the Revised Code, and this chapter of the Administrative Code, to which the applicant has been appointed while the application is being processed. The acknowledgment letter will serve as proof that the board has received the application and that the applicant is entitled to continue participation in the training program.
 - (2) If an applicant has not received an acknowledgment letter or training certificate from the board within forty-five days after submitting an application, then the applicant shall immediately inform the board and the director of his or her training program in writing.
 - (3) An acknowledgment letter issued under this rule shall authorize participation in a training program for one hundred twenty days, unless prior to that time the

4731-12-07

2

board:

(a) Issues the certificate; or

(b) Issues an order in accordance with Ohio law suspending without a prior hearing the authority to participate; or

(c) Accepts a withdrawal of the application; or

(d) Issues a notice of opportunity for hearing in accordance with Chapter 119. of the Revised Code, in which case the authority to participate shall continue until the board's issuance of a final order granting or denying the application, or until the end of the training year, whichever comes first; or

(e) In the case of an applicant for a license, advises the applicant in writing that a substantial question of a violation of this chapter or the rules adopted under it exists and that investigation is continuing, in which case the authority to participate shall continue until one of the following occur:

(i) The board issues a license; or

(ii) The board issues a final order in accordance with Chapter 119. of the Revised Code; or

(iii) The training year ends.

Except as provided in this rule, participation in a training program pursuant to an acknowledgment letter cannot be renewed or extended beyond one hundred twenty days.

(F) If at the end of one hundred twenty days following issuance of an acknowledgment letter to an applicant for a training certificate the board has commenced but not yet concluded investigation or inquiry into issues of possible violations of Chapter 4731. of the Revised Code, it shall issue a training certificate to the applicant but shall not be deemed to have waived any issues which would constitute grounds to impose discipline under Chapter 4731. of the Revised Code.

(G) If the applicant or training certificate holder changes training programs, the board must be notified in writing immediately. A new application need not be completed and a new training certificate will not be issued. The training certificate will continue to be valid until its date of expiration.

(H) A person who holds a suspended license to practice podiatric medicine and surgery is not eligible for a training certificate. Such a person must restore that license in accordance with sections 4731.222 and 4731.281 of the Revised Code before

beginning postgraduate training in Ohio. A person whose license to practice podiatric medicine and surgery has been permanently revoked or permanently denied is ineligible to participate in a training program in Ohio.

TO BE RESCINDED
*** DRAFT - NOT YET FILED ***

4731-12-07

Podiatric training certificates.

- (A) Upon the board's receipt of an application for a training certificate, or upon the board's receipt of written notice from an applicant for a certificate to practice podiatric medicine and surgery under section 4731.53 of the Revised Code, that the applicant intends to participate in a training program described in paragraph (A) of this rule, and after verifying that the applicant has paid the appropriate fee, the board will issue to the applicant an acknowledgment letter. Upon receipt of that acknowledgment letter the applicant may begin participating in the program that meets the requirements of section 4731.573 of the Revised Code, and this chapter of the Administrative Code, to which he or she has been appointed while the application is being processed. That acknowledgment letter will serve as proof that the board has received the application and that the applicant is entitled to continue participation in the training program. If an applicant has not received an acknowledgment letter from the board within forty-five days of submitting an application, then the applicant shall immediately inform the board and the director of his or her training program in writing.
- (B) An acknowledgment letter issued under this rule shall authorize participation in a training program for one hundred and twenty days, unless prior to that time the board:
- (1) Issues the certificate; or
 - (2) Issues an order in accordance with Ohio law suspending without a prior hearing the authority to participate; or
 - (3) Accepts a withdrawal of the application; or
 - (4) Issues a notice of opportunity for hearing in accordance with Chapter 119. of the Revised Code, in which case the authority to participate shall continue until the board's issuance of a final order granting or denying the application, or until the end of the training year, whichever comes first; or
 - (5) In the case of an applicant for a certificate under section 4731.53 of the Revised Code, advises the applicant in writing that a substantial question of a violation of this chapter or the rules adopted under it exists and that investigation is continuing, in which case the authority to participate shall continue until one of the following occur:
 - (a) The board issues a certificate; or
 - (b) The board issues a final order in accordance with Chapter 119. of the

Revised Code; or

(c) The training year ends.

Except as provided above, participation in a training program pursuant to an acknowledgment letter cannot be renewed or extended beyond one hundred twenty days.

- (C) If at the end of one hundred and twenty days following issuance of an acknowledgment letter to an applicant for a training certificate the board has commenced but not yet concluded investigation or inquiry into issues of possible violations of Chapter 4731. of the Revised Code, it shall issue a training certificate to the applicant but shall not be deemed to have waived any issues which would constitute grounds to impose discipline under Chapter 4731. of the Revised Code.
- (D) If the applicant or training certificate holder changes training programs before the end of the training year while maintaining the same finishing date of his or her post graduate training year (e.g., June thirtieth), the board must be notified in writing immediately. A new application need not be completed. However, acknowledgment by the board of receipt of written notification of change in training programs will be required prior to starting the new training program. The new training certificate will only be valid for the remainder of the training year for which the applicant has been issued a current certificate.
- (E) A training certificate shall be valid for one training year, but may, at the discretion of the board, be renewed annually for a maximum of five years. Renewal applications are mailed approximately April first for those who initiated their training on July first. Interns, residents, or clinical fellows who began their training after July first of the training year will be mailed their renewal application approximately three months prior to the expiration of their training certificate.
- (F) This rule and section 4731.573 of the Revised Code do not apply to or prohibit any graduate of a podiatric school or college from performing those acts that may be prescribed by or incidental to participation in an accredited podiatric internship, residency, or fellowship program accredited by the "Council on Podiatric Medical Education."
- (G) A person who holds a suspended certificate to practice podiatric medicine and surgery under section 4731.53 of the Revised Code is not eligible for a training certificate. Such a person must restore that certificate in accordance with sections 4731.222 and 4731.281 of the Revised Code before beginning postgraduate training in Ohio. A person whose certificate has been permanently revoked or permanently

denied is ineligible to participate in postgraduate training in Ohio.



MEMORANDUM

TO: Betty Montgomery, President

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Limited Branch Rules

DATE: April 7, 2022

In June 2021, amendments to rules related to the practice of the limited branch of medicine, including massage therapy, were circulated to interested parties.

The Board received a letter from Nancy Broadbent, Program Director for the Massage Therapy Program at the Cuyahoga Community College, which provided comments on Rules 4731-1-15, 4731-1-16, 4731-1-17, OAC and raised concerns on four issues that the Board wanted the newly formed Massage Therapy Advisory Council to review. Specifically, Ms. Broadbent was concerned about eliminating the requirement for a student to perform at least one therapeutic massage prior to completing the course of instruction; eliminating the requirement for massage therapy schools to renew the certificate of good standing and to put schools on the honor system to self-report a change that would impact their eligibility; eliminating the requirement for the schools to do a background check or to notify students that arrests, charges or convictions may prohibit them from obtaining license; and eliminating the requirements for instructional staff to have massage therapy experience or science or healthcare experience.

On February 7, 2022, the Massage Therapy Advisory Council had its first meeting and the rules and proposed amendments were discussed. The MTAC members were provided three weeks to review the rules and provide comments, which are attached for your review. In addition, Richard Greeley, former MTAC member provided comments.

Based on the comments received, I recommend amendments to two of the proposed rules. All rules are attached for your review.

4731-1-15(C)(1)(e) and 4731-1-15(C)(2)(e)-Added requirement for massage therapy student to complete at least one massage on a licensed massage therapist.

4731-1-15(D)-Require notification regarding criminal charges, arrests and convictions and advise students of disqualifying offense list and explanatory statement on the Board's website.

4731-1-15(I)-Return the language regarding two year renewal for certificate of good standing.

4731-1-17(C)(2) and (3)-Change rule from "proposed to be rescinded" to "proposed to be amended", and clean up language regarding the qualifications for instructors at massage therapy schools.

Requested action: Approve filing the proposed rules as amended with the Common Sense Initiative.

[illegible]

Richard A Greely, M.Ed.,LMT
7636 Dalglen Drive
Reynoldsburg, Ohio 43068
Phone: (614) 886-5714
Cell: (614) 832-1539
rgreely43068@yahoo.com

February 27, 2022

Chelsea Wonski
Director of Legislative Affairs
State Medical Board of Ohio
30 East Broad Street, Third Floor
Columbus, Ohio 43215-6127

Dear Ms. Wonski,

As an Ohio licensed massage therapist since 1987, a massage therapy educator for more than 20 years, previous member of the State Medical Board of Ohio Massage Therapy Advisory Committee, I am very concerned about the proposed changes to the Limited Branch rules. Some of these changes are being considered perhaps due to a lack of historic perspective. I believe, it represents a setback for the Massage Therapy profession in Ohio.

Re: points to be rescinded:

1. 4731-1-15 Determination of standing of school, college or institution

While I fully understand that charge in curriculum hours was a statutory change, I believe it to be a step backwards and a disservice to the citizen of the State of Ohio. I won't go on about this as I understand the intent is to simplify things and there really isn't much the Medical Board can do at this time. The curriculum hours are specified in statute.

"Deletes the following requirements:

(1) that a notice be provided to students regarding the effect that criminal history may have on licensure".

This requirement was inserted in the rule at the request of the State Legislature. Students were spending money, time and resources to complete their massage therapy education, taking the steps to complete the licensing process, including taking the exam, only to be denied a license due to a criminal history. Legislators were then dealing with irate constituents and requested that this notification be provided prior to the student enrolling in a massage therapy education program.

The section requiring students to perform at least one therapeutic massage on a licensed therapist was inserted into the rule when the Medical Board was no longer able to provide resources for a hands-on portion of the licensing exam. The Medical Board felt that the schools were equipped to handle this evaluation.

2. 4731-1-17:

“(A) An instructor in limited branch theory or clinical practice shall be a high school graduate or equivalent, shall be currently licensed in Ohio in the applicable limited branch and shall have practiced in the applicable limited branch for a minimum of three years.

(B) A classroom instructor teaching basic science or general education courses shall hold a bachelor's degree with a concentration in the discipline in which that instructor is providing instruction. The requirements of this paragraph may be waived for faculty who, on the date this rule becomes effective, have taught the course for more than one year at a limited branch school that holds a certificate of good standing issued by the board.

(C) An instructor in massage therapy business courses shall meet one of the following requirements:

- (1) Hold at least a bachelor's degree with a concentration in business;
- (2) Have experience in all aspects of a massage therapy business gained as an owner and operator of a massage therapy business for a minimum of three years;
- (3) Have experience in all aspects of a massage therapy business gained as a manager of a massage therapy business for a minimum of three years.”

I have heard that the reason to rescind this is that these requirements are covered by some other rule or regulation. If this is true, I am not aware of such. While I do believe there needs to be some changes made, I do not believe this should be rescinded. The changes I believe that should be made relate specifically to 4731-1-17 C 2 & 3. This requirement could completely rule out individuals with years of business experience simply because they have not owned or operated a massage therapy business. For example, a physician with a Master's degree in Business Administration (MBA) could not teach this course. The inclusion of the term "all" could be argued that this rule out most everybody because it would be difficult to have experienced "all" aspects of a business of any kind.

Thank you for the opportunity to share my thoughts.

Sincerely,

Richard A. Greeley M.Ed., LMT

Richard A. Greeley M.Ed., LMT

From: [Reardon, Jill](#)
To: [Anderson, Kimberly](#)
Subject: FW: Comments and Concerns
Date: Thursday, March 3, 2022 10:57:23 AM
Attachments: [Med Board MT Concerns.docx](#)

Letter attached.

From: Jackie Wolf <jackiewolflmt@gmail.com>
Sent: Sunday, February 27, 2022 4:17 PM
To: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Subject: Comments and Concerns

Hi Jill-

I want to officially state that I don't have any concerns regarding the changes to the rules we discussed in the February 2022 MTAC meeting with one exception. That being said, the members of AMTA and ABMP brought up the online product called MPower where massage students can get their online studies accomplished. However, they stated there's a potential problem regarding students completing their clinical work in an approved setting. We were told this product is not yet in Ohio; we might want to look into this and protect ourselves accordingly.

In addition, I have attached a letter with additional massage therapy concerns. Please review and let me know your thoughts.

I am invested, interested and willing to lead the work needed to explore the concerns attached.

I look forward to hearing from you.

Yours In Health,
Jacqueline (Jackie) Wolf

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As a member of the newly formed Massage Therapy Advisory Council (MTAC), I want to voice my concerns regarding the massage therapy profession and offer suggestions to help navigate a new path forward.

The recent decrease in massage therapy hours (750 to 600) is a substantive problem. The number of patients seeking massage therapy continues to increase along with their expectations of quality treatment in a variety of modalities. Currently, massage therapists are the least educated of the healthcare providers supporting our patients. This shortfall has contributed to the lack of respect from the general healthcare practitioners. I understand this hour change has been signed into law; I'm now looking at this as a positive opportunity for a reset.

Massage therapy faces a perception barrier not only in the medical field but with the public as well. Most people still perceive that massage therapy is "just a massage", something people do for relaxation and luxury (among other things). I believe what is missing is a deeper understanding of the types of medical cases patients present with for treatment by the massage therapists.

My clinic, The Stillpoint Therapeutic Massage Center, currently sees approximately 150 patients per week, with roughly 35% coming in with a written prescription for treatment and another 55% seeking treatments for specific maladies. Types of physicians referring patients to us are Primary Care, Osteopathic Doctors, Dentists, Neurologists, Oncologists, OB/GYNs, Surgeons, ER Doctors, Chiropractors, Physical Therapists, and Psychologists. Types of cases we treat on a weekly basis include patients with: Trauma (physical, mental, PTSD), Concussions and Brain Injuries, Migraines, Mouth Work, Lymphatic Issues, Visceral Issues, all orthopedic injuries, auto accidents, Chronic Pain, Mild to Severe Autoimmune Conditions, Unresolved Pain Issues, Post-Surgical Issues, and stress management. I do not believe that my team of therapists are the only ones doing this type of work.

One recommendation is to find out the types of medical cases LMTs are treating. A study that may include a survey and/or focus groups to begin the understanding of the types of patients seen, advanced training completed, and volume seen. These data will lead to acknowledging the two diverse tracks of massage. One being relaxation and one being therapeutic. Once acknowledged, we need to define the two tracks and clear up the confusion that exists in the profession, medical community, and consumer community. People are confused by terms such as massage, massotherapy, massage therapy, medical massage, clinical massage etc.

Next, we need to explore what the differences are between the separate tracks in terms of education, continuing education, licensure(s), marketing, employment requirements, ability to bill insurance etc. For example, the current 600-hour program might be enough for someone to do relaxation work. For those doing therapy, the requirements should be significantly more and include a focus of developing clinical/critical thinking skills. If we have two tracks and different sets of requirements, I believe we should consider having two licensures (i.e., Licensed Massage Practitioner and Licensed Medical Massage Therapist).

I have seen the needs and demands for massage therapy change and evolve over my 16 years as a therapist. Patients deserve noninvasive and effective medical treatments performed by highly educated and highly trained massage therapists.

I realize what I'm proposing is a daunting project; however, it's time to reset and elevate the massage therapy profession to be its best.

I am interested and willing to have these conversations and do the work to advance our profession. I am seeking advice on how to move these discussions forward. I am interested in your thoughts and feedback. Massage therapy has a very important place in healthcare. As individuals look to more holistic ways to stay healthy our profession will continue to be a significant means to support our patients.

Yours In Health,

Jacqueline M. Wolf

Jacqueline M. Wolf, LMT, CRM, BSIE

From: [Reardon, Jill](#)
To: [Anderson, Kimberly](#)
Subject: Fwd: My thoughts on the proposed changes to rules for Massage Therapy
Date: Monday, February 28, 2022 8:08:00 PM

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From: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Sent: Monday, February 28, 2022 8:07 PM
To: Heather Mello Roenker
Subject: Re: My thoughts on the proposed changes to rules for Massage Therapy

Thank you Heather. We appreciate and value your input

Jill

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From: Heather Mello Roenker <heather@mellomassagellc.com>
Sent: Monday, February 28, 2022 8:01:12 PM
To: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Subject: My thoughts on the proposed changes to rules for Massage Therapy

Hello,

Thank you for giving us the opportunity to have more time to read through all the materials that were given and give our opinion. I wanted to do my own research on certain points of the rules to make sure we are making the right decision. One of the research is reading the Administrative Code Rule for The State Board of Career Colleges and Schools. I noticed that Massage specific schools had approval from this state board along with the Medical Board. Additionally, consulting with a couple of my colleagues who are still working, the Director and an Instructor, at the SHI Integrative Medical Massage School in Lebanon, Ohio. Attached are their statements to the new proposed rules, as well.

To continue my argument about why we should keep Ohio Massage Therapists at high standards is because we, the Licensed Massage Therapists of Ohio, should not “dumb” ourselves or lower our standards just because other states do. In my quick research on which other states have the Medical Board overseeing Massage Therapists, only a few do. But should we change our ways since the majority of the country does not? I believe not. We should be proud that the Ohio Medical Board sees us Licensed Massage Therapist as an important asset and another tool for Ohioans can go to for wellness care. My lovely opponent, sorry I forgot his name, states that the public does not know that Ohio Massage Therapists are likely more educated than most Massage Therapists in the country. Well, Mr. Opponent, we shall teach and educate the public that we are overseen by the Ohio State Medical Board and have a rigorous education and training. That the public can rest assure and trust the Licensed Massage Therapist they are seeing to be competent and knowledgeable of their treatments. Also, my opponent stated that it is hard for the Board to verify a lot of things in the rules. Does

anybody ever have time or energy to verify that institutions or people are obeying the laws? No! But that does NOT mean we do away with the rules. We keep them so if an institution or person is found unlawful, it CAN be dealt with. If a person finds out that an institution was being untrustworthy or unethical, they are able to have a chance to have a hearing and receive possible compensation.

SIDE NOTE: I have no ill will towards Mr Opponent. It is my friendly title for him since he was on the “opposite” team of the debate. And I cannot remember his name. :(sorry!

So, let’s continue on to the rules at hand in 4731-1. I will be going down the list to make sure I am not missing anything.

4731-1-01 Definition of terms: I noticed 4731-1-10 of Distance Education is now in 4731-1-01-E and is brought up again in 4731-1-15 as well in different places. I am ok with the changes and see that we are just trying to clean up the verbiage but why isn’t 4731-1-15-A “hours” definition not in the updated 4731-1-01? It was (C) in the original version. Just more of a curious thought.

4731-1-02 Application of Rules Governing Limited Branches...: I am ok with the updates here but just curious on (C). Only AMTA is mentioned and not ABMP. In 4731-152 both organizations are listed and present at the Advisory Council meetings. So another curious thought.

4731-1-03 General prohibitions - OK

4731-1-04 Scope of Practice: Mechanotherapy - OK

4731-1-05 Scope of Practice: Massage Therapy - OK

4731-1-07 Eligibility of electrologists.... - OK

4731-1-08 Continuing Education... - OK

4731-1-09 Cosmetic Therapy... - OK

4731-1-10 Distance Education - I see that the definition, short and sweet, is in 4731-1-01-E and brought up in the updated 4731-1-15. OK

4731-1-11 Application and examination...cosmetic therapy... - OK

4731-1-12 Application and examination... Massage Therapists... - OK

4731-1-15 Determination of standing... This one was very tricky to decipher, but I think I got it. Looks like there was clean up involved in the literature. (A) is a definition, I wonder if it would be better placed in 4731-1-1. (B) is for the person seeking license. (C-H) is for the institution. I have a few concerns with the new update.

On the original 4731-1-15 (B), this whole paragraph has been eliminated. This is talking about how institutions must provide, “the student with written notice of arrests, charges, or convictions of criminal offenses” prior to acceptance. I am not sure this is wise to remove since there is no where in the 4731 rules, that I could find, states the institution must do a

background check to all prospecting students. Nor did I find it in the Ohio Administrative Code Rule 3332 - The State Board of Career Colleges and School. What I could find about background checks was to have specific personnel running them in 3332-1-30. Therefore, by taking out this paragraph might give a institution a possible loophole to not do a background check. This could possibly leave the other students in an unsafe/uncomfortable environment when doing practical work. Plus, the institution needs to FULLY inform the prospect student of their future of becoming a Licensed Massage Therapist. There might be some institutions who will not want to give the prospect student possible bad news so they can have their tuition since it is The MEDICAL BOARDS requirements and not the institution's. Seems quite unethical. We should be looking out for the students and not waste their time and money. Therefore, 4731-1-15(B) should be added to the updated rule.

For (C), The student must have a high school diploma or GED, is this one being removed since it is in 4731.19-A-2?

For the original (E), updated (H), from how it is written, does the 2 year renewal not apply anymore? Will the schools not be reviewed every 2 years to make sure they are staying within the requirements of good standing? Not sure if I am a fan of that. It is always good to verify institutions every couple years since the public who is seeking education trusts that they are in compliance with the Medical Board and have good standings. Unfortunately, the trust system might not be the right action to take when people's education and finances are involved.

4731-1-16 Massage Therapy Curriculum... - Kimberly Anderson has in her Memorandum that this rule has been codified in statute. Does this mean it is in 4731-19? Well, as you well know that a lot of us are not happy that our hour requirements are now 600 instead of 750 but there isn't anything we can do. However, to rescind this rule fully is not OK with me.

I would like to keep (A-3), which mentions all students are required to GIVE a massage to an Ohio Licensed Medical Massage Therapist. Yes, there is not a way for the Board to make sure every person is qualified but I believe this should be the responsibility of the Institution to make sure the rule is being completed properly. Our "job" as a Massage Therapist is HANDS ON. A prospect Licensed Massage Therapist needs to have some type of practical to ensure the student is competent in their assessment and treatment to his/her clients. If it was up to me, I would love to see at least 3 massages done on 3 different Ohio Licensed Massage Therapists to ensure their capabilities.

My next one of concern is (E), which states that students be given credit for off-site clinical activities. I believe this one is another important/essential component of the law to ensure educated AND competent Licensed Massage Therapists. Quite a few, if not all, other professions have to undergo clinicals to ensure the experience and understanding of the profession. Having the students have a chance to work at a Massage clinic with the public is very essential and it would be the responsibility of the institution to verify it properly, which is well worded in (E). If you don't want these 2 laws to be "floating around," why not add it to 4731-1-15? Everything else is there :-).

4731-1-17 Instructional Staff... - I can see where the Ohio Administrative Code Rule for Career Colleges and School takes up the slack on this one. In Rule 3332-1-16-C-5, "... instructor whose teaching assignment is in the occupational specialty must have a high school diploma/GED, other formal training or certification necessary to the program, and have demonstrated competency as a wage earner, for at least 3 years, in the related technical field..." This is pretty vague, in my opinion, to ensure proper instructors in Massage Therapy Institutions. So, because of that, this is where the Medical Boards ruling comes into play to make it more specific! Therefore, (A) and (C) should stay. (B) is represented in the rest of 3332-16-2-5, "...teaching general education courses shall hold a bachelor's degree with a

concentration in the discipline as a minimum.” Again, we are here to ensure future Massage Therapists are well educated and competent to help the public.

4731-1-18 Grounds for Suspension... - OK

4731-1-19 Probationary Status... - This should definitely be kept! If the school does not have a great pass rate on the mBLEX they should be reviewed and placed on probation! The students need to be fully aware of the Institution's pass rate as well so they can make an informed decision on where to invest their education. If the pass rate is lower than 75% then something is “possibly” wrong with the institution and needs to be addressed immediately. Yes, it is a bit of work but this is a must. If we could even add that the institution must PUBLICLY show their pass rate, that would be so helpful to the students. Unfortunately, the Ohio Administrative Code Rule for Career Colleges and Schools are a bit vague when it comes to MBlex pass rates. It does state in 3332-1-16-B-11 to provide appropriate assistance in preparing for state administered professional licensing exams and must maintain minimum acceptable passage rates on state licensing exams. But does that include the mBlex? Is this another loophole? There is also 3332-1-24 with job placements. Does this truly qualify Massage Therapy Institutions to ensure it stays in good standings with adequate performance? If it does, ok. I am just not a fan of loopholes when prospect student's future is in jeopardy.

And I believe that is it. Well, for now. I hope you have a great week and cannot wait for the next meeting. If you have any questions, please feel free to contact me.

Stay Healthy and Happy!!

Heather Mello Roenker, LMT

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From: [Reardon, Jill](#)
To: [Anderson, Kimberly](#)
Subject: FW: limited branch rules comments
Date: Thursday, March 3, 2022 11:56:00 AM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)

From: Beacon, Jack <JBeacon@STARKSTATE.EDU>
Sent: Thursday, February 10, 2022 11:48 AM
To: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Cc: Beacon, Jack <JBeacon@STARKSTATE.EDU>
Subject: limited branch rules comments

Hi Jill, here are my comments concerning the proposed rule changes.

4731-1-01, 4731-1-02, 4731-1-03, 4731-1-04, 4731-1-07, 4731-1-08, 4731-1-09, 4731-1-10, 4731-1-11, 4731-1-12, 4731-1-16, 4731-1-17, 4731-1-18, 4731-1-19 are all ok with me, no comments on the proposed changes.

4731-1-05 scope of practice-D2b-regarding the prescription device, most companies consider a Licensed Massage Therapist as a healthcare provider and will sell a ultrasound device to us. They will also sell a device to the public if they have a prescription. Since it sold to the public, there is no regulation on how they use the device, so why does an LMT need on-site "supervision"?

I purchased an ultrasound/e-stim unit for our school with no issues and currently train my students how to use it and have created documents for them regarding how to use the device. We do not use it on our clinical patients. I purchased the device so my students will already have the minimal standards of care when it comes to using these modalities.

The websites you can visit are: sourceortho.net and massagewarehouse.com

4731-1-15 massage therapy educational requirements-C2a equivalent to the board of regents-should that be Department of higher education ODHE?,

Once a certificate of good standing is issued, it has no expiration date. I would guess that other schools may have concerns regarding this as certificate of good standings could be issued and there could possibly be no self-reporting by schools, since the certificate is valid forever.

Jill, since it seems the medical board is transitioning away from having some much regulation over the massage profession and seems to just want to be just the licensing agent, what are the possibilities of the formation of a Massage Therapy board that can govern the school's curriculum and other details that the board currently governs?

I think since the medical board has had regulation over massage therapy for so long, it is hard from some to accept that the profession needs to step up and perhaps take over some of these responsibilities.

Thanks, have a great weekend,

Jack Beacon, LMT.

Program Coordinator/Associate Professor • Massage Therapy

330-494-6170 ext 4545 • J329

jbeacon@starkstate.edu • starkstate.edu

6200 Frank Ave NW • North Canton, OH 44720

[Massage therapy | Stark State College - North Canton, Ohio](#)



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From: [Reardon, Jill](#)
To: [Anderson, Kimberly](#)
Subject: Fwd: Expense Report - Thoughts on the Meeting
Date: Monday, February 28, 2022 8:36:43 AM
Attachments: [Feb 7th meeting.docx](#)
[Travel Reimbursement Invoice for Non-State Employee website 2-7-22.xlsx](#)

Ignore financial portion. Member of mtac

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From: Ken Morrow <info@healingsoulsmt.com>
Sent: Sunday, February 27, 2022 4:32:16 PM
To: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Subject: Expense Report - Thoughts on the Meeting

Good Evening Jill,

Hope you are doing well,

I wanted, to turn in my expense report and my additional comments from the Feb. 7th meeting.

Thank you very much,

Ken Morrow

Sent from [Mail](#) for Windows

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Comments from Feb 7th meeting

Dropping Requirement hours

makes more sense to be in line with other states.

Education in Massage Therapy: having one baseline educational format across other states would make it easier for school transfers, for basic relaxation massage. But I also agree with Jackie Wolfs' idea to use an additional curriculum for those who want to continue their education and do therapeutic massage and give them a different title.

Staffing from other states: Being able to find more reliable people willing to work who do not have a clientele base.

Proposed Amendments

The letter raises concern that the rescission of Rule 4731-1-16 results in the deletion of the requirement in Rule 4731-1-16(A)(3) that requires each student, prior to completing the course of instruction, perform, on a licensed massage therapist, at least one therapeutic massage.

If the institution wants to make that a part of its curriculum, it's just not a requirement of the State Board

The letter expresses concerns with the elimination of the need to renew the certificate and put schools on an honor system to self-report if there is a change that would affect their eligibility.

They could lie on a renewal just as easily as not reporting it. Without someone to monitor this constantly, what is the point? It would be a waste of time. I would require them to put up a poster "if you see a violation, report it" and give a website.

The letter expresses concerns about eliminating the need for a school to do a background check or to advise a student that arrests, charges, or convictions of criminal offenses may prohibit them from obtaining licensure. Students could pay thousands of dollars in tuition and then not be able to obtain a license in Ohio.

We need to explain to the schools that the State Medical Board doesn't require them to do a background check; however, the institution themselves may perform a background check for the institution's safety. Explain to them that we have a list of ineligible people and let them know the percentage of accepted people, maybe not make the experience so scary.

In rescinding Rule 4731-1-17, the Board would be rescinding any requirements for instructional staff. Concerns were raised that an individual with no massage therapy experience or no background in science or healthcare could be allowed to teach massage therapy students.

As far as Anatomy, Physiology, business classes are concerned, these subjects are right out of a textbook. But massage therapy should be taught by seasoned massage therapists. Becoming a massage therapist is why you're going to school. Knowing how to properly do a massage therapy session safely and without getting burned out, If teaching were in the hands of a spa or

chiropractor's office, they will use them up and toss them out as free labor. Most likely, the student will become discouraged and quit.

When I worked in a spa, it wasn't enjoyable. They did not understand how to treat their massage therapists or what type of treatments the client needed, and it became frustrating to do what was needed and what the spa wanted to profit from.

From: [Reardon, Jill](#)
To: [Anderson, Kimberly](#)
Subject: Fwd: MTAC Memo Regarding Rules and agenda and additional info
Date: Monday, February 28, 2022 10:29:41 AM
Attachments: [image002.png](#)
[image003.png](#)
[image005.png](#)
[image006.png](#)
[image008.png](#)
[image009.png](#)

Rules comments from MTAC stakeholders
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From: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Sent: Monday, February 28, 2022 10:29:01 AM
To: Laura Embleton <laura@abmp.com>
Subject: Re: MTAC Memo Regarding Rules and agenda and additional info

Laura. Thanks so much.

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From: Laura Embleton <laura@abmp.com>
Sent: Monday, February 28, 2022 10:22:37 AM
To: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Subject: RE: MTAC Memo Regarding Rules and agenda and additional info

Hi Jill,

We had the opportunity to review these proposed revisions and, after hearing the rationale for the amendments have no objection. Thank you!

Laura

Laura B. Embleton
Government Relations Director
Associated Bodywork & Massage Professionals
Laura@abmp.com
(303) 679-7645 (o)
(303) 809-8803 (c)





From: Jill.Reardon@med.ohio.gov <Jill.Reardon@med.ohio.gov>
Sent: Wednesday, February 9, 2022 1:54 PM
To: Laura Embleton <laura@abmp.com>
Subject: MTAC Memo Regarding Rules and agenda and additional info

Laura,

Good afternoon. Let me know if you can't open this and I will try and send another way.

Jill

From: Laura Embleton <laura@abmp.com>
Sent: Wednesday, February 9, 2022 3:49 PM
To: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Subject: RE: MTAC Memo Regarding Rules and agenda and additional info

Good Afternoon Jill,

I'm guessing the attachments for the rules were in this email. I'm having a time opening them. Would you please send the rules packet over? I'm sure I don't have issues, but want to look at the strike throughs and such. No hurry. Thank you.

Laura

Laura B. Embleton
Government Relations Director
Associated Bodywork & Massage Professionals
Laura@abmp.com
(303) 679-7645 (o)
(303) 809-8803 (c)



From: Jill.Reardon@med.ohio.gov <Jill.Reardon@med.ohio.gov>

Sent: Tuesday, February 1, 2022 12:45 PM

Subject: MTAC Memo Regarding Rules and agenda and additional info

Good afternoon,

We are looking forward to the first meeting of the MTAC coming up on Monday the 7th of February.

The last email sent contained draft rules that we will be discussing at the upcoming meeting. Because of the volume of the rules, we will not be printing those out for the meeting. Please feel free to print them or bring any notes of things you may want to discuss after reviewing them. We will print out the memo at the beginning of the rules package for your use at the meeting.

Please let me know if you won't be in attendance or have any questions or concerns.

Jill

From: Reardon, Jill

Sent: Saturday, January 29, 2022 3:32 PM

Subject: MTAC Memo Regarding Rules and agenda

Good afternoon, I hope this email finds you well and warm.

As you know, the first MTAC meeting is scheduled for February 7, 2022, in person in the Rhodes Tower 3rd floor in downtown Columbus at 2:00 pm.

The Rhodes Tower is located at: 30 East Broad Street. Parking may be available in the State House parking garage across from the Rhodes Tower. To enter the Rhodes from the State House parking

garage you will need to take the steps to the street level and enter in the front of the tower. If you park there, we will have vouchers we will give you to pay for your parking.

I have attached a tentative agenda for the meeting as well as a memo from our Chief Legal Counsel, Kim Anderson that contains information regarding rules that will be proposed by the Board after your input. Knowing that this council was going to be formed, we waited to file rules having to do with massage therapy until they could be reviewed by this council first. I am sending a copy to you ahead of the meeting hoping that you have time to review them before the council meeting.

I have also attached a copy of the Ohio Revised Code section that sets out the responsibilities of this council, the Ohio Revised Code section that describes the scope of practice for LMT's as well as a document that explains the state's administrative rule process.

Subsequent to this meeting, the next 3 meetings have been changed to Tuesdays, the day before the full Medical Board. The dates for the rest of the year are as follows:

May 10, 2022

August 9, 2022

November 8, 2022

Thank you for agreeing to serve on this council and represent the massage therapy profession in advising the State Medical Board of Ohio. I look forward to working with you.

Please let me know if you have any questions or concerns.

Best wishes,

Jill

Jill Phalen Reardon
Deputy Director of External Affairs
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
o: 614 466 0781
c: 614 551 9957
Jill.Reardon@med.ohio.gov
w: med.ohio.gov



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4731-1-01

Definition of terms.

- (A) "Board" means the state medical board of Ohio.
- (B) "Certificate of good standing" means a non-transferable certificate issued by the board to the person or persons signing the application on behalf of a limited branch school, college, or institution which states that it is in good standing with the board, pursuant to section 4731.16 of the Revised Code and this chapter of the Administrative Code.
- (C) "Limited branch school, college or institution" means a facility wherein a course of instruction in massage therapy is offered.
- (D) "MBLEx" means the massage and bodywork licensing examination as prepared by the federation of state massage therapy boards.
- (E) "Distance education" means an instructional delivery system in which students and teachers are in separate locations and in which education and training are delivered through video, audio, computer, multimedia communications or some combination.
- (F) "Home study" means a form of correspondence instruction through mail or e-mail in which the institution provides lesson materials for study and completion by a student on his or her own, with completed lessons being returned by the student to the school for evaluation by the school. "Home study" shall not be considered a form of distance education.

*** DRAFT - NOT YET FILED ***

4731-1-01

Definition of terms.

- (A) "Board" means the state medical board of Ohio.
- (B) "Certificate of good standing" means a non-transferable certificate issued by the board to the person or persons signing the application on behalf of a limited branch school, which states that the school is in good standing with the board to offer a course of instruction in one limited branch of medicine, pursuant to section 4731.16 of the Revised Code and this chapter of the Administrative Code.
- (C) "Clock hour" means a period of sixty minutes with a minimum of fifty minutes of instruction at the limited branch school. One semester hour is equivalent to fifteen clock hours. One quarter hour is equivalent to ten clock hours.
- (D) "Course of instruction" means the complete body of prescribed subjects or studies to prepare students for admission to an examination for licensure in the limited branch of medicine.
- (E) "Limited branch school" means a facility wherein a course of instruction in massage therapy or cosmetic therapy is offered.
- (F) "Person" means an individual, corporation, partnership, association, or any other type of organization.
- (G) "Schedule of operations" means the hours in which classes are being conducted and the hours in which other educationally related activities are in process in a limited branch school.
- (H) "Similar course of instruction" means a course of instruction with the same general objective which involves the same or related instructional content, processes, tools, materials and clock hours of instruction previously approved by the board.
- (I) "Subject" means a unit of learning which is an integral part of the course of instruction being pursued.
- (J) "MBLEEx" means the massage and bodywork licensing examination as prepared by the federation of state massage therapy boards.
- (K) "CCE examination" means the "Certified Clinical Electrologist Examination" prepared by "The Society for Clinical and Medical Hair Removal."

4731-1-02

Application of rules governing limited branches of medicine or surgery.

- (A) Rules adopted by the board governing the practice of limited branches of medicine apply to practitioners of those limited branches listed in sections 4731.15 and 4731.151 of the Revised Code.
- (B) Any person holding a valid ~~certificate~~[license](#) to practice one or more of the limited branches of medicine is subject to disciplinary action by the board, and may additionally be subject to criminal prosecution, if such person performs acts beyond the scope of the limited branch for which the person holds a ~~certificate~~[license](#) or which otherwise violates the rules governing practitioners of limited branches of medicine.
- (C) For purposes of division (B)(18) of section 4731.22 of the Revised Code, the code of ethics and standards of practice of the "American Massage Therapy Association" applies to all persons holding a ~~certificate~~[license](#) to practice massage therapy. The code of ethics may be obtained from the medical board's website at med.ohio.gov/.
- ~~(D) For purposes of division (B)(18) of section 4731.22 of the Revised Code, the code of ethics and standards of practice of the "Society for Clinical and Medical Hair Removal, Inc.," applies to all persons holding a certificate to practice cosmetic therapy. The code of ethics may be obtained from the medical board's website at med.ohio.gov/.~~

4731-1-03

General prohibitions.

- (A) No person holding a ~~certificate~~[license](#) to practice a limited branch of medicine shall perform or hold himself or herself out as able to perform surgery, or any other act which involves a piercing or puncturing of the skin or membranous tissues of the human body unless specifically permitted under Chapter 4731. of the Revised Code or this chapter of the Administrative Code. ~~This rule does not prohibit a licensed cosmetic therapist with appropriate training from removing an ingrown hair.~~
- (B) No person holding a ~~certificate~~[license](#) to practice a limited branch of medicine shall prescribe, dispense, personally furnish or administer any drug or medicine.
- (C) Except as is specifically permitted under the rules defining the scope of a limited branch of medicine, no person holding such a ~~certificate~~[license](#) shall diagnose or treat infectious, contagious or venereal diseases, or any wound, fracture or bodily injury, infirmity, or disease.
- (D) The designation "Dr." or "Doctor" shall not precede the name of the limited practitioner. No person holding a ~~certificate~~[license](#) to practice a limited branch of medicine shall employ, or cause to be employed, the designation "Dr." or "Doctor" without also qualifying such designation by the name or an abbreviation of the limited branch for which the person holds a ~~certificate~~[license](#). The appropriate designation must follow the name of the limited practitioner (e.g., "John Doe, Doctor of Mechanotherapy" or "John Doe, D.M.") and may be employed or caused to be employed by the limited practitioner only if the limited practitioner has received a degree granting such a title from a school legally empowered to grant the degree.
- (E) No person holding a ~~certificate~~[license](#) to practice a limited branch of medicine shall employ, or cause to be employed, the designation "Physician" or "Surgeon" no matter how qualified or how employed in combination with other language.
- (F) No person holding a ~~certificate~~[license](#) to practice any limited branch or branches of medicine shall hold himself or herself out as holding a ~~certificate~~[license](#) in or as being able to practice any limited branch of medicine for which that person does not hold a ~~certificate~~[license](#).
- (G) No person holding a ~~certificate~~[license](#) to practice any limited branch or branches of medicine shall conduct such practice under any name or title, either as an individual, company or concern, that is misleading.

4731-1-04

Scope of practice: mechanotherapy.

- (A) A practitioner of mechanotherapy shall examine patients only by verbal inquiry, examination of the musculoskeletal system by hand, and visual inspection and observation. A practitioner of mechanotherapy shall specifically not employ any techniques which involve extraction or analysis of body tissue or fluids.
- (B) A practitioner of mechanotherapy shall not diagnose a patient's condition except as to whether or not there is a disorder of the musculoskeletal system present.
- (C) A practitioner of mechanotherapy, in the treatment of patients, may apply only those techniques listed in this paragraph, but he may apply such techniques only to those disorders of the musculoskeletal system which are amenable to treatment by the listed techniques and which are identifiable by examination and diagnosis as described in this rule:
 - (1) Advised or supervised exercise;
 - (2) Massage or manipulation;
 - (3) ~~Employment~~[Application](#) of air, water, heat, cold, sound or infrared rays; or
 - (4) Electrical neuromuscular stimulation.

4731-1-05

Scope of practice: massage therapy.

- (A) Massage therapy is the treatment of disorders of the human body by the manipulation of soft tissue through the systematic external application of massage techniques including touch, stroking, friction, vibration, percussion, kneading, stretching, compression, and joint movements within the normal physiologic range of motion; and adjunctive thereto, the external application of water, heat, cold, topical preparations, and mechanical devices.
- (B) A massage therapist shall not diagnose a patient's condition. A massage therapist shall evaluate whether the application of massage therapy is advisable. A massage therapist may provide information or education consistent with that evaluation, including referral to an appropriate licensed health care professional, provided that any form of treatment advised by a massage therapist falls within the scope of practice of, and relates directly to a condition that is amenable to treatment by, a massage therapist. In determining whether the application of massage therapy is advisable, a massage therapist shall be limited to taking a written or verbal inquiry, visual inspection including observation of range of motion, touch, and the taking of a pulse, temperature and blood pressure.
- (C) No person shall use the words or letters "massage therapist," "licensed massage therapist," "L.M.T." or any other letters, words, abbreviations, or insignia, indicating or implying that the person is a licensed massage therapist without a valid license under Chapter 4731. of the Revised Code.
- (D) A massage therapist may perform the following services in compliance with the following:
- (1) A massage therapist may treat temporomandibular joint dysfunction provided that the patient has been directly referred in writing for such treatment to the massage therapist by a physician currently licensed pursuant to Chapter 4731. of the Revised Code, by a chiropractor currently licensed pursuant to Chapter 4734. of the Revised Code, or a dentist currently licensed pursuant to Chapter 4715. of the Revised Code.
 - (2) A massage therapist may apply ultrasound, diathermy, electrical neuromuscular stimulation, or substantially similar modalities provided that the patient has been directly ~~referred~~referred in writing for such treatment to the massage therapist by a physician or podiatric physician licensed under Chapter 4731. of the Revised Code, physician assistant licensed under Chapter 4730. of the Revised Code, chiropractor licensed under Chapter 4734. of the Revised Code, advanced practice registered nurse licensed under Chapter 4723. of the Revised Code, or physical therapist licensed under Chapter 4755. of the Revised Code, who is acting within the scope of their professional license.

- (a) The massage therapist must perform the modality within the minimal standards of care.
 - (b) If the food and drug administration classifies the device as a prescription device, as that term is defined in 21 CFR 801.109 amended as of June 15, 2016, or a restricted device that can only be sold, distributed, or used upon the order of an authorized healthcare provider, the massage therapist's application of the device must be done under the on-site supervision of the referring practitioner.
 - (c) If the food and drug administration classifies the device as an over-the-counter device, the massage therapist may apply the device without the on-site supervision of the referring practitioner.
- (E) All persons who hold a ~~certificate~~[license](#) to practice massage therapy issued pursuant to section 4731.17 of the Revised Code shall prominently display that ~~certificate~~[license](#) in the office or place where a major portion of the ~~certificate~~[license](#) holder's practice is conducted. If a ~~certificate~~[license](#) holder does not have a primary practice location, the ~~certificate~~[license](#) holder shall at all times when practicing keep either the wall certificate on the holder's person or provide verification of licensure status from the board's internet web site upon request. ~~The board's website is: www.med.ohio.gov.~~
- (F) Massage therapy does not include:
- (1) Colonic irrigation;
 - (2) The practice of chiropractic, including the application of a high velocity-low amplitude thrusting force to any articulation of the human body;
 - (3) The use of graded force applied across specific joint surfaces for the purpose of breaking capsular adhesions;
 - (4) The prescription of therapeutic exercise for the purpose of rehabilitation or remediation of a disorder of the human body;
 - (5) The treatment of infectious, contagious or venereal diseases;
 - (6) The prescription, dispensing, personally furnishing or administration of drugs;
and

(7) The performance of surgery or practice of medicine in any other form.

(G) As used within this rule:

- (1) "External" does not prohibit a massage therapist from performing massage therapy inside the mouth or oral cavity; and
- (2) "Mechanical devices" means any tool or device which mimics or enhances the actions possible by the hands that is within the scope of practice as defined in section 4731.04 of the Revised Code and this rule.

*** DRAFT - NOT YET FILED ***

4731-1-07

Eligibility of electrologists licensed by the Ohio state board of cosmetology to obtain licensure as cosmetic therapists pursuant to Chapter 4731. of the Revised Code and subsequent limitations.

A person who was issued a cosmetic therapist's license prior to February 1, 1993 based upon holding a certificate to practice electrolysis and registration issued under Chapter 4713. of the Revised Code, may be registered by the board as a cosmetic therapist but may not apply "systematic friction, stroking, slapping, and kneading or tapping of the face, neck, scalp, or shoulders" as defined in division (A) of section 4731.04 of the Revised Code until that person has completed coursework in that area that has been approved by the board at a school approved by the board pursuant to this chapter of the Administrative Code.

*** DRAFT - NOT YET FILED ***

4731-1-08

Continuing cosmetic therapy education requirements for renewal, reinstatement, or restoration of a license to practice cosmetic therapy.

- (A) "License renewal" is the extension of a current license by fulfilling the requirements of division (C) of section 4731.15 of the Revised Code and the continuing education requirements of this rule.
- (B) "License reinstatement" is the reactivation of a license which has lapsed or been in a suspended or inactive status for two years or less for any reason including a failure to comply with division (C) of section 4731.15 of the Revised Code or the continuing education requirements of this rule.
- (C) "License restoration" is the reactivation of a license which has lapsed or been in a suspended or inactive status for more than two years for any reason including a failure to comply with division (C) of section 4731.15 of the Revised Code or the continuing education requirements of this rule.
- (D) On or before the expiration dates established in table 1 of this rule, each applicant for license renewal shall certify to the board that since the start of the applicant's registration period, the applicant has completed twelve hours of "Continuing Cosmetic Therapy Education" (hereinafter "CCTE") less any reduction in hours allowed by the board under paragraph (K) or (L) of this rule.

Table 1

First Initial of Last Name	License Expiration Date
A-B	July of odd numbered years
C-D	April of odd numbered years
E-G	January of odd numbered years
H-K	October of even numbered years
L-M	July of even numbered years
N-R	April of even numbered years
S	January of even numbered years
T-Z	October of odd numbered years

- (E) All applicants who apply for license reinstatement shall certify to the board that in the preceding registration period, they have completed the twelve hour CCTE

requirement less any reduction in hours allowed by the board under paragraph (K) or (L) of this rule.

(F) All applicants who apply for license restoration shall have completed twelve hours of CCTE within the preceding two years from the date of the application.

(G) If a person has not completed the requisite hours of CCTE, that person is not eligible for license renewal, reinstatement, or restoration until such time as those hours have been completed. Any CCTE undertaken after the end of a registration period and utilized for purposes of reinstatement or restoration of a suspended license cannot also be utilized to meet the CCTE requirement for the current registration period.

(H) Persons who are residing or practicing out of the state who wish to renew or reinstate their license to practice cosmetic therapy in Ohio must complete the required CCTE within the registration period even though not currently residing or practicing in Ohio.

(I) The certification required by paragraphs (D) and (E) of this rule shall be evidence of completion of the CCTE requirement as set forth in this rule, provided that:

(1) The board may randomly select applications for verification that all CCTE requirements have been met. Persons whose applications are selected shall submit additional documentation of compliance with CCTE requirements as the board may require.

(2) Records of all CCTE undertaken shall be retained for after the end of the registration period. Failure to maintain evidence of completion and supporting documentation as required by paragraph (N) of this rule rebuts the presumption established in paragraph (I) of this rule that the CCTE requirements have been completed.

(J) Nothing in this rule shall limit the board's authority to investigate and take action under section 4731.22 of the Revised Code.

(K) Reduction of hours can be granted on an individual basis to those who have been ill for more than six consecutive months or out of the United States for more than six consecutive months during the registration period. The applicant will have the burden of establishing that that person's illness or absence affected that person's reasonable opportunity to participate in CCTE activities. One half hour will be subtracted from the CCTE requirement for each month which is approved for reduction of hours. Requests for reduction of hours must be made in writing to the state medical board and submitted to the board at least sixty days prior to the end of

the registration period.

(L) The CCTE requirement for persons licensed after the start of a registration period or for whom the license has been restored shall be computed in the following manner:

- (1) If the license is initially issued prior to the first day of the second year of the registration period, the licensee shall be required to earn six total hours;
- (2) If the license is issued on or after the first day of the second year of the registration period and prior to the first day of the eighteenth month of that period, the licensee shall be required to earn three total hours;
- (3) If the license is issued on or after the first day of the eighteenth month of the registration period, the licensee shall not be required to earn any hours of CCTE credits for that period.

(M) If the board proposes to refuse to renew, reinstate, or restore a license for failure to meet the CCTE requirements of this rule, the applicant shall be entitled to a hearing on the issue of such proposed denial. Notice and hearing requirements incident to such proposed denial will be in compliance with the provisions of Chapter 119. of the Revised Code.

(N) CCTE course requirements:

- (1) All hours of CCTE shall be:
 - (a) In one or more of the following subject matter areas
 - (i) Laser hair removal;
 - (ii) Electrolysis/ETB/hair removal;
 - (iii) Sterilization and hygiene;
 - (iv) Professional ethics;
 - (v) Blood borne pathogens;
 - (vi) Endocrinology;

(vii) Anatomy and physiology as it relates to the dermis;

(viii) Diseases of the skin;

(ix) Cosmetic therapy law;

(x) Massage of the face, neck, scalp, or shoulders.

(b) Offered by one of the following entities:

(i) A college or university approved by the state department of education;

(ii) A state or national professional cosmetic therapy or electrology association;

(iii) A cosmetic therapy school approved by the board pursuant to this chapter of the Administrative Code;

(iv) A health department or hospital which offers program which had been previously approved for continuing medical education (CME) credits or for continuing nursing education credits (CNE):
or

(v) A provider accredited by the international association for continuing education and training.

(2) CCTE courses may be completed via in-person, webinar, or on-line.

(3) A cosmetic therapist shall obtain evidence of completion (i.e., a certificate) from the provider of the CCTE for all CCTE hours that are successfully completed. In the event that evidence of completion includes hours of education in a subject not included in paragraph (N)(1) of this rule, the cosmetic therapist shall only claim the hours that meet the requirements of this rule. Cosmetic therapists shall also retain supporting documentation of all of the following:

(a) Description of the CCTE activity;

(b) The location of the CCTE activity;

- (c) The date of attendance;
 - (d) The hours of each CTE activity.
- (4) Evidence of completion and supporting documentation shall be retained by the applicant for renewal for one year after the end of the registration period.
- (O) An expired license to practice as a cosmetic therapist shall be renewed upon payment of the biennial renewal fee provided in section 4731.15 of the Revised Code and without a late fee or re-examination if the holder meets all of the following requirements:
 - (1) The licensee is not otherwise disqualified from renewal because of mental or physical disability.
 - (2) The licensee meets the requirements for renewal under section 4731.15 of the Revised Code.
 - (3) Either of the following situations applies:
 - (a) The license was not renewed because of the licensee's service in the armed forces, or
 - (b) The license was not renewed because the licensee's spouse served in the armed forces, and the service resulted in the licensee's absence from this state.
 - (4) The licensee or the licensee's spouse, whichever applicable, has presented satisfactory evidence of the service member's discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.
- (P) Extension of the continuing education period based on active duty status:
 - (1) The holder of a cosmetic therapy license may apply for an extension of the current continuing education reporting period in the manner provided in section 5903.12 of the Revised Code.
 - (2) The board shall consider relevant education, training, or service completed by the licensee as a member of the armed forces in determining whether a

licensee has met the continuing education requirements to renew the license.

(3) Upon receiving the application and proper documentation, the board shall act in accordance with section 5903.12 of the Revised Code.

(Q) For purposes of this paragraphs (O) and (P) of this rule, "armed forces" has the same meaning as in section 5903.01 of the Revised Code and "reporting period" has the same meaning as in section 5903.12 of the Revised Code.

*** DRAFT - NOT YET FILED ***

4731-1-09

Cosmetic therapy curriculum requirements.

- (A) To qualify to receive a certificate of good standing for a course of instruction in cosmetic therapy, a school's course of instruction shall:
- (1) Consist of both practical and theoretical instruction covering a period of not less than one year and a minimum of six hundred clock hours. The course of instruction shall include a minimum of seven hundred and fifty clock hours covering a period of not less than nine months.
 - (2) Teach at least the minimum required hours in the following subjects in dedicated clock hours, as appropriate to cosmetic therapy:
 - (a) Anatomy and physiology; pathology: three hundred twenty-five clock hours;
 - (b) Cosmetic therapy theory and practical, including infection control and hygiene: three hundred twenty-five clock hours;
 - (c) Ethics: twenty-five clock hours, at least ten of which shall be in a class dedicated exclusively to ethics. For purposes of this rule, "ethics" shall be defined to include sexual boundary issues and impairment and chemical dependency issues;
 - (d) Business and law: twenty-five clock hours; and
 - (e) Such other subjects as the board deems necessary and appropriate to cosmetic therapy: fifty clock hours.
- (B) Educational objectives shall be clearly defined and simply stated and shall indicate what the educational program can do for reasonably diligent students.
- (C) The course of instruction shall be outlined in detail showing major subjects and clock hours devoted to each subject, entrance requirements and occupational objectives.
- (D) A limited branch school shall submit for approval on an appropriate form its daily or weekly schedule of instruction. The approved schedule shall be made available whenever requested by the board.
- (E) Students may be given credit for off-site clinical activities.
- (1) Such credit may not exceed ten percent of the required clock hours in the theory

and practical category of the program.

- (2) The off-site clinical activities shall be conducted under the direction and on-site supervision of an appropriately licensed practitioner.
- (3) The school shall be required to enter into a written affiliation agreement with a representative of the facility where the off-site clinical activities are being provided, and to maintain records of each student's clinical activities. Upon request of the board, schools shall forward those records to the board for review.
- (4) The student participating in off-site clinical activities shall identify him or herself at all times as a cosmetic therapy student and shall obtain signed acknowledgement of receipt of that notice from the patient.

*** DRAFT - NOT YET FILED ***

4731-1-10

Distance education.

(A) For purposes of this chapter of the Administrative Code:

- (1) "Asynchronous instructional methods" means an educational technique in which the communication between parties does not take place simultaneously and in which students may access a prepared educational program electronically or by other means at a time of their own choosing rather than at a specified time;
- (2) "Brick and mortar school" means an educational institution in which students and faculty are co-located during the entirety of the course of instruction.
- (3) "Distance education" means an instructional delivery system in which students and teachers are in separate locations during at least half of the total number of hours offered during the course of study and in which education and training are delivered through video, audio, computer, multimedia communications or some combination of these with other traditional delivery methods;
- (4) "Home study school" means a form of correspondence instruction through mail or e-mail in which the institution provides lesson materials for study and completion by a student on his or her own, with completed lessons being returned by the student to the school for evaluation by the school. "Home study school" shall not be considered a form of distance education.
- (5) "Synchronous instructional methods" means an educational technique in which the communication between parties takes place simultaneously and in real-time.

(B) Each distance education program shall apply for and receive a separate certificate of good standing from the board prior to the students who have completed a course of instruction from that school being admitted to the licensure examination. A certificate of good standing held by a brick and mortar school shall not be sufficient for any distance learning program operated by that school.

(C) To be eligible to receive a certificate of good standing from the board, a distance education school or program shall submit evidence that complies with all of the following:

- (1) Meet all of the requirements for receipt of a certificate of good standing required pursuant to Chapter 4731. of the Revised Code and this chapter of the Administrative Code;

- (2) Have in place a procedure whereby applicants for a distance education course of instruction are assessed as to their psychological predisposition toward distance learning and their capabilities to use computer technologies appropriate to the particular course of study;
 - (3) Have in place a plan for on-line attendance and assessment of student performance;
 - (4) Require instructors, in addition to the requirements of rule 4731-1-17 of the Administrative Code, to have documented training or certification in the development of distance education course materials, curricula and instructional methods;
 - (5) Demonstrate possession of minimally sufficient technical resources to meet the requirements of this rule;
 - (6) Offer a mix of synchronous and asynchronous instruction and identify the number of clock hours required for each form of instruction;
 - (7) Of the three hundred twenty-five clock hours in theory and practical required in rules 4731-1-09 and 4731-1-16 of the Administrative Code, a minimum of two hundred hours shall be hands-on instruction in the limited branch theory and practical portion of the course of instruction.
 - (8) Of the minimum of twenty-five hours of instruction in ethics required in rules 4731-1-09 and 4731-1-16 of the Administrative Code, a minimum of ten hours shall be taught in a dedicated interactive manner during the hands-on instruction;
 - (9) Provide to all applicants an explanation of the types of delivery systems used in the distance education course of instruction, hardware and software requirements, whether the school will provide remedial technical training, and any other information the board deems appropriate.
- (D) Home study schools are considered to be inappropriate for the education required to be given by limited branch schools. Therefore, any home study school is not in good standing with the board for purposes of admitting graduates from that school for examination for licensure in a limited branch of medicine or surgery.
- (E) The certificate of good standing issued pursuant to this rule is valid for two years from the date of issuance. It may be renewed upon the holder's submission of

evidence demonstrating that all of the requirements of paragraph (C) of this rule are satisfied, as determined by the board.

*** DRAFT - NOT YET FILED ***

4731-1-11

Application and examination for certificate to practice cosmetic therapy.

- (A) No application for a certificate to practice cosmetic therapy shall be considered complete until the applicant has complied with the requirements of paragraph (A) of rule 4731-4-02 of the Administrative Code and the board has received the results of criminal records checks and any other forms required to be submitted pursuant to paragraph (A) of rule 4731-4-02 of the Administrative Code.
- (B) An applicant seeking a certificate to practice cosmetic therapy who meets the requirements of section 4731.19 of the Revised Code shall apply to the board in compliance with section 4731.19 of the Revised Code.
- (C) Any person seeking a certificate to practice cosmetic therapy shall have passed the CCE examination.
 - (1) An applicant for the CCE examination shall apply directly to "The Society for Clinical & Medical Hair Removal." The website address is: <https://www.scmhr.org/>.
 - (2) The passing performance for the CCE examination as reported by "The Society for Clinical & Medical Hair Removal" shall constitute successful completion of the examination.

4731-1-12

**Application and examination for ~~certificate~~license to practice
massage therapy.**

- (A) No application shall be considered complete until the applicant has complied with the requirements of paragraph (A) of rule 4731-4-02 of the Administrative Code and the board has received the results of criminal records checks and any other forms required to be submitted pursuant to paragraph (A) of rule 4731-4-02 of the Administrative Code.
- (B) All applicants seeking a ~~certificate~~license to practice massage therapy who meet the requirements of section 4731.19 of the Revised Code, shall apply to the board in compliance with section 4731.19 of the Revised Code.
- (C) Any person seeking a ~~certificate~~license to practice massage therapy shall have passed the MBLEx available through the federation of state massage therapy boards.
 - (1) An applicant for the MBLEx shall apply directly to the federation of state massage therapy boards.
 - (2) The passing performance for the examination as reported by the federation of state massage therapy boards shall constitute successful completion of the examination.

4731-1-15

Massage Therapy Educational Requirements and
Determination of standing of school, college or institution.

(A) For purposes of this rule, “hours” as used in section 4731.19 of the Revised Code, means a period of sixty minutes with a minimum of fifty minutes of instruction.

(B) A person seeking a license to practice massage therapy must hold one of the following:

(1) A diploma or certificate from a limited branch school, college or institution located in Ohio that held a certificate of good standing at the time the person obtained the diploma or certificate.

(2) A diploma or certificate from a limited branch school, college, or institution located outside of Ohio that held a certificate of good standing at the time the person obtained the diploma or certificate.

(3) A diploma or certificate from a limited branch school, college, or institution located outside of Ohio that required the completion of a course of instruction meeting the requirements section 4731.19 of the Revised Code. No more than one-half of the course of instruction required by section 4731.19 of the Revised Code may have been provided via distance education.

(4) During the five-year period immediately preceding the date of application, a current license, registration, or certificate in good standing in another state for massage therapy.

(C) A person desiring to have the board determine the standing of a limited branch school, college, or institution shall file an application for a certificate of good standing in the form and manner prescribed by the board. The completed application shall be signed by the owner or owners and shall provide evidence of the following:

(1) If the limited branch school, college or institution is located in this state, that:

(a) It holds a certificate of authorization issued by the Ohio department of higher education pursuant to Chapter 1713. of the Revised Code; or

(b) It holds a valid certificate of registration and a valid program authorization for the program in the limited branch of medicine issued by the state board of career colleges and schools pursuant to Chapter 3332. of the Revised Code; or

(c) It holds a certificate of authorization issued by the Ohio department of education, division of career/technical adult education; and

(d) It offers a course of instruction in compliance with section 4731.19 of the Revised Code. No more than one-half of the course of instruction

required by section 4731.19 of the Revised Code may be provided via distance education.

(e) It requires that each student, prior to completing the course of instruction, perform, on a licensed massage therapist, at least one therapeutic massage. The school shall ensure that the student massage is evaluated as to whether the student demonstrates at least minimally acceptable competency.

(2) If the limited branch school, college or institution is located outside this state, that:

(a) It holds a current or valid registration authorizing its operation issued by the appropriate regulatory body in the state of location that is substantially equivalent to the board of regents, the state board of career colleges and schools, or the department of education in this state; or

(b) approval or recognition by the state board or agency authorized to regulate the limited branch of medicine in the state in which the limited branch school, college, or institution is located; or

(c) in the event that the limited branch school, college, or institution is located in a state that does not approve or recognize such facilities or educational programs, approval by the Federation of State Massage Therapy Boards for purposes of permitting graduates to sit for the MBLEx; and

(d) It offers a course of instruction in compliance with section 4731.19 of the Revised Code. No more than one-half of the course of instruction required by section 4731.19 of the Revised Code may be provided via distance education.

(e) It requires that each student, prior to completing the course of instruction, perform, on a licensed massage therapist, at least one therapeutic massage. The school shall ensure that the student massage is evaluated as to whether the student demonstrates at least minimally acceptable competency.

(D) At or before the time a school, college or institution in this state accepts a student for admission to a massage therapy course of instruction, the school, college or institution shall provide the student with written notice that arrests, charges, or convictions of criminal offenses may be cause to deny or limit licensure or employment opportunities in specific careers and occupations and may limit the student's ability to obtain federal, state, and other financial aid. The notice shall direct students to the explanatory statement and disqualifying offense list on the board's website at www.med.ohio.gov/The-Board/Disqualifying-Criminal-Convictions.

- (E) An application for a certificate of good standing shall be signed by all owners and may not be signed by a person who has been found guilty of a felony or a crime involving moral turpitude, or by a person who has been disciplined by the board pursuant to section 4731.22 of the Revised Code.
- (F) The board may refuse to issue, suspend, place on probation, revoke, or permanently revoke a certificate of good standing for any one or any combination of the following causes:
- (1) Non-compliance with or failure to fulfill the provisions of this chapter of the Administrative Code or applicable provisions of Chapter 4731. of the Revised Code
 - (2) Furnishing of false, misleading, or incomplete information requested by the board
 - (3) Violation of state or federal laws including discrimination in the acceptance and education of students upon the basis of race, color, religion, sex, or national origin
- (G) If the board refuses to issue, suspend, place on probation, revoke, or permanently revoke a certificate of good standing, the applicant or the certificate holder shall be entitled to a hearing. Notice and hearing requirements will be in compliance with the provisions of Chapter 119. of the Revised Code and any rules adopted by the board.
- (H) In determining the effective date of any suspension, revocation, or permanent revocation of a certificate, the board shall take into consideration those students currently enrolled in the course of instruction.
- (I) The certificate of good standing issued pursuant to this rule is valid for two years from the date of issuance. It may be renewed upon the holder's submission of evidence demonstrating that the requirements of paragraph (C) of this rule are satisfied as determined by the board.

*** DRAFT - NOT YET FILED ***

4731-1-15

Determination of standing of school, college or institution.

(A) A person desiring to have the board determine the standing of a school, college or institution that offers instruction in a limited branch of medicine shall file a completed application for a certificate of good standing with the board on a form prescribed by the board. The completed application form and other data shall be submitted in full. The completed application shall be signed by the owner or owners and shall include the following information:

(1) If the school, college or institution is located in this state, that:

- (a) It holds a certificate of authorization issued by the Ohio board of regents pursuant to Chapter 1713. of the Revised Code; or
- (b) It holds a valid certificate of registration and a valid program authorization for the program in the limited branch of medicine issued by the state board of career colleges and schools registration pursuant to Chapter 3332. of the Revised Code; or
- (c) It holds a certificate of authorization issued by the Ohio department of education, division of career/technical adult education; and
- (d) It offers a course of instruction in compliance with this chapter of the Administrative Code.

(2) If the school, college or institution is located outside this state, that:

- (a) It holds a current or valid registration authorizing its operation issued by the appropriate regulatory body in the state of location that is substantially equivalent to the board of regents or the state board of career colleges and schools registration in this state; and
- (b) It offers a course of instruction in compliance with this chapter of the Administrative Code.

(B) At or before the time a school, college or institution in this state accepts a student for admission to a cosmetic therapy or massage therapy course of instruction, the school, college or institution shall provide the student with written notice regarding arrests, charges, or convictions of criminal offenses.

(1) The notice must inform the student that arrests, charges, or convictions of criminal offenses may be cause to deny or limit licensure or employment opportunities in specific careers and occupations and may limit the student's

ability to obtain federal, state, and other financial aid. The notice must encourage students to investigate these possibilities.

- (2) The notice provided under this rule must direct students to paragraph (D) of rule 4731-4-02 of the Administrative Code for factors the board may consider when reviewing the results of a criminal records check.
- (C) At or before the time a school, college, or institution in this state accepts a student for admission to a cosmetic therapy or massage therapy course of instruction, the student must have attained high school graduation or its equivalent.
- (D) A school, college or institution not meeting the requirements of paragraph (A) of this rule shall not be considered a school in good standing, provided that a school, college or institution that offers instruction in a limited branch of medicine and that holds a valid provisional certificate of good standing or a valid certificate of good standing on the effective date of this rule shall continue to be recognized as a school in good standing for one year following the effective date of this rule, unless suspended, revoked or placed on probation by the board pursuant to this chapter of the Administrative Code.
- (E) The certificate of good standing issued pursuant to this rule is valid for two years from the date of issuance. It may be renewed upon the holder's submission of evidence demonstrating that all of the requirements of paragraph (C) of this rule are satisfied, as determined by the board

*** DRAFT - NOT YET FILED ***

4731-1-16

Massage therapy curriculum requirements.

- (A) To qualify to receive a certificate of good standing for a course of instruction in massage therapy, a school's course of instruction shall:
- (1) Consist of both practical and theoretical instruction meeting one of the following requirements:
 - (a) For classes enrolling no later than December 30, 2005, a period of not less than one year and a minimum of six hundred clock hours; or
 - (b) For classes enrolling on and after December 31, 2005, a minimum of seven hundred fifty clock hours.
 - (2) Beginning with classes enrolling on or after December 31, 2005, teach at least the minimum required hours in the following subjects in dedicated clock hours, as appropriate to massage therapy:
 - (a) Anatomy and physiology; pathology: three hundred twenty-five clock hours;
 - (b) Massage theory and practical, including hygiene: three hundred twenty-five clock hours;
 - (c) Ethics: twenty-five clock hours, at least ten of which shall be in a class dedicated exclusively to ethics. For purposes of this rule, "ethics" shall be defined to include sexual boundary issues and impairment and chemical dependency issues;
 - (d) Business and law: twenty-five hours; and
 - (e) Such other subjects as the board deems necessary and appropriate to massage therapy: fifty clock hours; and
 - (3) Require that each student, prior to completing the course of instruction, perform, on a licensed massage therapist, at least one therapeutic massage. The school shall ensure that the student massage is evaluated as to whether the student demonstrates at least minimally acceptable competency.
- (B) Educational objectives shall be clearly defined and simply stated and shall indicate what the educational program can do for reasonably diligent students.

- (C) The course of instruction shall be outlined in detail showing major subjects and clock hours devoted to each subject, entrance requirements and occupational objectives.
- (D) A limited branch school shall submit for approval on an appropriate form its daily or weekly schedule of instruction. The approved schedule shall be made available whenever requested by the board.
- (E) Students may be given credit for off-site clinical activities. Such credit may not exceed ten per cent of the required clock hours in the theory and practical category of the program. The off-site clinical activities shall be conducted under the direction and on-site supervision of an appropriately licensed practitioner. The school shall be required to enter into a written affiliation agreement with a representative of the facility where the off-site clinical activities are being provided. The student participating in off-site clinical activities shall identify him or herself as a massage therapy student and shall obtain signed acknowledgement of receipt of that notice from the patient.

4731-1-17

Instructional staff in Ohio cosmetic therapy and massage therapy programs.

- (A) An instructor in limited branch theory or clinical practice shall be a high school graduate or equivalent, shall be currently licensed in Ohio in the applicable limited branch and shall have practiced in the applicable limited branch for a minimum of three years.
- (B) A classroom instructor teaching basic science or general education courses shall hold a bachelor's degree with a concentration in the discipline in which that instructor is providing instruction. The requirements of this paragraph may be waived for faculty who, on the date this rule becomes effective, have taught the course for more than one year at a limited branch school that holds a certificate of good standing issued by the board.
- (C) An instructor in massage therapy business courses shall meet one of the following requirements:
 - (1) Hold at least a bachelor's degree with a concentration in business;
 - (2) Have experience in ~~all aspects of~~ a massage therapy business gained as an owner and operator of a massage therapy business for a minimum of three years;
 - (3) Have experience in ~~all aspects of~~ a massage therapy business gained as a manager of a massage therapy business for a minimum of three years.

*** DRAFT - NOT YET FILED ***

4731-1-18

Grounds for suspension, revocation or denial of certificate of good standing; hearing rights.

- (A) The board may refuse to issue or renew, suspend, place on probation, or permanently revoke a certificate of good standing for any one or any combination of the following causes:
- (1) Non-compliance with or failure to fulfill the provisions of this chapter of the Administrative Code or applicable provisions of Chapter 4731. of the Revised Code;
 - (2) Furnishing of false, misleading, or incomplete information requested by the board;
 - (3) The signing of an application or the holding of a certificate of good standing by a person who has pleaded guilty or has been found guilty of a felony or has pleaded guilty or been found guilty of a crime involving moral turpitude;
 - (4) The signing of an application or the holding of a certificate of good standing by a person who has been disciplined by the board pursuant to section 4731.22 of the Revised Code;
 - (5) Violation of any commitment made in an application for a certificate of good standing; or
 - (6) Discrimination in the acceptance and education of students upon the basis of race, color, religion, sex, or national origin;
 - (7) Failure of a school's graduates to demonstrate minimally adequate performance on the MBLEx or the CCE examination as determined under paragraph (A) of rule 4731-1-19 of the Administrative Code; or
 - (8) Failure to provide the notice required in paragraph (B) of rule 4731-1-15 of the Administrative Code.
- (B) If the board proposes to refuse to issue or renew, suspend, place on probation, or permanently revoke a certificate of good standing or provisional certificate of good standing, the applicant or the certificate holder shall be entitled to a hearing such proposal. Notice and hearing requirements will be in compliance with the provisions of Chapter 119. of the Revised Code and any rules adopted by the board.
- (C) In determining the effective date of any suspension or permanent revocation of a certificate, the board shall take into consideration those students currently enrolled

in the course of instruction subject to the permanent revocation or suspension.

*** DRAFT - NOT YET FILED ***

4731-1-19

Probationary status of a limited branch school.

- (A) If the graduates of a course of instruction at any limited branch school holding a certificate of good standing collectively fail to demonstrate minimally adequate performance as determined by the board on the CCE examination for cosmetic therapy or the MBLEx for massage therapy, the board may place that school's certificate of good standing on probationary status.
- (1) Graduates of a course of instruction in cosmetic therapy at a limited branch school shall be deemed to have failed to demonstrate minimally adequate performance on the CCE examination if:
- (a) The average overall examination score for all first time test takers from that school during the past calendar year was below the established passing score for the examination for that year; and
 - (b) Such a finding is supported by other relevant factors as the board may deem appropriate.
- (2) Graduates of a course of instruction in massage therapy at a limited branch school shall be deemed to have failed to demonstrate minimally adequate performance on the MBLEx if:
- (a) The average overall examination score for all first time test takers from that school during the past calendar year was below the established passing score for the examination for that year; and
 - (b) Such a finding is supported by other relevant factors as the board may deem appropriate.
- (B) If a certificate of good standing of a limited branch school is placed on probationary status and graduates of that course of instruction collectively fail to demonstrate improved performance as determined by the board during the succeeding twelve months, the board may refuse to renew, or revoke or suspend that certificate.
- (1) In determining whether graduates of a course of instruction in cosmetic therapy at a limited branch school have demonstrated improved performance the board shall review the following:
- (a) Whether the overall examination score for all first time test takers from that school during the previous calendar year is above the established passing score for the examination; and

- (b) Such other relevant factors as the board may deem appropriate.
- (2) In determining whether graduates of a course of instruction in massage therapy at a limited branch school have demonstrated improved performance the board shall review the following:
 - (a) Whether the average overall examination score for all first time test takers from that school during the previous calendar year is above the established passing score for the examination; and
 - (b) Such other relevant factors as the board may deem appropriate.
- (C) If the board proposes to refuse to issue or renew, suspend, place on probation, or revoke a certificate of good standing, the certificate holder shall be entitled to a hearing on such proposal. Notice and hearing requirements will be in compliance with the provisions of Chapter 119. of the Revised Code and with any rules adopted by the board.
- (D) No partner, officer or stockholder of a school that is on probation shall be permitted to apply for a certificate of good standing for a new school.

MEMORANDUM

TO: Betty Montgomery, President
Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Controlled Substance Rules, 4731-11-03, 11-04, 11-04.1

DATE: April 8, 2022

Proposed amendments to Rules 4731-11-03, 11-04, and 11-04.1 were circulated to interested parties. A spreadsheet outlining the comments is attached.

I. Rule 4731-11-03

Three comments were received regarding Rule 4731-11-03, Utilization of anabolic steroids, schedule II controlled substance cocaine hydrochloride, and schedule II controlled substance stimulants. I reviewed these comments with Dr. Schottenstein because he had recommended the amendments to this rule.

- John Smith, J.D., Government Relations Coordinator had questions regarding the meaning of the term, mental status examination in section (B)(1)(b). Specifically, he questioned whether there was a standard mental status examination for patients that may be prescribed a stimulant and whether comprehensive neuropsych testing was required.

Recommendation: No change. A mental status examination is the psychological equivalent of the physical examination, including the clinician's observations and impressions of the patient at the time of the interview. Neuropsych testing is not required.

- Lee Reynolds, MD. Of 4KidHelp provided a comment that telehealth should be available for patients with ADD/ADHD being treated with stimulants.

Recommendation: Proposed rules on telehealth as authorized by HB 122 will address this issue.

- Kinsey Jolliff, Principal, Government Relations for The MetroHealth System provided the following recommendations:
 - Add a section requiring a 30-day follow up for the first 90 days and then every 90 days to be consistent with requirements for Schedule III and IV anorexiant since Schedule II drugs have a higher potential for addiction.
- Recommendation: No change. The degree of follow-up should be based on clinician judgment.**
- Questions why Schedule II stimulants may not be used for weight reduction or control but may be used in paragraph (B)(2)(f) for binge eating disorder.

Recommendation: The language in paragraph (B)(2)(f) is based on FDA approval of Vyvanse for the indication of binge eating disorder. Schedule II stimulants are not used for weight reduction or control due to a perceived increased risk of addiction and diversion when prescribed for that indication.

- Concerned with allowing Schedule II stimulant in (B)(2)(e) for the treatment of chronic pain. Use of stimulants for treatment of chronic pain is outdated.

Recommendation: Stimulants are not recommended for primary treatment of pain but may be helpful for the physical and mental health function in patients who are being treated for pain.

II. Rule 4731-11-04

The majority of the comments received were concerning the proposed amendment to Rule 4731-11-04, OAC, and many of the comments addressed the same rule provisions.

- 4731-11-04(B)(1) Delete “caloric restriction” because it is duplicative with nutritional counseling. (Ohio Health Weight Management, Cleveland Clinic). **Recommend this change.**
- 4731-11-04(B)(3)(d) Dr. Lazarus of the Obesity Medicine Association raised issues that BMI is a population based measurement and should not be strictly enforced with the individual and that the language as drafted does not make allowance for on-label use of medication in children, like Saxenda, with is based on BMI percentile. He recommends adding language to allow for clinical discretion whether the benefits of weight loss treatment for the patient would significantly outweigh any risks of the medication being used or adding language that prescribing should be pursuant to guidance from package inserts. Since we are trying to address restrictions from the package inserts for phentermine, I would not recommend adding language regarding package inserts. **I would like feedback from the Board on adding language to allow for clinical discretion related to BMI.**

Dr. Bruce Barker, Ohio Health Weight Management requested adding the following as comorbid risk factors with the BMI of 27: insulin resistance, metabolic syndrome, prediabetes. **I would like feedback from the Board on adding the three co-morbidities.**

- 4731-11-04(B)(3)(f) Delete language prohibiting initiation of treatment with a controlled substance if the patient was unsuccessful in previous attempts to lose weight. (Obesity Medicine Association, Obesity Action Coalition, Ohio Health Weight Management, Ohio State Medical Association, and Angela Fitch, MD) **Recommend this change.**
- 4731-11-04(C)(1) Delete the requirement for an assessment every thirty days for the first three months of utilization of controlled substances for weight reduction. (Obesity Action Coalition, Academy of Medicine of Cleveland and Northern Ohio, Cleveland Clinic, Angela Fitch, MD, Ohio State Medical Association, and Obesity Society) **Recommend this change, but would like feedback from the Board.**

- 4731-11-04(C)(2) Delete the requirement to limit prescriptions to 30 days. Language regarding personally furnishing needs updated to accurately reflect the language of Section 4729.291 of the Revised Code which places restrictions on the aggregate and individual amounts of controlled substances that can be personally furnished. (Academy of Medicine of Cleveland and Northern Ohio, American Society of Bariatric and Metabolic Surgery, Cleveland Clinic, Angela Fitch, MD, MetroHealth System, The Obesity Society, University Hospitals) **Recommend this change with the following updated language:**

The prescriber shall ~~not personally furnish or prescribe more than a 30-day supply of~~ controlled substances, ~~at one time,~~ for weight reduction or chronic weight management only in accordance with section 4729.291 of the revised code. For any controlled substance that is personally furnished to or for patients, taken as a whole, the prescriber shall not exceed a total of two thousand five hundred dosage units in any thirty-day period and for an individual patient, shall not in any seventy-two hour period, personally furnish an amount that exceeds the amount necessary for that patient's use in a seventy-two hour period. Dosage unit means any of the following:

- (a) A single pill, capsule, ampule, or tablet;
- (b) In the case of a liquid solution, one milliliter;
- (c) In the case of a cream, lotion, or gel, one gram; or
- (d) Any other form of administration available as a single unit.

- 4731-11-04(C)(4)(a) Several comments recommended the addition of language that would allow the assessments to be conducted via telemedicine. (Obesity Action Coalition, Academy of Medicine of Cleveland, and Northern Ohio, American Society of Bariatric and Metabolic Surgery, American Society of Bariatric and metabolic Surgery, Cleveland Clinic, Angela Fitch, MD, Ohio State Medical Association, and The Obesity Society). **Rules 4731-11-09 and 4731-37-01 will specifically address telemedicine, but a change is recommended to replace the word, "check" with "obtain" to allow the patient's weight, blood pressure, pulse, heart, and lung assessment to be completed through remote monitoring.**
- 4731-11-04(C)(4)(b) Several comments recommended the elimination of the requirement to continue to lose weight or to maintain a goal weight as these concepts are not consistent with the treatment of obesity as a chronic, progressive disease. (Obesity Medicine Association, Ohio Health Weight Management, Cleveland Clinic, Angela Fitch, MD, and The Obesity Society). **Recommend use of the suggested revised language set forth below:**

For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must maintain a 5% weight reduction ~~continue to lose weight during the active weight reduction treatment or maintain goal weight.~~ The prescriber shall document the patient's weight loss or maintenance in the record.

- 4731-11-04(C)(5)(c) Several comments recommended modification of this language to eliminate the thirty day timeframe and to eliminate weighing the patient at least every thirty days. (Obesity Medicine Association, Academy of medicine of Cleveland and Northern Ohio, Ohio Health Weight Management, Cleveland Clinic, Angela Fitch, MD, The Obesity Society)

Recommend use of the suggested revised language as set forth below:

That the patient has not responded by achieving less than 5% weight reduction after three months ~~failed to lose weight~~ while under treatment with a controlled substance or controlled substances ~~for weight reduction 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;~~

Requested Action: Discuss the rule comments and approve any amendments. Approve filing rules, as amended, with the Common Sense Initiative.

Name	Organization	Summary of comment	Recommendation
Ethan Lazarus, MD	Obesity Medicine Association	Obesity has been recognized as a chronic disease by the AMA since 2013 and should be treated the same as other diseases such as hypertension and Type 2 diabetes. The rule draft is a step in the right direction, but has concerns. 4731-11-04(B)(3)(d) : BMI is a population-based measurement and should not be strictly enforced with the individual patient. The language as drafted does not make allowance for on-label use of medication in children, like Saxenda, which is based on BMI percentile, not BMI. Recommends adding language "or the benefits of weight loss treatment for the patient would significantly outweigh any risks of the medication being used" or "pursuant to guidance from package inserts." 4731-11-04(B)(3)(f) : The language is castigatory, blaming the patient for the disease of obesity and should be removed. Past poor performance does not indicate that the patient can't do well moving forward. Under this language, the patient gets one shot at treating obesity and if they don't do well, cannot be treated again. 4731-11-04(C)(3) : Some patients with the most severe obesity do not lose 5% or more body weight within the first three months. Qsymia package insert states that it can be continued if at 3 months the patient has lost 3% or more. Recommends adding language that in the event 5% weight loss is not achieved within 3 months, the provider should document pros and cons of continuing medication to see if 5% can be achieved at 6 months. 4731-11-04(C)(4)(b) : Recommends striking this language because it is inconsistent with the disease of obesity as a chronic progressive disease. Also, the concept of "goal weight" is a myth and should be retired. 4731-11-04(C)(5) : Recommends clarifying that weight loss program would be discontinued if the patient made a false or misleading statement regarding the patient's use of other stimulants, whether prescription or illicit. 4731-11-04(C)(5)(c) : Recommends striking this language. 4731-11-04(C)(5)(f) : Recommends striking this language because it is duplicative.	Delete language in 4731-11-04(B)(3)(f). Modify language in 4731-11-04(C)(4)(b) to eliminate the requirement to continue to lose weight or to maintain a goal weight. Recommend requiring patient to maintain a 5% weight reduction. Recommend modification of language in 4731-11-04(C)(5)(c) that the patient has "not responded by achieving less than 5% weight reduction after three months while under treatment with a controlled substance or controlled substances.
Joe Nadglowski	Obesity Action Coalition	4731-11-04(C)(1) : Monthly assessment is not necessary. Patients with chronic diseases like obesity are typically assessed every 2-3 months. 4731-11-04(C)(3) : Recommend changing language to encourage the patient to maintain 5% weight reduction. With a growing understanding of obesity, it is difficult to mandate that patients must continue to lose weight or achieve their goal weight to continue on anti-obesity medication. This is treating obesity different than other chronic diseases, such as high blood pressure or high cholesterol. 4731-11-04(C)(4)(a) : Agree with the assessment at least every three months, but telemedicine should be an option. 4731-11-04(B)(3)(f) : Language is castigatory and stigmatizing and should be removed. Past poor performance is not an indication that the patient can't do well moving forward.	Change 4731-11-04(C)(1) that assessment is once in the first 3 months. 4731-11-04(C)(4)(a) assessments may be able to be completed via telemedicine pursuant to Rules 4731-37-01 and 4731-11-09. See above regarding deletion of language in 4731-11-04(B)(3)(f).
Kristin Englund, MD, MLS	Academy of Medicine of Cleveland and Northern Ohio	4731-11-04(C)(1) : Monthly assessments are not necessary. Recommend that the prescriber follow up with the patient once in the first three months of treatment. 4731-11-04(C)(2) : Phentermine should not be restricted to a 30 day prescription. 4731-11-04(C)(4)(a) : Patients do not need to be seen monthly while on phentermine. Patient may use heart rate and blood pressure monitors at home and alert provider if concerns arise. 4731-11-04(C)(5)(c) : Patients do not need to be weighed by the physician every 30 days. Each patient responds differently to medication and should be assessed on an individual basis by the provider. Care can be delivered through telemedicine.	Change 4731-11-04(C)(1) that assessment is once in the first 3 months. Delete "or prescribe" in 4731-11-04(C)(2). 4731-11-04(C)(4)(a) assessments may be able to be completed via telemedicine pursuant to Rules 4731-37-01 and 4731-11-09. See above regarding deletion of language in 4731-11-04(B)(3). Modify language in 4731-11-04(C)(5)(c) to eliminate requirement for weighing patient every thirty days.
Sergio J. Bardaro, MD	Ohio/Kentucky Chapter of American Society of Bariatric and Metabolic Surgery	4731-11-04(C)(1) : Monthly assessment is not necessary. Typical follow up is every 2-3 months. 4731-11-04(C)(2) : Eliminate the word "prescribe" so that the 30 day limitation applies only to personally furnishing of phentermine. 4731-11-04(C)(4)(a) : Add language that telemedicine may be used to assess the patient in lieu of a face-to-face encounter when clinically appropriate. 4731-11-04(C)(4)(b) : Recommend changing language to read, "For the continuation of Schedule III or IV controlled substances designated for the treatment of obesity beyond three months, the patient must maintain a 5% weight reduction." It is difficult to mandate that patients must continue to lose weight or achieve their goal weight. 4731-11-04(B)(3)(f) : The language "indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program" is castigatory and stigmatizing and should be removed. Under this language, the patient has one chance to treat obesity and if they don't do well, are barred from being treated again.	Recommend making all suggested changes.
Bernard Lenchitz	University of Cincinnati	Supports the proposed rule that eliminates the 12 week restriction on phentermine.	

Bruce Barker, MD	Ohio Health Weight Management	4731-11-04(B)(1): Recommends removal of caloric restriction. It is redundant with nutritional counseling. 4731-11-04(B)(3)(d): See Dr. Lazarus comment, above. 4731-11-04(B)(3)(f): Language is derogatory and weight biased, blaming the patient for the disease of obesity. Past poor performance does not indicate patient cannot do well moving forward. 4731-11-04(C)(3): See Dr. Lazarus comment, above. 4731-11-04(B)(3)(d): comorbid risk factors with BMI of 27 should also include insulin resistance, metabolic syndrome, prediabetes. 4731-11-04(C)(4)(b): See Dr. Lazarus comment, above. 4731-11-04(C)(5): See Dr. Lazarus comment, above. 4731-11-04(C)(5)(c): No other drug class prohibits pursuing further treatment on the basis of a treatment failure. The process of determining the most effective tool strategy often takes time and multiple trials. Combination therapies are commonly required. This statement should be removed in its entirety. 4731-11-04(C)(5)(f): This statement is duplicative. Sent a separate comment to proposed telehealth rules and indicates that follow up visits for treating chronic obesity can be done via telehealth.	Recommend removal of "caloric restriction" in 4731-11-04(B)(1). Obtain Board feedback on adding insulin resistance, metabolic syndrome and prediabetes to the co-morbid conditions in paragraph (B)(3)(d).
Barto Burguera, MD, PH.D, Diana Issaacs, PharmD, Marcio Griebeler, MD, W. Scott Butsch, MD, Roy Kim, MD	Cleveland Clinic	4731-11-04(B)(3)(e): Recommend deletion of the reference to caloric restrict as duplicative as the concept is embedded in nutritional counseling and intensive behavioral therapy. 4731-11-04(C)(1): Monthly assessments are not necessary and the language should be changed so that the prescriber shall assess the patient once in the first three months of utilization of controlled substances. 4731-11-04(C)(2): Strike the words, "prescribe". Anti-obesity medication are commonly prescribed with a 30 day prescription with two refills. 4731-11-04(C)(4)(a): See Dr. Englund comments, above. 4731-11-04(C)(4)(b): Disagree with the statement, "the patients must continue to lose weight" and "maintain goal weight" as it fails to recognize the multifactorial nature of weight loss. Recommend changing the language to, "For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must maintain a 5% weight reduction. 4731-11-04(C)(5)(c): Concerned that the patient may be removed from Anti Obesity Medication if they do not lose weight. There are other variables that cause weight gain and some patients are rapidly gaining weight prior to starting an AOM and the AOM may lead to weight stabilization. Recommend the deletion of this language.	Recommend acceptance of all suggested changes.
Angela Fitch, MD	Harvard Medical School, Massachusetts General Hospital Weight Center, Obesity Medicine Association	Comments substantially similar to those from Cleveland Clinic, above.	Recommend acceptance of all suggested changes.
Jennifer Hayhurst	Ohio State Medical Association	Comments substantially similar to those from Obesity Action Coalition, above.	See Obesity Action Coalition, above.
Kinsey Jolliff	MetroHealth System	4731-11-03: Recommend adding a section requiring 30 day follow up for first 90 days and then every 90 days to be consistent with rules for Schedule II and IV anorexians. Schedule II medications in this rule have a higher potential for addiction and no follow up is proposed. Is there inconsistency with 4731-11-03(A)(3)(a) and (B)(2)(f)? 4731-11-03(B)(2)(e): Concerned with indications for schedule II stimulant for chronic pain is long outdated and a schedule II stimulant should not have a primary role as adjunctive therapy for chronic pain treatment. 4731-11-04(C)(2): Need clarification on the personally furnishing limits.	Changes to 4731-11-03 not recommended. Recommend clarification of language so that it matches 4729.291.

[illegible]

2/12/2022

State Medical Board of Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 42315
(614) 466-3934
www.med.ohio.gov

Dear members of the Ohio Medical Board:

Thank you for the opportunity to review proposed rule 4731-11-04. In opening, I like medical boards to consider that obesity has been recognized as a chronic disease by our American Medical Association in 2013, to be treated the same as other diseases such as hypertension and type 2 diabetes. I was personally involved in the passing of that resolution, and I was the author of the later resolution calling on the AMA to help remove barriers to treatment so that physicians can practice the current standard of care with regards to the treatment of obesity without fear of reprisal.

I appreciate the State's concerns regarding mis-use of older medications due to the fact that they are Schedule IV controlled substances; however, as you review your rules, please consider the following question – would you have the same rule in place for a disease such as diabetes or hypertension? Also, will the rule improve the care the patient receives, or will it be a barrier for them to receive treatment?

With that in mind, this proposed rule represents a good step in the right direction. In particular, eliminating the rule to only use medication short-term for a chronic condition is extremely helpful, and allows the current standard of care to be provided for many more Ohio patients living with obesity.

That being said, I do have several concerns with the proposed language where I think it is overly prescriptive and will still represent a barrier to care for many patients, particularly with those with difficult to treat obesity.

Item B (3) (d) – BMI is intended as a population-based measurement, and should not be strictly enforced with the individual patient. This language could be improved by adding language to the effect that “or the benefits of weight loss treatment for the patient would significantly outweigh any risks of the medication being used.” Further, this does not make allowance for on-label use of current or future medications in kids, where it is based on BMI percentile, not BMI (see Saxenda label, for example). You could address this with additional language, “Or pursuant to guidance from package inserts.”

Item B (3) (f) This language is very castigatory, blaming the patient for the disease of obesity. It has no place in a medical board rule and should be removed. Past poor performance does not indicate the patient can't do well moving forward. Under this rule, a patient gets one shot at treating their obesity, and if they don't do well, is barred from ever being treated again.

Item C (3) While we desire all patients to lose 5% or more body weight within the first 3 months, some of the patients with the most severe obesity do not. Oftentimes we can simply stop weight gain, or are lucky to achieve any weight loss. Even the PI for Qsymia states that it can be continued if at 3 months the patient has lost 3% or more, or that if the response is less than 3%, the medication dose can be increased from 7.5 mg phentermine to 15 mg phentermine. You could add language that in the event 5% weight loss is not achieved within 3 months, the provider document pros and cons of continuing medication to see if 5% can be achieved at 6 months, if there is a compelling reason why the benefits outweigh the risks of continuing treatment, or can change the treatment (phentermine to diethylpropion), augment treatment (add topiramate), raise dose (from 8 or 15 mg to 30 or 37.5 mg), etc. This language is overly prescriptive and will result in the more complex patient not being able to continue on treatment.

Item C (4) (b) – this language is not consistent with how the disease of obesity acts. Obesity is a chronic progressive disease. Virtually everybody that successfully loses weight regains it over time. However, they will sustain a percentage weight loss vs. where they would have been untreated. For example, if you treat a patient who is 200 pounds and they lose 10% of their weight in the first 6 months and sustain that for 6 more, they will be 180 pounds at the end of the year. But most slowly gain weight – 1-2 pounds per year. Within 10 years, they will likely be back up to 200 pounds. Conversely, were they not treated, they would gain a similar amount of weight and now be 220 pounds. A requirement to sustain weight loss is not consistent even with the newest medications like Saxenda, where in their 3 year trial patients regained about 1/4th of the weight that was lost. Even bariatric surgical patients regaine about 1/3rd of the lost weight.

Further, there is no “goal weight.” This is a myth that should be retired. I encourage you to strike item C (4) (b) as it will result in all treated patients having their treatment stopped. When treatment is stopped, weight regain is quite rapid posing further risks to the person's health.

Item C (5) – Why would you need to stop a weight loss program due to alcohol use? These do not appear related. Further “Drugs” is non-specific – I'd clarify – “other stimulants, whether prescription or illicit.”

Item C (5) (c) – see above. This language should be stricken.



Item C (5) (f) – duplicative – language already included above.

I hope you find these comments helpful, and applaud you for allowing Ohio patients to receive the current standard of care with regards to the treatment of obesity.

Sincerely,

A handwritten signature in blue ink, appearing to read "E. Lazarus MD". The signature is fluid and cursive, with a large initial "E" and "L".

Ethan Lazarus, MD
President, Obesity Medicine Association



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(813) 872-7835
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info@obesityaction.org
www.ObesityAction.org

March 1, 2022

Ms. Kimberly Anderson, Esq.
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Rule: 4731-11-04

Submitted electronically via Kimberly.Anderson@med.ohio.gov

Dear Ms. Anderson:

Throughout the past decades, the prevalence of obesity skyrocketed across our country – with more than 35% of Ohioans now affected by obesity. Despite this fact, many policymakers continue to view obesity as a lifestyle choice or personal failing. Others acknowledge that obesity is a chronic and complex disease, but they believe that all that's needed is more robust prevention. These perceptions and attitudes, coupled with bias and stigma, have resulted in health plans and state medical boards taking vastly different approaches in determining what and how obesity treatment services are available or covered for those affected by this complex and chronic disease. As a nation, we must move to eliminate arbitrary, random and unscientific barriers to care – both for the long term and immediate health of those affected by obesity!

For these reasons, the Obesity Action Coalition (OAC), a national non-profit organization dedicated to giving a voice to the individual affected by the disease of obesity, is pleased to comment on the State Medical Board of Ohio's (SMBO) published proposed rules (4731-11-04), entitled "Controlled substances for the treatment of obesity."

The proposed rule represents a positive step toward eliminating the old regulations that limited medication to short-term use — especially given that obesity is a chronic disease, and this change now allows the current standard of care to be provided for many more Ohioans living with obesity. We would especially like to thank Dr. Amol Soin, Chair of the Board's Policy Committee, who convened a lengthy listening session with numerous stakeholders from the obesity community to learn more about the current standard of care surrounding obesity pharmacotherapy.

While we are pleased with the new content of the regulation, we are concerned that some of the proposed language is still overly prescriptive and will continue to present barriers to care for many patients, particularly those with difficulty to treat obesity. For example, the requirement for monthly assessments, adoption of disparate chronic disease management outcomes and discontinuation of telemedicine options for monitoring care could become avenues for health plans to restrict patient access to obesity treatment.

Monthly Assessment of Patients

When treating chronic diseases like obesity with pharmacotherapy, patients are typically educated on risks and benefits of medications and assessed every 2-3 months. Potential adverse effects are often reviewed by the patient, in conjunction with the provider and the pharmacist, and concerns are typically communicated in a fashion like any other chronic disease. There is no reason to treat obesity differently and have patients be assessed monthly.

Disparate Outcomes for Chronic Disease Management

The regulation states that the patient “must continue to lose weight during the active weight reduction treatment or maintain goal weight.” We would suggest changing that language to encouraging the patient to maintain a 5% weight reduction. Given our growing understanding of obesity, it is difficult to mandate that patients must continue to lose weight or achieve their goal weight to continue an anti-obesity medication (AOM). When trying to optimize a patient’s blood pressure or cholesterol with a single pharmacological agent, we will typically not stop the initial medication if the target blood pressure or LDL is not achieved. In fact, physicians would consider adding a second agent, and often more than one medication is needed to optimize blood pressure. It should be no different with obesity and the continuation of an AOM should be based on its ability to achieve a 5% weight reduction.

Supporting the Continued Broad Application of Telemedicine

We agree that patients with obesity on phentermine should be assessed every three months. However, newly adapted technology such as virtual encounters via telemedicine, which has become broadly adopted because of the COVID-19 public health emergency, should remain as an option for these quarterly encounters. Patients with obesity already experience numerous barriers to appropriate care because of weight bias and stigma. For example, studies show that individuals with obesity receive less time with a physician compared to individuals who are not affected by obesity. This bias can also lead to inaccurate assessments because of lack of size-appropriate diagnostic tools such as poorly fitting blood pressure cuffs, imaging equipment or examination tables. And, while there is no specific language in this section stating the ability to use telemedicine, we are concerned that the inclusion of “pulse, heart and lungs” will be interpreted by health plans as a requirement for an in-person clinical encounter.

Elimination of Stigmatizing Language

Finally, we are troubled that the regulation states that the prescriber shall not initiate treatment utilizing a controlled substance for the treatment of obesity upon ascertaining or having reason to believe that “the review of the prescriber's own records of prior treatment or review of records of prior treatment provided by another physician, prescriber, dietitian, or weight-loss program **indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program...**”

This language is very castigatory and stigmatizing. **Blaming a patient for struggling to address their chronic disease of obesity has no place in a medical board regulation and should be removed.** Past poor performance does not indicate the patient can’t do well moving forward. Under this rule, a patient gets one chance at treating their obesity, and if they don’t do well they could be barred from ever being treated again.

Again, OAC appreciates the hard work and stakeholder engagement that the state medical board conducted to greatly improve the Ohio prescribing regulations pertaining to controlled substances for management of obesity. We look forward to continuing this dialogue with the board and are happy to serve as a resource on issues affecting patient access to care.

Sincerely,



Joe Nadglowski, OAC President and CEO



March 1, 2022

Kimberly Anderson
Chief Legal Counsel
Ohio State Medical Board
30 E. Broad St., 30th Floor
Columbus, OH 43215

RE: Rule 4731-11-04

Dear Ms. Anderson:

Thank you for the opportunity to comment on Rule 4731-11-04. We appreciate the ongoing discussion the board has had on this issue with interested parties.

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), founded in 1824, is the region's professional medical association, and the oldest professional association in Ohio. We are a non-profit 501(c)6 representing physicians and medical students from all the contiguous counties in Northern Ohio. We are proud to be the stewards of Cleveland's medical community of the past, present and future.

The mission of the Academy of Medicine of Cleveland & Northern Ohio is to support physicians in being strong advocates for all patients and promote the practice of the highest quality of medicine. With that in mind, we offer the following comments.

Proposed Language: C(1)

The prescriber shall assess the patient, at a minimum, every thirty days for the first three months of utilization of controlled substances 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.

We believe that obesity should be treated as a chronic illness, and therefore would recommend that the prescriber follow-up once with the patient in the first three months of treatment, versus the proposed monthly requirement. We also believe this will help expand access to treatment for individuals who may have restrictions in accessing their provider three times in the first three months of treatment.

Proposed Language: C(2)

The prescriber shall not personally furnish or prescribe more than a 30-day supply of controlled substances, at one time, for weight reduction or chronic weight management.

We do not believe phentermine for the purpose of weight loss should be restricted to 30-days. Many patients need to continue this medication to aid in weight loss, and the 30-day requirement causes undue burden to the prescriber and could hinder patient access to the medication.

Proposed Language: C(4)(a)

The prescriber shall assess the patient at least once every three months and shall check the patient's weight, blood pressure, pulse, heart and lungs. The findings shall be entered in the patient's record.

As stated previously we do not believe patients need to be seen monthly while on phentermine. Providers are responsible for communicating risks of any prescription medication to patients, and the patient can reach out to their provider should any concerns arise while taking a medication. Additionally, many patients now use heart rate and blood pressure monitors at home which can help assist in determining the presences of uncommon side effect with this medication.

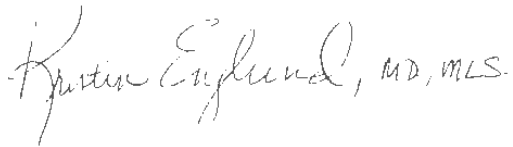
Proposed Language: C(5)(c)

That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances for weight reduction 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;

Again, we do not believe patients need to be seen in person to be weighed by the provider at every 30 days while on these medications. Each patient responds differently to medication and should be assessed on an individual basis by the provider. We also believe assessing weight and assuming weight loss is consistent does not consider the physiological response known as metabolic adaptation that occurs with weight loss. Additionally, with the improvements offered via telemedicine, much of the care delivered can be done remotely, helping to increase access to patients suffering from obesity.

Thank you again for the opportunity to provide comment.

A handwritten signature in black ink that reads "Kristin Englund, MD, MLS". The signature is written in a cursive, flowing style.

Kristin Englund, MD, MLS
President, AMCNO



ASMBS OHIO/KENTUCKY CHAPTER

March 1, 2022

Ms. Kimberly Anderson, Esq.
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Rule: 4731-11-04

Submitted electronically via Kimberly.Anderson@med.ohio.gov

Dear Ms. Anderson:

The Ohio/Kentucky State Chapter of the American Society for Metabolic and Bariatric Surgery (ASMBS) is pleased to comment on the State Medical Board of Ohio's (SMBO) published proposed rules (4731-11-04), entitled "Controlled substances for the treatment of obesity." The proposed rule represents a positive step in the right direction by eliminating the old regulations that limited medication to short-term use — especially given that obesity is a chronic disease, and this change will now allow the current standard of care to be provided for many more Ohioans living with obesity. We would especially like to thank Dr. Amol Soini, Chair of the Board's Policy Committee who convened a lengthy listening session with numerous stakeholders from the obesity community to learn more about the current standard of care surrounding obesity pharmacotherapy. While we are pleased with the new content of the regulation, we do have a number of concerns that the proposed language is still overly prescriptive and will continue to present barriers to care for many patients, particularly those with difficult to treat obesity.

Throughout the past decades, the prevalence of obesity has skyrocketed across our country — with more than 35 percent of Ohioans now affected by obesity. Despite this fact, many policymakers continue to view obesity as a lifestyle choice or personal failing. Others acknowledge that obesity is a chronic and complex disease, but they believe that all that's needed is more robust prevention. These perceptions and attitudes, coupled with bias and stigma, have resulted in health plans and state medical boards taking vastly different approaches in determining what and how obesity treatment services are available or covered for those affected by this complex and chronic disease. As a nation we must move to eliminate arbitrary, random and unscientific barriers to care — both for the long term and immediate health of those affected by obesity!



ASMBS OHIO/KENTUCKY CHAPTER

Monthly Assessment of Patients: We disagree with the need for the prescriber to assess the patient every thirty days for the first three months of the utilization of a controlled substance. When treating chronic diseases like obesity with pharmacotherapy, patients are typically educated on risks and benefits of medications and assessed every 2-3 months. Potential adverse effects are often reviewed by the patient, in conjunction with the provider and the pharmacist, and concerns are typically communicated in a fashion like any other chronic disease. There is no reason to treat obesity differently and have patients be assessed monthly. We understand the trepidation about controlled substances, but these concerns are not warranted with this medication and therefore monthly follow-up is not needed during the first three months.

Regulation of Physicians or Clinics that furnish Phentermine: The regulation states that “the prescriber shall not personally furnish or prescribe more than a 30-day supply of controlled substances, at one time, for weight reduction or chronic weight management.” We suggest striking the words “or prescribe” from the current regulatory language so that the language only pertains to the limitation of furnishing this medication.

We agree that there should be language in the rule that regulates those physicians or clinics that furnish phentermine. However, we disagree with the restriction on prescribing this medication as we maintain that phentermine is not an addictive-controlled substance and is already being prescribed in prescriptions for more than thirty days (i.e. 30 days Rx with refills) for the treatment of obesity when in combination with topiramate (brand name Qsymia), an FDA-approved anti-obesity medication for chronic weight management.

Supporting the Continued Broad Application of Telemedicine: The regulation states that “the prescriber shall assess the patient at least once every three months and shall check the patient’s weight, blood pressure, pulse, heart and lungs. The findings shall be entered in the patient’s record.” We suggest that an additional line be added to the current regulatory language which states, “Telemedicine may be used to assess the patient if lieu of a face-to-face encounter when clinically appropriate.”

We agree that patients with obesity on phentermine should be assessed every three months. However, we believe newly adapted technology such as virtual encounters via telemedicine, which has become broadly adopted because of the COVID-19 public health emergency, should remain as an option for these quarterly encounters. Patients with obesity already experience numerous barriers to appropriate care because of weight bias and stigma. For example, studies show that individuals with obesity receive less time with a physician compared to individuals who are not affected by obesity. This bias can also lead to inaccurate assessments because of lack of size-appropriate diagnostic tools such as poorly fitting blood pressure cuffs, imaging



ASMBS OHIO/KENTUCKY CHAPTER

equipment or examination tables. And, while there is no specific language in this section stating the ability to use telemedicine, we are concerned that the inclusion of “pulse, heart and lungs” hints at the need for an in-person clinical encounter.

Disparate Outcomes for Obesity Treatment: The regulation states that “for the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must continue to lose weight during the active weight reduction treatment or maintain goal weight. The prescriber shall document the patient’s weight loss or maintenance in the record”

We suggest the language read: “For the continuation of Schedule III or IV controlled substances designated for the treatment of obesity beyond three months, the patient must maintain a 5% weight reduction.” Given our growing understanding of obesity, it is difficult to mandate that patients must continue to lose weight or achieve their goal weight in order to continue an anti-obesity medication (AOM). Similar to other chronic diseases like hypertension, dyslipidemia and diabetes, obesity often requires a multi-modal treatment regimen and improvement is not always linear in achieving remission. Saying that a patient must “must continue to lose weight” and “maintain goal weight” assumes that weight loss continues without stabilization (e.g., metabolic adaptation) and that goal weights are achieved with monotherapy. When trying to optimize a patient’s blood pressure or cholesterol with a single pharmacological agent, we typically will not stop the initial medication if the target blood pressure or LDL is not achieved. In fact, we would consider adding a second agent, and often more than one medication is needed to optimize blood pressure. It should be no different with obesity and the continuation of an AOM should be based on its ability to achieve a 5% weight reduction.

Elimination of Stigmatizing Language: The regulation states that the prescriber shall not initiate treatment utilizing a controlled substance for the treatment of obesity upon ascertaining or having reason to believe that “the review of the prescriber's own records of prior treatment or review of records of prior treatment provided by another physician, prescriber, dietitian, or weight-loss program **indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program** utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substances.

This language is very castigatory and stigmatizing. **Blaming a patient for struggling to address their chronic disease of obesity has no place in a medical board regulation and should be removed.** Past poor performance does not indicate the patient can’t do well moving forward. Under this rule, a patient gets one chance at treating their obesity, and if they don’t do well, is barred from ever being treated again.



ASMBS OHIO/KENTUCKY CHAPTER

Again, the Ohio/Kentucky ASMBS State Chapter appreciates the opportunity to comment on this critical issue. Should you have any questions, please feel free to contact me via email at sbardaro@metrohealth.org. Thank you.

Sincerely,

Sergio J. Bardaro, MD, FACS, FASMBS

President, Ohio/Kentucky Chapter - American Society of Bariatric and Metabolic Surgery

From: [Lenchitz, Bernard \(lenchib\)](#)
To: [Anderson, Kimberly](#)
Subject: RE: February eNews from the State Medical Board of Ohio
Date: Friday, February 18, 2022 2:44:59 PM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)

My comment:

I support this

From: Kimberly.Anderson@med.ohio.gov <Kimberly.Anderson@med.ohio.gov>
Sent: Friday, February 18, 2022 2:44 PM
To: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Subject: RE: February eNews from the State Medical Board of Ohio

Yes, that is the proposal.

Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
o: 614-466-7207
c: 614-230-9077
Kimberly.Anderson@med.ohio.gov



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From: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Sent: Friday, February 18, 2022 2:42 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: RE: February eNews from the State Medical Board of Ohio

I need help in interpreting before I can comment

Here is my question

Assuming all other requirements are met, will the 12 week restriction on phentermine be eliminated under the new regulations?

From: Kimberly.Anderson@med.ohio.gov <Kimberly.Anderson@med.ohio.gov>

Sent: Friday, February 18, 2022 2:35 PM

To: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>

Subject: RE: February eNews from the State Medical Board of Ohio

Dr. Lenchitz,

The full text of the proposed rules are available on the Board's website. I have also attached them to this e-mail. The Medical Board would appreciate any written comments that you may have on these rules. You can send those comments to me at the e-mail address below and I will present those comments to the Board. Please let me know if you have additional questions.

Kimberly Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
o: 614-466-7207
c: 614-230-9077
Kimberly.Anderson@med.ohio.gov



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From: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>

Sent: Friday, February 18, 2022 1:04 PM

To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>

Subject: FW: February eNews from the State Medical Board of Ohio

Hi Ms Anderson:

Would you have a few moments to clarify the proposals below:

4731-11-03 Utilization of anabolic steroids, schedule II controlled substance cocaine hydrochloride, and schedule II controlled substance stimulants *Propose to Amend*

4731-11-04 Controlled substances: Utilization of short term anorexiant for weight reduction *Propose to Rescind*

4731-11-04 Controlled substances for the treatment of obesity *Proposed New Rule*

4731-11-04.1 Controlled substances: Utilization for chronic weight management *Propose to Rescind*

If so, what is best way to communicate?

Bernard Lenchitz MD FACP
Professor of Clinical Medicine
University of Cincinnati College of Medicine/Academic Health Center
231 Albert Sabin Way, Room 7559
ML 0535
Cincinnati, OH 45267-0535
Phone 513-558-7581
Fax 513-558-4399

Vice President, Primary Care Network
UC Health - University of Cincinnati Physicians
2830 Victory Parkway
Cincinnati, OH 45206

UCPhysicians
425 Walnut St.
Suite 200
Cincinnati Ohio 45202
Phone 513-475-7676 and fax 513-381-1830
Cell phone 513 909 5488

email:bernard.lenchitz@uc.edu

CAUTION: This is an external email and may not be safe. If the email looks suspicious, please do not click links or open attachments and forward the email to csc@ohio.gov or click the Phish Alert Button if available.

2/24/2022

State Medical Board of Ohio

Attn: Kimberly Anderson

30 E. Broad St., 3rd Floor

Columbus, Ohio 42315

(614) 466-3934

www.med.ohio.gov

Dear members of the Ohio Medical Board:

Thank you for the opportunity to review proposed rule 4731-11-04. In opening, I would like to thank the medical board for taking steps to treat obesity as a chronic progressive disease. Obesity has been recognized as a chronic disease by the American Medical Association in 2013, to be treated the same as other diseases such as hypertension and type 2 diabetes. The AMA members have pursued legislation to help remove barriers to treatment so that physicians can practice the current standard of care with regards to the treatment of obesity without fear of reprisal.

I appreciate the State's concerns regarding mis-use of older medications due to the fact that they are Schedule IV controlled substances; however, as you review your rules, please consider the following question – would you have the same rule in place for a disease such as diabetes or hypertension? Also, will the rule improve the care the patient receives, or will it be a barrier for them to receive treatment?

With that in mind, this proposed rule represents a good step in the right direction. In particular, eliminating the rule to only use medication short-term for a chronic condition is extremely helpful, and allows the current standard of care to be provided for many more Ohio patients living with obesity.

That being said, I do have several concerns with the proposed language where I think it is overly prescriptive and will still represent a barrier to care for many patients, particularly with those with difficult to treat obesity.

Item B (1) - Caloric restriction should be removed. This is redundant with the nutritional counseling as this is the method or methods utilized to obtain caloric restriction.

Item B (3) (d) – BMI is intended as a population-based measurement, and should not be strictly enforced with the individual patient. This language could be improved by adding language to the effect that “or the benefits of weight loss treatment for the patient would significantly outweigh any risks of the medication being used.” Further, this does not make allowance for on-label use of current or future medications in children, where it is based on BMI percentile, not BMI (see Saxenda label, for example). You could address this with additional language, “Or pursuant to guidance from package inserts.”

Item B (3) (f) -This language is very derogatory and frankly weight biased, blaming the patient for the disease of obesity. Past poor performance does not indicate the patient can't do well moving forward. Under this rule, a patient gets one shot at treating their obesity, and if they don't do well, is barred from ever being treated again.

Item C (3) While we desire all patients to lose 5% or more body weight within the first 3 months, some of the patients with the most severe obesity do not. Oftentimes we can simply stop weight gain, or are lucky to achieve any weight loss. Even the PI for Qsymia states that it can be continued if at 3 months the patient has lost 3% or more, or that if the response is less than 3%, the medication dose can be increased from 7.5 mg phentermine to 15 mg phentermine. You could add language that in the event 5% weight loss is not achieved within 3 months, the provider document pros and cons of continuing medication to see if 5% can be achieved at 6 months, if there is a compelling reason why the benefits outweigh the risks of continuing treatment, or can change the treatment (phentermine to diethylpropion), augment treatment (add topiramate), raise dose (from 8 or 15 mg to 30 or 37.5 mg), etc. This language is overly prescriptive and will result in the more complex patient not being able to continue on treatment.

Item 3(d) The co-morbid risk factors for use with a bmi 27 should also include insulin resistance and metabolic syndrome as well as prediabetes. These processes are directly tied to the weight gaining process for many patients and subsequently lead to type 2 diabetes in time. Failing to include this set of diagnoses will preclude a large set of eligible patients that would benefit greatly from treatment until their disease of obesity progresses to the bmi of 30 or they develop the later consequence of type 2 diabetes and all the increased risk factors that accompany it. It would make much more sense to begin treatment earlier in the disease process when it is more amenable to therapy. The other approach is akin to waiting to treat someone's hypertension or hyperlipidemia until they have their myocardial infarction.

Item C (4) (b) – this language is not consistent with how the disease of obesity acts. Obesity is a chronic progressive disease. Virtually everybody that successfully loses weight regains it over time. However, they will sustain a percentage weight loss vs. where they would have been untreated. For example, if you treat a patient who is 200 pounds and they lose 10% of their weight in the first 6 months and sustain that for 6 more, they will be 180 pounds at the end of the year. But most slowly gain weight – 1-2 pounds per year. Within 10 years, they will likely be back up to 200 pounds. Conversely, were they not treated, they would gain a similar amount of weight and now be 220 pounds. A requirement to sustain weight loss is not consistent even with the newest medications like Saxenda, where in their 3 year trial patients re-gained about 1/4th of the weight that was lost. Even bariatric surgical patients re-gain about 1/3rd of the lost weight.

Further, there is no “goal weight.” This is a myth that should be retired. I encourage you to strike item C (4) (b) as it will result in all treated patients having their treatment stopped.

When treatment is stopped, weight regain is quite rapid posing further risks to the person’s health.

Item C (5) – Why would you need to stop a weight loss program due to alcohol use? These do not appear related. Further “Drugs” is non-specific – I’d clarify – “other stimulants, whether prescription or illicit.”

Item C (5) (c) – NO OTHER DRUG CLASS CONTROLLED OR OTHERWISE PROHIBITS PURSUING FURTHER TREATMENT ON THE BASIS OF A TREATMENT FAILURE. THE PROCESS OF DETERMINING THE MOST EFFECTIVE TOOL STRATEGY OFTEN TAKES TIME AND MULTIPLE TRIALS. COMMONLY, COMBINATION THERAPIES ARE REQUIRED. THIS STATEMENT HAS NO BUSINESS IN A REGULATORY STATUTE CONCERNING THE ONGOING CARE OF PATIENTS WITH A CHRONIC PROGRESSIVE DISEASE. THIS STATEMENT SHOULD BE REMOVED IN ITS ENTIRETY.

Item C (5) (f) – duplicative – language already included above.

Thank for the opportunity for comments on this very important piece of legislation that will potentially affect the care of up to 70% of Ohioans. As a native Ohioan, I look forward to seeing patients struggling with the chronic progressive disease of obesity to be able to enjoy the ability to obtain treatment that is consistent with the current science without bias or ostracization.

Sincerely,

Bruce Barker MD

OhioHealth Weight Management

Diplomate American Board of Obesity Medicine

Diplomate American Board of Family Medicine

801 OhioHealth Blvd Ste.160

Delaware Ohio 43015

2/24/2022

State Medical Board of Ohio

Attn: Nathan Smith

30 E. Broad St., 3rd Floor

Columbus, Ohio 42315

(614) 466-3934

www.med.ohio.gov

Dear members of the Ohio Medical Board:

Thank you for the opportunity to review proposed rule 4731-37-01 and 4731-11-09. In opening, I would like to thank the medical board for taking steps to treat obesity as a chronic progressive disease. Obesity has been recognized as a chronic disease by the American Medical Association in 2013, to be treated the same as other diseases such as hypertension and type 2 diabetes. The AMA members have pursued legislation to help remove barriers to treatment so that physicians can practice the current standard of care with regards to the treatment of obesity without fear of reprisal. The use of telehealth in the treatment of obesity has helped numerous individuals decrease their risk particularly in light of the COVID-19 pandemic.

I appreciate the State's concerns regarding mis-use of medications that are controlled substances; however, as you review your rules, please consider the following question – would you have the same rule in place for a patient in person? Also, will the rule improve the care the patient receives, or will it be a barrier for them to receive treatment?

With that in mind, this proposed rule represents a good step in the right direction. In particular, establishing the rule for telehealth treatment opportunities improves access to care for individuals in Ohio and in my opinion, improves compliance as it removes the barriers of leaving work, driving to office and waiting to be seen that patients commonly cite for not following up as instructed. The standard of care to be provided for many more Ohio patients living with obesity can be met with the proposed telehealth rules. This population is particularly venerable due to mobility issues related to fat mass disease.

That being said, I do have several concerns with the proposed language where I think it is overly prescriptive and will still represent a barrier to care for many patients, particularly with those with difficult to treat obesity.

4731-11-09 Item E This language is overly prescriptive and will result in the more complex patient not being able to continue on treatment. The proposed rule for anorectic management (4731-11-04) allows after 3 in person visits for patients to have medication refilled without an in person visit for 3 months. Patients struggling with obesity are commonly seen every 1-4 weeks, often by telehealth and adjustments in appetite suppressants such as dosing changes due to metabolic adaptation or needs to

change within the class should be allowed with subsequent in person follow up the following month. With validated home based blood pressure monitoring and remote monitoring such as blue tooth scales, the standard of care as provided in an in person visit is easily reproduced. I would advocate that anorectic therapy be added to the exemption list as well. Certainly, requiring in person visit to follow up on telehealth visit for adverse reactions to anorectic therapy is warranted but that is already addressed earlier in this proposal.

The other concern in this proposal is related to sedative hypnotics, particularly low level sleep aides such as Ambien and lunesta. There are individuals that require short term use of such agents for circadian rhythm disorders that utilize these for sleep induction. Under the proposed rule, prescribing these during a telehealth visit would be prohibited. That again, seems overly prescriptive. Some compromise where an in-person visit and exam has established need for these agents and subsequent follow up and adjustments over telehealth services would be more reasonable approach. Sleep disorders are common in the obese population and contribute significantly to the burden of disease due to the adverse effects of sleep deprivation on the appetite regulatory mechanisms.

Thank for the opportunity for comments on this very important piece of legislation that will potentially affect the care of up to 70% of Ohioans. As a native Ohioan, I look forward to seeing patients struggling with the chronic progressive disease of obesity to be able to enjoy the ability to obtain treatment that is consistent with the current science without bias or ostracization. Helping eliminate barriers to care access through telehealth with appropriate monitoring will markedly improve the opportunity to impact the significant disease burden of Obesity in Ohio.

Sincerely,

Bruce Barker MD

OhioHealth Weight Management

Diplomate American Board of Obesity Medicine

Diplomate American Board of Family Medicine

801 OhioHealth Blvd Ste.160

Delaware Ohio 43015



March 1, 2022

Ms. Kimberly Anderson, Esq.
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Rule: 4731-11-04

Submitted electronically via: Kimberly.Anderson@med.ohio.gov

Dear Ms. Anderson:

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching and research. Cleveland Clinic has been caring for patients struggling with obesity for many years. Every day, Cleveland Clinic sees nearly 14,000 unique patients who suffer with obesity (BMI $>30 \text{ kg/m}^2$). Of those, 1,500 have a BMI over 35 kg/m^2 and 1,000 have a BMI at or above 40 kg/m^2 . To support these patients, Cleveland Clinic employs more than 40 physicians who are specifically licensed in obesity medicine and who are certified by the American Board of Obesity Medicine. Finally, Cleveland Clinic established a fellowship in obesity medicine in 2021; there are more than 20 medical subspecialty programs in obesity medicine and more than 5,000 certified ABOM in the United States. Cleveland Clinic also employs more than 10 advanced practice providers (APPs) whose practice is dedicated to seeing patients with obesity and who are licensed by the Ohio State Medical Board to prescribe anti-obesity medications. Below are our comments in respect to the above captioned rule, based on our significant experience with treating patients with obesity.

First and foremost we want to emphasize that obesity is a chronic disease that is associated with more than 200 other medical comorbidities – including diabetes, fatty liver disease, sleep apnea and hypertension – along with an increased mortality. Historically, the disease of obesity was thought to be a lifestyle choice, a behavior problem that exists in weak individuals who lack the coping mechanisms or willpower to resist high calorie foods and are “too lazy” to pursue routine exercise. That premise led physicians to recommend that everyone “restrict” food intake and to treat “overeating” with appetite suppressants, as if all patients with obesity have a problem with hunger. The belief was that patients should be able to lose weight and keep it off with behavioral changes.

However, 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 and that appetite is tightly regulated through metabolic adaptation. The cornerstone for treatment of obesity is behavioral modification and lifestyle changes, including physical activity, sleep and stress. We know it is difficult to maintain weight loss with lifestyle intervention alone, and many regain their lost weight, in part due

to adaptive physiologic responses (e.g. a decrease in metabolism and an increased appetite) that occur with weight loss.

Anti-obesity medications (AOM) are not “diet pills” or “appetite suppressants” and are often required as adjuvant therapy for weight loss induction and maintenance; these medications have the potential to augment further weight loss when combined with a lifestyle intervention and are paramount for long-term success (Wadden TA et al *NEJM* 2005; LeRoux et al. *Lancet*, 2017). The most commonly prescribed AOM not only in our practice, but in the United States, is phentermine. Phentermine is not only effective, it is also inexpensive, safe, and has a very low potential of addiction. In addition, a recent study completed at Cleveland Clinic demonstrated the effective use of phentermine in patients with obesity via telemedicine compared to the standard face-to-face encounters.

Over the last two decades, as more knowledge of the disease of obesity is understood, the management of obesity has shifted away from using AOMs for short-term weight loss; instead, a chronic disease management model has been adapted that incorporates combination therapies of behavioral, pharmacological and surgical interventions to achieve sustainable weight loss in the setting of metabolic adaptation. Obesity as a medical specialty is growing exponentially nationwide and its care has shifted since these rules were written many years ago.

Cleveland Clinic appreciates the ongoing discussions that has led to the Board’s decision to amend to Rule 4731-11-04 and to rescind 4731-11-04.1. We believe this is a significant improvement to the appropriate care of patients with obesity in the State of Ohio.

Below we have included comments on specific sections of each of the rules.

4731-11-04 Controlled substances for the treatment of obesity

Proposed Language 4731-11-04(B)(3)(e)

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

Cleveland Clinic Comments

We recommend deleting the reference to “caloric restriction” as duplicative, since this concept is embedded in nutritional counseling and intensive behavioral therapy. Thus, the rule would read as follows: “The review of the prescriber's own records of prior treatment or review of records of prior treatment provided by another physician, prescriber, dietitian, or weight-loss program indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substance.”

Proposed Language 4731-11-04(C)(1)

The prescriber shall assess the patient, at a minimum, every thirty days for the first three months of utilization of controlled substances 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.

Cleveland Clinic Comments:

In the treatment of obesity with pharmacotherapy, like in other disease states, patients are not typically forced to be assessed on a monthly basis. Patients are all educated on the benefits and risks of medications, and it is typically the patient's responsibility to communicate the presence of contraindications and adverse effects that would necessitate cessation of treatment utilization. We understand the concern with controlled substances but believe monthly follow-up is not needed as there is no evidence that this is an addictive medication. We suggest the language be changed to read: "The prescriber shall assess the patient ~~at a minimum, every thirty days for the~~ once in the first three months of utilization of controlled substances 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."

Proposed Language 4731-11-04(C)(2)

The prescriber shall not personally furnish or prescribe more than a 30-day supply of controlled substances, at one time, for weight reduction or chronic weight management. For any controlled substance that is personally furnished, the prescriber shall not exceed a total of two thousand five hundred dosage units in any thirty-day period and shall not in any seventy-two hour period, personally furnish an amount that exceeds the amount necessary for the patient's use in a seventy-two hour period. Dosage unit means any of the following:

- (a) A single pill, capsule, ampule, or tablet;
- (b) In the case of a liquid solution, one milliliter;
- (c) In the case of a cream, lotion or gel, one gram; or
- (d) Any other form of administration available as a single unit.

Cleveland Clinic Comments

We recommend striking the words "or prescribe" from the proposed language as we believe that phentermine should not follow this restrictive prescribing pattern that is typical for controlled substances thought to be addictive. Phentermine is not an addictive controlled substance and therefore may be prescribed in a similar pattern currently used for other anti-obesity medications (AOMs) which are commonly prescribed with a 30 day prescription with two refills. We agree with the proposed language without "or prescribe".

Proposed Language 4731-11-04 (C)(4)(a)

The prescriber shall assess the patient at least once every three months and shall check the patient's weight, blood pressure, pulse, heart and lungs. The findings shall be entered in the patient's record.

Cleveland Clinic Comments

As stated above, we believe patients do not need to be assessed monthly while on phentermine. Patients are all educated on the benefits and risks of medications, and it is typically the patient's responsibility to communicate the presence of contraindications and any adverse effects. Patients can use heart rate and blood pressure monitors at home to assess the presence of uncommon side effects with this medication. Telemedicine is an important method of delivering appropriate care that extends care to the home, while breaking down typical barriers that come with face-to-face care such as long

commutes and wait times. This is accomplished by using new technologies via a modality that patients are already using in their personal lives. Telemedicine has the potential to decrease costs and increase access while maintaining quality of care. We urge the Board to make permanent the option to prescribe anti-obesity medications via telemedicine, which would greatly benefit the care of patients with obesity.

Proposed Language 4731-11-04 (C)(4)(b)

For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must continue to lose weight during the active weight reduction treatment or maintain goal weight. The prescriber shall document the patient's weight loss or maintenance in the record.

Cleveland Clinic Comments

We disagree with the statement “the patients must continue to lose weight..” and “maintain goal weight..” as it fails to recognize the multifactorial nature of weight loss. Weight stability occurs after active weight loss because of metabolic adaptation therefore the effectiveness of a therapeutic medication like phentermine should not be tied only to weight loss. In addition, like we see in other chronic disease states, one medication may not achieve the therapeutic goal. For example, in treating blood pressure, oftentimes more than one medication is needed to optimize blood pressure. This is also seen in hyperlipidemia. Similarly, it is difficult to reach a therapeutic goal (“goal weight”) or normalize a patient's weight with one medication. We don't take that patient off a blood pressure medication, we add a second medication. Under these circumstances, a controlled substance may be continued if the patient responds well, but may not be at their goal weight. Therefore, we suggest the language should read as follows: “For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must maintain a 5% weight reduction.”

Proposed Language 4731-11-04 (C)(5)(c)

That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances for weight reduction 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 an AOM if they do not lose weight. We refer back to 4731-11-04(C)(3) which is consistent with current medical guidelines in assessing the efficacy of an anti-obesity medication after 12 weeks. We believe assessing weight and assuming weight loss is consistent does not take into account the physiological response known as metabolic adaptation that occurs with weight loss. In addition, the assumption that is the patient's fault if they “fail” to lose weight is unfair and incorrect. We suggest that this language be removed from the rule because in our experience, there may be several other variables (e.g. changes in lifestyle factors including sleep, physical activity, stress and diet, the presence of medications that cause weight gain or the weight trajectory of the patient prior to initiation of an anti-obesity medication) that may confound the weight outcome, whether after thirty days or three months.

It is critical to understand, that some patients are rapidly gaining weight prior to starting an anti-obesity medication and the medication may lead to weight stabilization. Although the scale weight has not

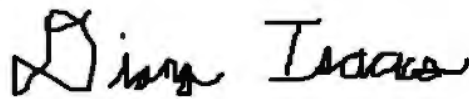
decreased, the AOM is effective in stopping the weight gain trajectory. In this instance, we believe patients should be allowed to remain on the medication. In addition, fluctuations in weight may occur with water retention with monthly menses in women, with heart failure or even with changes in muscle mass that may alter a scale weight. For these reasons and more, we suggest the language in this section be deleted, making the shared clinical decision whether to continue the controlled substance based on several factors including a body weight reduction of 5% at 12 weeks as stated in 4731-11-04 (C)(3).

Thank you for conducting a thoughtful process that allows us to provide input on such an important issue as obesity which effects millions of Ohioans. Should you need further information, please don't hesitate to contact us.

Sincerely,



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



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



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



W. Scott Butsch, M.D. MSc. FTOS
Director of Obesity Medicine, Bariatric and
Metabolic Institute



Roy Kim MD, MPH
Pediatric Endocrinology, Section Head

March 1, 2022

Ms. Kimberly Anderson, Esq.
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Rules: 4731-11-04

Dear Ms. Anderson:

We appreciate the ongoing discussions and amendments the Board has made to Rule 4731-11-04. We believe this will be a significant improvement to the appropriate care of patients with obesity in the State of Ohio and have included some important edits below. As President-elect of the Obesity Medicine Association and as a physician originally from Ohio (I created the Weight Loss Center at UCHHealth many years ago but have since moved to Massachusetts because I could not treat obesity effectively in Ohio given the limitations to access to care placed by outdated laws), I am passionate about changing restrictive and stigmatizing practices that limit access to evidenced based obesity care to Ohioans.

4731-11-04 Controlled substances for the treatment of obesity

Proposed Language

4731-11-04(B)(3)(e) The review of the prescriber's own records of prior treatment or review of records of prior treatment provided by another physician, prescriber, dietitian, or weight-loss program indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on ~~caloric restriction~~, nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substances

Comments

We suggest to delete “caloric restriction as it is redundant. We also would consider deleting the whole section. We do not make patients try and fail lifestyle interventions for severe disease states in other diseases. The fact that we make patients try lifestyle interventions before access to effective pharmacotherapy is stigmatizing and should be considered malpractice. 25% of patients will be able to lose 10% of their weight with lifestyle treatments while 50% of patients can lose 10% of their weight with the addition of phentermine and topiramate. If this were a cancer treatment and one treatment had a 25% success rate and another a 50% success rate but we made people try the 25% success rate first that would not be encouraged given the better advanced treatment option. Patients and providers

using shared decision making should assess the treatment goals and come to a decision on using effective treatment.

Proposed Language

4731-11-04(C)(1)

The prescriber shall **assess** the patient, at a minimum, **every thirty days for the first three months** of utilization of controlled substances 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.

Comments:

In the treatment of obesity with pharmacotherapy, like in other disease states, patients are not typically regulated to be assessed on a monthly basis. Patients are all educated on the benefits and risks of medications, and it is typically at the patients responsibility to communicate presence of contraindications and adverse effects that would necessitate cessation of treatment utilization. We understand the concern about controlled substances, but believe monthly follow-up is not needed. In Massachusetts we are not restricted by the law however we typically see patients in 4-6 weeks clinically to assess for response and side effects. We suggest the prescriber shall assess the patient once in the first three months instead of every thirty days.

Proposed Language

4731-11-04(C)(2)

The prescriber shall not personally furnish ~~or prescribe~~ more than a 30-day supply of controlled substances, at one time, for weight reduction or chronic weight management. For any controlled substance that is personally furnished, the prescriber shall not exceed a total of two thousand five hundred dosage units in any thirty-day period and shall not in any seventy-two hour period, personally furnish an amount that exceeds the amount necessary for the patient's use in a seventy-two hour period. Dosage unit means any of the following:

- (a) A single pill, capsule, ampule, or tablet;
- (b) In the case of a liquid solution, one milliliter;
- (c) In the case of a cream, lotion or gel, one gram; or
- (d) Any other form of administration available as a single unit.

Comments: We suggest that phentermine follow the prescribing pattern that is currently used for other anti-obesity medications and should not be restricted. Here in Massachusetts some patients find a 90 day supply is more cost effective and may need a larger supply if traveling out of the country etc. We don't think obesity should be treated differently than other diseases.

Proposed Language

4731-11-04 (C)(4)(a)

The prescriber shall assess the patient at least once every three months and shall check the patient's weight, blood pressure, pulse, heart and lungs. The findings shall be entered in the patient's record.

Comments:

As stated above in our comments to **4731-11-04(C)(1)** we believe patients do not need to be assessed monthly while on phentermine. Patients are all educated on the benefits and risks of medications, and it is typically at the patient's responsibility to communicate presence of contraindications and adverse effects. Patients can use heart rate and blood pressure monitors at home to assess the presences of uncommon side effect with this medication. Telemedicine is a growing segment of medical care with the potential to improve access by removing geographic barriers and extending care to the home. This is accomplished by using new technologies via a modality that patients are already using in their personal lives. Telemedicine has the potential to decrease costs and increase access while maintaining quality of care. The federal government and the Medical Board relaxed standards for prescribing controlled substances, so providers are now able to prescribe phentermine (and other anti-obesity medications) via telemedicine. We urge the Board to make permanent the option to prescribe anti-obesity medications via telemedicine, which would greatly benefit the care of patients with the disease of obesity, many of which have mobility issues that make it harder to come to the clinic as well. There is also no medical reason to listen to the heart and lungs of a patient taking phentermine that cannot be accomplished via pulse and blood pressure monitoring routinely. Listening to the heart and lungs if patients are complaining of palpitations or shortness of breath may be indicated however this should be a clinical judgement vs a mandated practice. We do not mandate treatment of people with other diseases.

Proposed Language

4731-11-04 (C)(4)(b)

For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must continue to lose weight during the active weight reduction treatment or maintain ~~goal~~ 5% weight reduction. The prescriber shall document the patient's weight loss or maintenance in the record

Comments

We suggest using the criteria put forth in our guidelines for clinical treatment that there be documented a 3-5% weight loss over the first 12-16 weeks to document the treatment is effective or other treatment or dose adjustment be considered.

Proposed Language

4731-11-04 (C)(5)(c)

~~That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances for weight reduction 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;~~

Comments

We are concerned that the rule requires patients to be removed from an anti-obesity medication if they do not lose weight. We would refer back to **4731-11-04 (C)(3)** which is consistent with current medical guidelines in assessing the efficacy of an anti-obesity medication after 12 weeks. We believe assessing weight and assuming weight loss is consistent does not take into account the physiological response known as metabolic adaptation that occurs with weight loss. In addition, the assumption that is the patient's fault if they "fail" to lose weight is biased and stigmatizing. We do not do this with other

disease treatments if for example we do not get good control of blood pressure with the first dose or medication we choose. We suggest that this language be removed because in our experience, there may be several other variables (e.g. changes in lifestyle factors including sleep, physical activity, stress and diet, the presence of medications that cause weight gain or the weight trajectory of the patient prior to initiation of an anti-obesity medication) that may confound the weight outcome. For example, some patients prior to starting an anti-obesity medication are rapidly gaining weight and the medication may lead to weight stabilization. Other patients may not lose weight but reduce their need for insulin that is causing weight gain. 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. In addition, fluctuations in weight may occur with water retention with monthly menses in women, with heart failure or even changes in muscle mass that may alter a scale weight. Clinically in obesity treatment we are moving toward direct measurement of adiposity as well as some may lose fat mass and gain muscle mass while the total weight stays relatively stable. For these reasons and more, we suggest the language in this section be deleted, making the shared clinical decision whether to continue the controlled substance based on several factors including a body weight reduction of 5% at 12 weeks as stated in **4731-11-04 (C)(3)**. Or considering language of 3-5% to have more flexibility as we see clinically in practice. These shared treatment goals should be a decision between patient and provider vs. a mandated law. There is data to show that phentermine and other controlled substances for weight management are not additive in nature. Patients do not seek to take these medications or any medication for that matter when they are not effective. All medications have side effects and most patients do not want to take a medication if it is not helping them.

Sincerely,



Angela Fitch, MD, FACP, Dipl. ABOM
Assistant Professor Harvard Medical School
Co-Director Massachusetts General Hospital Weight Center
President-Elect Obesity Medicine Association

References:

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From: [Jennifer Hayhurst](#)
To: [Anderson, Kimberly](#)
Cc: ["Chris Gallagher"](#); [Butsch, Winfield](#); [Todd Baker](#); [Reardon, Jill](#)
Subject: OSMA Comments re: Draft OAC 4731-11-04 Controlled substances for the treatment of obesity
Date: Tuesday, March 1, 2022 1:41:20 PM

Kim,

Good afternoon.

Thank you for giving the OSMA an opportunity to comment on the draft weight loss prescribing rule (OAC 4731-11-04). As you are aware, the OSMA has been working on this issue for many years and we are very pleased that the medical board has decided to review the existing rules and make some positive changes. There are recent studies that reflect just how many residents of Ohio are affected by obesity and the numbers are staggering. There are so many other chronic conditions that stem from obesity and allowing physicians to treat a patient's obesity, without unnecessary regulations that limit that treatment, is our goal.

The meetings we participated in with the medical board on this topic were very informative and we agree with the national and local weight loss physician experts that the medical board's rules are ready for an update.

The OSMA was pleased to see the proposed changes to the current weight loss prescribing rules. However, many physicians continue to have a number of concerns that the proposed language is still overly prescriptive and will continue to present barriers to care for many patients, particularly those with difficult to treat obesity.

The OSMA urges the medical board to take the following concerns into consideration and incorporate the requested changes into the board's draft rule.

Monthly Assessment of Patients

When treating chronic diseases like obesity with pharmacotherapy, patients are typically educated on risks and benefits of medications and assessed every 2-3 months. Potential adverse effects are often reviewed by the patient, in conjunction with the provider and the pharmacist, and concerns are typically communicated in a fashion like any other chronic disease. There is no reason to treat obesity differently and have patients be assessed monthly.

Disparate Outcomes for Chronic Disease Management

The regulation states that the patient "must continue to lose weight during the active weight reduction treatment or maintain goal weight." We would suggest changing that language to encouraging the patient to maintain a 5% weight reduction. Given our growing understanding of obesity, it is difficult to mandate that patients must continue to lose weight or achieve their goal weight to continue an anti-obesity medication (AOM). When trying to optimize a patient's blood pressure or cholesterol with a single pharmacological agent, we will typically not stop the initial medication if the target blood pressure or LDL is not achieved. In fact, physicians would consider adding a second agent, and often more than one medication is needed to optimize blood pressure. It

should be no different with obesity and the continuation of an AOM should be based on its ability to achieve a 5% weight reduction.

Supporting the Continued Broad Application of Telemedicine

We agree that patients with obesity on phentermine should be assessed every three months. However, newly adapted technology such as virtual encounters via telemedicine, which has become broadly adopted because of the COVID-19 public health emergency, should remain as an option for these quarterly encounters. Patients with obesity already experience numerous barriers to appropriate care because of weight bias and stigma. For example, studies show that individuals with obesity receive less time with a physician compared to individuals who are not affected by obesity. This bias can also lead to inaccurate assessments because of lack of size-appropriate diagnostic tools such as poorly fitting blood pressure cuffs, imaging equipment or examination tables. And, while there is no specific language in this section stating the ability to use telemedicine, we are concerned that the inclusion of “pulse, heart and lungs” will be interpreted by health plans as a requirement for an in-person clinical encounter.

Elimination of Stigmatizing Language

Finally, we are troubled that the regulation states that the prescriber shall not initiate treatment utilizing a controlled substance for the treatment of obesity upon ascertaining or having reason to believe that “the review of the prescriber's own records of prior treatment or review of records of prior treatment provided by another physician, prescriber, dietitian, or weight-loss program indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program...”

This language is very castigatory and stigmatizing. Blaming a patient for struggling to address their chronic disease of obesity has no place in a medical board regulation and should be removed. Past poor performance does not indicate the patient can't do well moving forward. Under this rule, a patient gets one chance at treating their obesity, and if they don't do well they could be barred from ever being treated again.

Again, thank you for giving the OSMA an opportunity to comment on the draft rule and to participate in the discussions leading up to the proposed draft rule. We appreciate the medical board's consideration of our comments and look forward to working with the medical board on this issue.

Please feel free to reach me if you have any questions.

Thank you.

Jennifer

Jennifer Hayhurst

Director, Regulatory Affairs
Ohio State Medical Association

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From: [Kinsey Jolliff](#)
To: [Anderson, Kimberly](#); [Reardon, Jill](#)
Cc: [Allison Poulos](#)
Subject: The MetroHealth System Comments - SMBO Rules 4731-11-03, 4731-11-04
Date: Monday, February 28, 2022 3:25:53 PM

Good Afternoon,

On behalf of our physicians, thank you for considering comments on proposed changes to OAC 4731-11-03 and 4731-11-04.

Below are our comments and suggested changes. If you'd like to further discuss the comments with our physician leaders, please don't hesitate to reach out. Dr. Joan Papp leads our Office of Opioid Safety and is very active in peer-to-peer reviews/coaching and prescribing policy for the System; she would be a great resource to consult with on these types of rule updates.

4731-11-03

- Recommend adding a section requiring 30 day follow up for first 90 days and then every 90 days to be consistent with the rules for schedule III and IV anorexiant. Schedule II medications in this rule have a higher potential for addiction and no such follow up is being proposed.
- In paragraph (A)(3)(a) the rule states that schedule II stimulants shall not be used for purposes of "weight reduction or control"; however in paragraph (B)(2)(f) it allows its use for binge eating disorder. Please clarify the policy.
- We have concerns regarding the indications for a schedule II stimulant listed in (B)(2)(e). The chronic pain indication is long outdated and a schedule II stimulant shouldn't have a primary role as an adjunctive therapy for chronic pain treatment.

4731-11-04

- Paragraph (C)(2) reads that a "prescriber shall not personally furnish or prescribe more than a 30-day supply of controlled substances, at one time, for weight reduction or chronic weight management. For any controlled substance that is personally furnished, the prescriber shall not exceed a total of two thousand five hundred dosage units in any thirty-day period..." The rule goes on to define a dosage unit as a single pill or capsule, or 1 mL, etc. If we are reading this correctly, that could potentially be 833 tablets per day. Please clarify whether the maximums apply to all patients that a physician prescribes or personally furnishes at a location or per patient, or some other unit.

Kinsey Jolliff
The MetroHealth System
Principal, Government Relations

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kjolliff@metrohealth.org

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February 28, 2022

Ms. Kimberly Anderson, Esq.
Chief Legal Counsel
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Rule: 4731-11-04: Controlled Substances: Utilization for Weight Reduction

Submitted electronically via: Kimberly.Anderson@med.ohio.gov

Dear Ms. Anderson:

The Obesity Society is one of the leading scientific professional societies in the United States focusing on the disease of obesity with approximately 2400 members, including physicians, providers, scientists, and public health experts. Leaders in our society have been instrumental in the development of the current professional guidelines in the treatment of obesity. Based on our society's expertise in the science of obesity and obesity care, we would like to provide comment in respect to the above captioned rule.

Obesity is a chronic disease which commands a comprehensive treatment paradigm. Pharmacotherapy is an effective treatment option used in obesity care. Historically, sympathomimetics like phentermine were considered appetite suppressants to treat the "overeating" problem of people with obesity with the simple belief that obesity is a behavioral problem associated with hunger. The goal of treatment therefore was to help patients lose weight and keep it off with behavioral changes.

While many may believe our weight is modifiable and therefore obesity is just a characteristic flaw, most in the scientific world do not commonly accept this belief. Weight regulation (which includes regulation of appetite) consists of a complex network of physiological pathways that interconnect the brain, digestive track, muscle, and adipose tissue. We understand this is a tightly controlled system and the disease of obesity is a dysregulation of normal weight and energy regulatory mechanisms. This is supported by scientific evidence explaining both metabolic adaption (slowing of the metabolism after weight loss) and changes in the intestinal hormones (for example GLP-1, PYY, amylin) that counter weight loss attempts and create an environment making it difficult to sustain body weight loss. Furthermore, obesity is highly genetic, as there are several monogenetic subtypes of obesity, however most obesity is thought to be polygenetic. Therefore, to continue to believe at the population level that strides will be made with lifestyle modification alone is archaic.

We know it is difficult to maintain weight loss with lifestyle intervention alone; anti-obesity medications (AOM) are often required as adjuvant therapy for weight loss induction and maintenance. Several studies have shown the increased effectiveness of AOM when combined with a lifestyle intervention versus lifestyle alone. Phentermine is the most commonly prescribed AOM, first approved for the treatment of obesity in 1959, and used safely for over a half of a

The leading society dedicated to the study, prevention and treatment of obesity.

1110 Bonifant Street, Suite 500, Silver Spring, MD 20910 ▪ Phone: 301-563-6526 ▪ www.obesity.org

century. Over the last two decades, as more knowledge of the disease of obesity is understood, the management of obesity has shifted away from using AOMs for short-term weight loss; instead, a chronic disease management model has been adapted that incorporates combination strategies with behavioral, pharmacological, and surgical interventions to achieve sustainable healthy weight.

The Obesity Society is in favor of the amendments the Medical Board has made to Rule 4731-11-04 and their decision to rescind 4731-11-04.1. We believe this is a significant advancement from the current Rules and speaks to our current understanding of obesity and appropriate use of AOMs in patients with obesity.

Below, we have included comments on specific sections of **Rule 4731-11-04: Controlled substances for the treatment of obesity** based on our understanding of the science and treatment of obesity. In general, we believe there remain limitations in this amended Rule that lead to inappropriate care of patients with obesity in the State of Ohio, in which >35% of adult Ohioans have obesity.

A. Section 4731-11-04(C)(1)

States “The prescriber shall assess the patient, at a minimum, every thirty days for the first three months of utilization of controlled substances 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.

We suggest the language be changed to read: “The prescriber shall assess the patient at a minimum, ~~every thirty days for the once in the~~ first three months of utilization of controlled substances 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.”

The Obesity Society rationale:

Phentermine is used for “long term” treatment of the chronic disease of obesity.

We disagree with the need for the prescriber to assess the patient every thirty days for the first three months of the utilization of a controlled substance. When treating chronic diseases like obesity with pharmacotherapy, patients are typically educated on risks and benefits of medications and assessed every 2-3 months. Potential adverse effects are often reviewed by the patient with the provider and the pharmacist and concerns are typically communicated in a fashion like any other chronic disease. There is no reason to treat obesity differently and have patients be assessed monthly. We understand the concern about controlled substances, but it is not warranted with this medication and thus monthly follow-up is not needed during the first three months.

B. Section 4731-11-04(C)(2)

States “The prescriber shall not personally furnish or prescribe more than a 30-day supply of controlled substances, at one time, for weight reduction or chronic weight management. For any controlled substance that is personally furnished, the prescriber shall not exceed a total of two thousand five hundred dosage units in any thirty-day period and shall not in any seventy-two-hour period, personally furnish an amount that exceeds the amount necessary for the patient's use in a seventy-two hour period. Dosage unit means any of the following:

- (a) A single pill, capsule, ampule, or tablet;
- (b) In the case of a liquid solution, one milliliter;
- (c) In the case of a cream, lotion or gel, one gram; or
- (d) Any other form of administration available as a single unit.”

We suggest deleting the words “or prescribe” from the above regulatory language and keep the language to reflect the limitation of furnishing this medication.

The Obesity Society rationale

In line with our comments above, we believe phentermine is not an addictive-controlled substance and is prescribed in prescriptions for more than thirty days (i.e. 30 days Rx with refills) for the treatment of obesity in many States in the country. We agree that there should be language in this Rule that regulates those physicians or clinics (eg IV hydration clinics and medical spas) that furnish this medication. However, we disagree with the proposed restriction on prescribing this medication.

C. Section 4731-11-04 (C)(4)(a)

States “The prescriber shall assess the patient at least once every three months and shall check the patient’s weight, blood pressure, pulse, heart and lungs. The findings shall be entered in the patient’s record.”

We suggest that an additional line be added to the current regulatory language which states, **“Telemedicine may be used to assess the patient if lieu of a face-to-face encounter when clinically appropriate.”**

The Obesity Society rationale

We agree that patients with obesity on phentermine should be assessed every three months. However, we believe newly adapted technology (i.e., virtual encounters, in addition to face-to-face, can also be applied to achieve this frequency of encounters). Patients with obesity already experience numerous barriers to appropriate care, from less time spent in an encounter compared with normal weight individuals to inaccurate assessments (e.g., due to poorly fitting BP cuffs). There is no specific language in this section stating the ability to use telemedicine but the inclusion of “pulse, heart and lungs” hints at the need for a clinical encounter.

D. Section 4731-11-04 (C)(4)(b)

States “For the continuation of Schedule III or IV controlled substances designated as FDA short term use-controlled substances beyond three months, the patient must continue to lose weight during the active weight reduction treatment or maintain goal weight. The prescriber shall document the patient’s weight loss or maintenance in the record”

We suggest the language read: **“For the continuation of Schedule III or IV controlled substances designated for the treatment of obesity beyond three months, the patient must maintain a 5% weight reduction.”**

The Obesity Society rationale

In our understanding of the disease of obesity, we believe it is difficult to mandate that patients must continue to lose weight or achieve their goal weight to continue an AOM. Similar to other chronic diseases like hypertension, dyslipidemia and diabetes, obesity often requires a multi-modal treatment regimen and improvement is not always linear in achieving remission. Our concern with the language in this section, specifically “must continue to lose weight” and “maintain goal weight” is that it assumes weight loss continues without stabilization (e.g. metabolic adaptation) and that goal weights are achieved with monotherapy. When trying to optimize a patient’s blood pressure or cholesterol with a single pharmacological agent, we typically will not stop the initial medication if the target blood pressure or LDL is not achieved. In fact, we would consider adding a second agent, and often more than one medication is needed to optimize blood pressure. Obesity should not be different, and the continuation of an anti-obesity medication (AOM) should be based on its ability to achieve a 5% weight reduction.

E. Section 4731-11-04 (C)(5)(c)

States “That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances for weight reduction 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;”

We suggest the language in this section read, “That the patient has failed not responded by achieving less than 5% weight reduction after three months to lose weight while under obesity treatment with a controlled substance or controlled substances; ~~for weight reduction 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;~~ “

The Obesity Society rationale

As stated above, in our understanding of the disease of obesity, we believe it is difficult to assume weight loss is linear as it disregards what we know about energy and weight regulation. In addition, the language in this section assumes weight loss is volitional and, if not achieved, the patient is the one who is at fault. This is simply not true. We believe assessing weight and assuming weight loss is consistent fails to accept the known physiological responses eg metabolic adaptation that occur with weight loss and impede continued weight loss.

In addition, we know bodyweight fluctuates and may be confounded by changes in many variables, from changes in hydration status and lean muscle mass, to lifestyle changes in diet, sleep, stress, or physical activity, to changes with the initiation of a medication that may cause weight gain. Furthermore, if a patient is gaining weight before the initiation of an AOM, the lack of continued gain, or weight stability, would be an initial therapeutic goal, supporting continued use of a medication. These are just a few variables that make it difficult to determine the effectiveness of a medication after 30 days.

Consistent with current obesity treatment guidelines, co-written by The Obesity Society, the effectiveness of an AOM should be determined assessing the individual’s weight after 12 weeks. This was stated in 4731-11-04 (C)(3). The reality is that patients and providers alike want these medications to augment weight loss and typically are the first to discontinue an AOM if there is not a significant weight loss response.

We disagree with the current language used in this section on the management of individuals on phentermine. In particular there is no rationale to differentiate an individual with no past history of obesity treatment. The evaluation of the patient on phentermine should be consistent in this case, with, again, the timeline of 12 weeks given in place of 30 days.

Again, thank you for amending these Rules on controlled substances used to treat obesity. We hope you consider our suggestions as one of the leading obesity organizations in the world.

Please don’t hesitate to contact us if you have any further comments or questions.

Sincerely,



W. Scott Butsch, M.D. MSc. FTOS
Chair, Policy and Advocacy Committee of The Obesity Society
857-998-9150



Anthony G. Comuzzie, Ph.D., FTOS
Chief Executive Officer



4KidHelp, 4368 Dressler Rd NW, Suite 103, Canton, OH 44718 330-433-1300 www.4KidHelp.com

April 4, 2022

State Medical Board of Ohio

Re: Comments on Controlled Substance rule in Telehealth

To the Board,

Suggested change to rules: Exempt children with Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) from requiring in person session(s) to receive stimulants.

Rationale: I am a board-certified child and adolescent psychiatrist (as well as an addiction psychiatrist) in an underserved part of Ohio. About 60% of my patients have complicated ADD/ADHD, where primary care physicians have not been able to manage the illness and they are sent to me as a specialist. Given that 7% of children have ADD/ADHD, we are talking about a sizeable number of children in Ohio. As you are aware, ADHD has significant morbidity and mortality – higher rates of dropout, death through accidents, substance abuse and teenage pregnancy. Stimulants remain the primary treatment for ADD/ADHD, which are a class 2 controlled substance. They work in 75% of patients and after decades of experience have few serious side effects. Moreover persons with ADD/ADHD who receive stimulants cut their risk of addiction by 50%!

My patients travel from about a 2-hour radius to see me. Telehealth has been so helpful for parents who are already overwhelmed with the extra responsibilities of raising these children (e.g., attending multiple school meetings, taking the child to counseling or other health services such as Occupational Therapy). Going back to requiring in person sessions would add another burden to these families. As a practitioner, I don't see how face to face meetings decreases the likelihood of misuse or diversion of these substances. I think the effect of requiring face to face meetings would be to limit care and deny children services. As you are aware there is no physical examination which establishes the diagnosis or guides treatment. Such decisions are made through questionnaires and history. The one group of physical health data that is required, vital signs, can be collected through local resources and reported at the visit. I believe that telehealth has been very helpful in serving more children, particularly rural children, with ADD/ADHD. Many of these families are the rural poor and the cost of gasoline and availability of a car limits access to care. For these reasons I suggest that children with ADD/ADHD who receive stimulants not require face to face examination.

Thank you.

Sincerely,

Lee Reynolds, MD

Thomas (Lee) Reynolds, MD, Nationally Board-Certified in Child & Adolescent, Adult, and Addiction Psychiatry

From: [Prem, Emily](#)
To: [Anderson, Kimberly](#)
Subject: OAC 4731-11-04
Date: Monday, February 28, 2022 3:19:28 PM
Attachments: [image001.png](#)
[TriHealth Comments on OAC 4731-11-04.docx](#)

Hi Kimberly –

Please see my very brief comments attached.

Emily S. Prem, JD, RN | Associate General Counsel for Risk Management
Office 513 569 5163 | Fax 513 569 5171
emily_prem@trihealth.com

Corporate Office

TriHealth | Baldwin - 11th Floor | 625 Eden Park Drive | Cincinnati, OH 45202.



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OAC 4731-11-04

- Clarification regarding who may prescribe controlled substances for the treatment of obesity
 - Suggested addition: (A)(1) "Prescriber" shall have the same meaning as defined in ORC 4729.01(I)

From: [Smith, Jonathan R](#)
To: [Reardon, Jill](#); [Anderson, Kimberly](#)
Subject: UH Comments - SMBO seeking public comments on rules-2/22
Date: Monday, February 28, 2022 6:35:11 PM
Importance: High

Good afternoon,

After reviewing the proposed updates, UH would like to raise the following (comments in red below):

- 4731-11-03 (B)(1)(b) – Stimulant prescribing
 - New requirement to complete a mental status examination
 - **What is an acceptable “mental status examination” the term is generic and would benefit from additional parameters on frequency and level of detail.**
 - **Is there a standard “mental status examination” that is used to evaluate patients that may be prescribed a Stimulant?**
 - **Is this is leaning towards a mandate for comprehensive neuropsych testing? The concern with this is that it is very few people do complete neuropsych testing for ADHD. Other issues with this is that it takes many hours and often patients end up paying for those costs.**
- 4731-11-04 (new) – Treatment of Obesity
 - (C)(2) “...and shall not in any seventy-two hour period, personally furnish an amount that exceeds the amount necessary for the patient’s seventy-two hour period.”
 - **While a vague statement, I understand it to mean not prescribing more than should be consumed based on the prescription, is that correct?**

Please reach out if you have any questions, thanks!

Best,

John Smith, J.D.
Government Relations Coordinator
University Hospitals and Rainbow Babies & Children's Hospital
11100 Euclid Avenue
Cleveland, OH 44106
(216)-536-4012
Jonathan.Smith@UHhospitals.org



From: Jill.Reardon@med.ohio.gov <Jill.Reardon@med.ohio.gov>

Sent: Friday, February 11, 2022 8:09 AM

Subject: SMBO seeking public comments on rules-2/22

Good morning,

PROPOSED RULES: Seeking comments on the Medical Board's initial review of rules

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 rules. A memo explaining the proposed action and the rules are attached.

4731-11-03 Utilization of anabolic steroids, schedule II controlled substance cocaine hydrochloride, and schedule II controlled substance stimulants: **Propose to Amend**

4731-11-04 Controlled substances: Utilization of short term anorexiant for weight reduction: **Propose to Rescind**

4731-11-04 Controlled substances for the treatment of obesity **Proposed New Rule**

4731-11-04.1 Controlled substances: Utilization for chronic weight management **Propose to Rescind**

Deadline for submitting comments: **March 1, 2022**

Comments to: Kimberly Anderson
State Medical Board of Ohio
Kimberly.Anderson@med.ohio.gov

Visit us at www.UHhospitals.org.

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4731-11-03

Utilization of anabolic steroids, schedule II controlled substance cocaine hydrochloride, and schedule II controlled substance stimulants.

(A) A physician shall not:

- (1) Utilize anabolic steroids, growth hormones, testosterone or its analogs, human chorionic gonadotropin ("HCG"), or other hormones for the purpose of enhancing athletic ability.
- (2) Utilize the schedule II controlled substance cocaine hydrochloride for a purpose other than one of the following:
 - (a) As a topical anesthetic in situations in which it is properly indicated; or
 - (b) For in-office diagnostic testing for pupillary disorders.
- (3) Utilize a schedule II controlled substance stimulant in any of the following circumstances:
 - (a) For purposes of weight reduction or control;
 - (b) When the physician knows or has reason to believe that a recognized contra-indication to its use exists; or
 - (c) In the treatment of a patient who the physician knows or should know is pregnant, except if the following criteria are met:
 - (i) After the physician's medical assessment the physician and patient determine that the benefits of treating the patient with a schedule II controlled substance stimulant outweigh the risks, and
 - (ii) The basis for the determination is documented in the patient record.

(B) Utilizing a schedule II controlled ~~substance~~ substance stimulant:

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

- (b) Perform an appropriate physical examination and mental status examination of the patient; and
 - (c) Rule out the existence of any recognized contra-indications to the use of the controlled ~~substance~~substance stimulant to be utilized.
- (2) A physician may utilize a schedule II controlled substance stimulant only for one of the following purposes:
- (a) The treatment of narcolepsy, idiopathic hypersomnia, and hypersomnias due to medical conditions known to cause excessive sleepiness;
 - (b) The treatment of ~~abnormal behavioral syndrome~~ (attention deficit hyperactivity disorder, ~~hyperkinetic syndrome~~), and/or related disorders;
 - (c) The treatment of major or mild neurocognitive disorder due to traumatic brain injury or substance/medication-induced major or mild neurocognitive disorder; ~~drug-induced or trauma-induced brain dysfunction~~;
 - ~~(d) The differential diagnostic psychiatric evaluation of depression;~~
 - ~~(e)~~(d) The treatment of depression shown to be refractory to other therapeutic modalities, including pharmacologic approaches, such as antidepressants;
 - ~~(f)~~(e) As adjunctive therapy in the treatment of chronic pain, as defined in rule 4731-11-01 of the administrative code, ~~the following~~:
 - ~~(i) Chronic severe pain;~~
 - ~~(ii) Closed head injuries;~~
 - ~~(iii) Cancer-related fatigue;~~
 - ~~(iv) Fatigue experienced during the terminal stages of disease;~~
 - ~~(v) Depression experienced during the terminal stages of disease; or~~
 - ~~(vi) Intractable pain, as defined in rule 4731-21-01 of the Administrative Code.~~

~~(g)~~(f) The treatment of binge eating disorder.

- (3) Upon ascertaining or having reason to believe that the patient has a history of or shows a propensity for alcohol or drug abuse, or that the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions, the physician shall perform both of the following:
 - (a) Reappraise the desirability of continued utilization of schedule II controlled substance stimulants and shall document in the patient record the factors weighed in deciding to continue their use; and
 - (b) Actively monitor such patient for signs and symptoms of drug abuse and drug dependency.
- (C) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:
 - (1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;
 - (2) "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code;
 - (3) "A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

*** DRAFT - NOT YET FILED ***

4731-11-04

Controlled substances for the treatment of obesity.

- (A) A prescriber may utilize a schedule III or IV controlled substance for the treatment of obesity only if it has an F.D.A approved indication for this purpose and then only in accordance with all of the provisions of this rule.
- (B) Before initiating treatment for obesity utilizing any schedule III or IV controlled substance, the prescriber shall complete all of the following requirements:
- (1) The prescriber shall review the prescriber's own records of prior treatment or review the records of prior treatment by another treating physician, prescriber, dietitian, or weight-loss program to determine the patient's past efforts to lose weight in a treatment program utilizing a regimen of weight reduction based on ~~calorie restriction~~, nutritional counseling, intensive behavioral therapy, and exercise, without the utilization of controlled substances, and that the treatment has been ineffective
 - (2) The prescriber shall complete and document the findings of all of the following:
 - (a) Obtain a thorough history;
 - (b) Perform an appropriate examination of the patient;
 - (c) Determine the patient's BMI;
 - (d) Rule out the existence of any recognized contraindications to the use of the controlled substance to be utilized;
 - (e) Assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects.
 - (f) Access OARRS for the patient's prescription history during the preceding twelve month period and document in the patient's record the receipt and assessment of the report received; and
 - (g) Develop and record in the patient record a treatment plan that includes, at a minimum, a diet and exercise program for weight loss.
 - (3) The prescriber shall not initiate treatment utilizing a controlled substance for the treatment of obesity 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 prescriber physician related to the patient's use of drugs or alcohol;
 - (b) The patient has consumed or disposed of any controlled substance other

than in strict compliance with the treating prescriber's directions;

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

(d) The patient has a BMI of less than thirty, unless the patient has a BMI of at least twenty seven with comorbid factors, including Type 2 diabetes, cardio vascular disease, hypertension, hyperlipidemia, obstructive sleep apnea, nonalcoholic fatty liver disease, osteoarthritis, or major depression;

(e) The patient has any condition that would contraindicate the use of the controlled substance to be utilized;

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

(C) A prescriber may utilize a schedule III or IV controlled substance that bears appropriate F.D.A. approved labeling for weight loss, in the treatment of obesity as an adjunct, in a regimen of weight reduction based on caloric restriction, provided that:

(1) The prescriber shall assess the patient, at a minimum, once in every thirty days for the first three months of utilization of controlled substances for weight reduction, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.

(2) The prescriber shall ~~not personally furnish or prescribe more than a 30-day supply of~~ controlled substances, ~~at one time,~~ for weight reduction or chronic weight management only in accordance with section 4729.291 of the revised code. For any controlled substance that is personally furnished to or for patients, taken as a whole, the prescriber shall not exceed a total of two thousand five hundred dosage units in any thirty-day period and for an individual patient, shall not in any seventy-two hour period, personally furnish an amount that exceeds the amount necessary for that patient's use in a seventy-two hour period. Dosage unit means any of the following:

(a) A single pill, capsule, ampule, or tablet;

(b) In the case of a liquid solution, one milliliter;

- (c) In the case of a cream, lotion or gel, one gram; or
- (d) Any other form of administration available as a single unit.
- (3) The prescriber shall not personally furnish or prescribe additional controlled substances to treat obesity for a patient who has not achieved a weight loss of at least 5% of the patient's initial weight, during the initial three months of treatment using controlled substances to treat obesity.
- (4) The prescriber may personally furnish or prescribe controlled substances to treat obesity when the prescriber observes and records that the patient significantly benefits from the controlled substances and has no serious adverse effects related to the drug regimen. A patient significantly benefits from the controlled substances when weight is reduced or when weight loss is maintained and any existing co-morbidity is reduced.
- (a) The prescriber shall assess the patient at least once every three months and shall ~~check~~ obtain the patient's weight, blood pressure, pulse, heart and lungs. The findings shall be entered in the patient's record.
- (b) For the continuation of Schedule III or IV controlled substances designated as FDA short term use controlled substances beyond three months, the patient must maintain a 5% weight reduction~~continue to lose weight during the active weight reduction treatment or maintain goal weight.~~ The prescriber shall document the patient's weight loss or maintenance in the record.
- (c) The prescriber shall document the patient's progress with the treatment plan.
- (d) The prescriber shall access OARRS in accordance with rules 4731-11-11 and 4730-2-10 of the Administrative Code.
- (5) The prescriber shall discontinue utilizing all controlled substances for purposes of weight reduction immediately upon ascertaining or having reason to believe:
- (a) That the patient has made any false or misleading statement to the prescriber relating to the patient's use of drugs or alcohol;
- (b) That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions;
- ~~(c) That the patient has not responded by achieving less than 5% weight reduction after three months~~failed to lose weight~~ while under treatment with a controlled substance or controlled substances~~for weight reduction over a period of thirty days during the current course of treatment, which determination shall be made by weighing the patient at least every~~~~

~~thirtieth day, except that a patient who has never before received treatment for obesity utilizing any controlled substance who fails to lose weight during the first thirty days of the first such treatment attempt may be treated for an additional thirty days;~~

- (d) That the patient has repeatedly failed to comply with the prescriber's treatment recommendations;
 - (e) That the patient demonstrates any signs that the controlled substance is not safe for or well tolerated by the patient; or
 - (f) That the prescriber knows or should know the patient is pregnant.
 - (D) A violation of any provision of this rule, as determined by the board, shall constitute the following:
 - (1) For a physician:
 - (a) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;
 - (b) "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; and
 - (c) "A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.
 - (2) For a physician assistant:
 - (a) "A departure from, or failure to conform to, minimal standards of care of similar physician assistants under the same or similar circumstances, regardless of whether actual injury to a patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code;
 - (b) "Failure to comply with the requirements of this chapter, Chapter 4731. of the Revised Code, or any rules adopted by the board," as that clause is used in division (B)(2) of section 4730.25 of the Revised Code; and
 - (c) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter, Chapter 4731. of the Revised Code, or the rules adopted by the

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[board," as that clause is used in division \(B\)\(3\) of section 4730.25 of the Revised Code.](#)

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4731-11-04

Controlled substances: Utilization of short term anorexiant for weight reduction.

TO BE RESCINDED

- (A) A physician shall utilize a schedule III or IV controlled substance short term anorexiant for purposes of weight reduction only if it has an F.D.A. approved indication for this purpose and then only in accordance with all of the provisions of this rule.
- (B) Before initiating treatment for weight reduction utilizing any schedule III or IV controlled substance short term anorexiant, the physician shall complete all of the following requirements:
 - (1) The physician shall review the physician's own records of prior treatment or review the records of prior treatment by another treating physician, dietician, or weight-loss program to determine the patient's past efforts to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise, without the utilization of controlled substances, and that the treatment has been ineffective.
 - (2) The physician shall complete and document the findings of all of the following:
 - (a) Obtain a thorough history;
 - (b) Perform an appropriate physical examination of the patient;
 - (c) Determine the patient's BMI;
 - (d) Rule out the existence of any recognized contraindications to the use of the controlled substance to be utilized;
 - (e) Assess and document the patient's freedom from signs of drug or alcohol abuse, and the presence or absence of contraindications and adverse side effects.
 - (f) Access OARRS for the patient's prescription history during the preceding twelve month period and document in the patient's record the receipt and assessment of the report received; and
 - (g) Develop and record in the patient record a treatment plan that includes, at a minimum, a diet and exercise program for weight loss.

- (3) The physician shall not initiate treatment utilizing a controlled substance short term anorexiant upon ascertaining or having reason to believe any one or more of the following:
- (a) The patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the physician related to the patient's use of drugs or alcohol;
 - (b) The patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions;
 - (c) The physician knows or should know the patient is pregnant;
 - (d) The patient has a BMI of less than thirty, unless the patient has a BMI of at least twenty seven with comorbid factors;
 - (e) The review of the physician's own records of prior treatment or review of records of prior treatment provided by another physician, dietician, or weight-loss program indicate that the patient made less than a substantial good faith effort to lose weight in a treatment program utilizing a regimen of weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substances.
- (C) A physician may utilize a schedule III or IV controlled substance short term anorexiant, that bears appropriate F.D.A. approved labeling for weight loss, in the treatment of obesity as an adjunct, in a regimen of weight reduction based on caloric restriction, provided that:
- (1) The physician shall personally meet face-to-face with the patient, at a minimum, every thirty days when controlled substances are being utilized for weight reduction, and shall record in the patient record information demonstrating the patient's continuing efforts to lose weight, the patient's dedication to the treatment program and response to treatment, and the presence or absence of contraindications, adverse effects, and indicators of possible substance abuse that would necessitate cessation of treatment utilizing controlled substances.
 - (2) The controlled substance short term anorexiant is prescribed strictly in accordance with the F.D.A. approved labeling. If the F.D.A. approved labeling of the controlled substance short term anorexiant being utilized for weight loss states that it is indicated for use for "a few weeks," the total course of treatment using that controlled substance shall not exceed twelve

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weeks. That time period includes any interruption in treatment that may be permitted under paragraph (C)(3) of this rule.

- (3) A physician shall not initiate a course of treatment utilizing a controlled substance short term anorexiant for purposes of weight reduction if the patient has received any controlled substance for purposes of weight reduction within the past six months. However, the physician may resume utilizing a controlled substance short term anorexiant following an interruption of treatment of more than seven days if the interruption resulted from one or more of the following:
 - (a) Illness of or injury to the patient justifying a temporary cessation of treatment; or
 - (b) Unavailability of the physician; or
 - (c) Unavailability of the patient, if the patient has notified the physician of the cause of the patient's unavailability.
- (4) After initiating treatment, the physician may elect to switch to a different controlled substance short term anorexiant for weight loss based on sound medical judgment, but the total course of treatment for any short term anorexiant combination of controlled substances each of which is indicated for "a few weeks" shall not exceed twelve weeks.
- (5) The physician shall not initiate or shall discontinue utilizing all controlled substance short term anorexiants for purposes of weight reduction immediately upon ascertaining or having reason to believe:
 - (a) That the patient has a history of or shows a propensity for alcohol or drug abuse, or has made any false or misleading statement to the physician relating to the patient's use of drugs or alcohol;
 - (b) That the patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions;
 - (c) That the patient has failed to lose weight while under treatment with a controlled substance or controlled substances over a period of thirty days during the current course of treatment, which determination shall be made by weighing the patient at least every thirtieth day, except that a patient who has never before received treatment for obesity utilizing

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any controlled substance who fails to lose weight during the first thirty days of the first such treatment attempt may be treated for an additional thirty days;

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

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

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

- (1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;
- (2) "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; and
- (3) "A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

4731-11-04.1

Controlled substances: utilization for chronic weight management.

TO BE RESCINDED

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

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

(a) Obtain a thorough history;

(b) Perform a physical examination of the patient;

(c) Determine the patient's BMI;

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

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

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

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

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

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

- (a) The patient has a history of, or shows a propensity for, alcohol or drug abuse, or has made any false or misleading statement to the physician or physician assistant relating to the patient's use of drugs or alcohol;
 - (b) The patient has consumed or disposed of any controlled substance other than in strict compliance with the treating physician's directions; or
 - (c) The physician knows or should know the patient is pregnant.
 - (3) The physician shall not initiate treatment utilizing a controlled substance anorexiant if any of the following conditions exist:
 - (a) The patient has an initial BMI of less than thirty, unless the patient has an initial BMI of at least twenty seven with comorbid factors.
 - (b) The review of the patient's attempts to lose weight in the past indicates that the patient has not made a substantial good faith effort to lose weight in a regimen for weight reduction based on caloric restriction, nutritional counseling, intensive behavioral therapy, and exercise without the utilization of controlled substance anorexiant. The review shall include available records from the physician's own prior treatment of the patient, prior treatment provided by another physician, prior participation in a weight-loss program, or prior treatment by a dietitian.
 - (4) The physician shall prescribe the controlled substance anorexiant strictly in accordance with the F.D.A. approved labeling;
 - (5) Throughout the course of treatment with any controlled substance anorexiant the physician shall comply with rule 4731-11-11 of the Administrative Code and the physician assistant shall comply with rule 4730-2-10 of the Administrative Code.
- (B) A physician shall provide treatment utilizing a controlled substance anorexiant for weight management in compliance with paragraph (A) of this rule and the following:
- (1) The physician shall meet face-to-face with the patient for the initial visit and at least every thirty days during the first three months of treatment. If the F.D.A. approved labeling for the controlled substance anorexiant requires induction of treatment at one dose and an increase to a higher dose after a stated period of less than thirty days, the physician may give the patient a prescription for

the higher dose at the initial visit and the first thirty day period then starts from the date the prescription for the higher dose may be filled.

- (2) Following the initial visit and two follow-up visits, the treatment may be continued under one of the following means:
 - (a) The physician may authorize refills for the controlled substance anorexiant up to five times within six months after the initial prescription date;
 - (b) The treatment may be provided by a physician assistant in compliance with this rule, the supervisory plan or policies of the healthcare facility, and the physician assistant formulary adopted by the board.
- (3) When treatment for chronic weight management is provided by a physician assistant, the following requirements apply:
 - (a) The supervising physician shall personally review the medical records of each patient to whom the physician assistant has prescribed a controlled substance anorexiant following each visit; and
 - (b) A physician assistant shall not initiate utilization of a different controlled substance anorexiant, but may recommend such change for the supervising physician's initiation.
- (4) A physician shall discontinue utilizing any controlled substance anorexiant immediately upon ascertaining or having reason to believe:
 - (a) That the patient has repeatedly failed to comply with the physician's treatment recommendations; or
 - (b) That the patient is pregnant.
- (C) A violation of any provision of this rule, as determined by the board, shall constitute the following as applicable:
 - (1) For a physician:
 - (a) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of

section 4731.22 of the Revised Code;

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

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

(2) For a physician assistant:

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

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

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



MEMORANDUM

TO: Betty Montgomery, President, State Medical Board of Ohio
Members, State Medical Board of Ohio

FROM: Nathan T. Smith, Senior Legal and Policy Counsel

DATE: April 7, 2022

RE: Telehealth rules proposed for filing with CSI

The Board received sixty-two (62) comments on the telehealth rules approved by the Board for initial circulation at its February 9, 2022 meeting. This is in addition to seven (7) other comments received before the February Board meeting. Attached to this memo are: (1) revised proposed telehealth rules with recommended changes; (2) a spreadsheet summarizing the comments and their disposition; and (3) the actual written comments. This memo analyzes the written comments in the subject areas in which most of the comments were received. Recommendations are provided for changes to the proposed telehealth rules for filing with the Common Sense Initiative (CSI). Additional recommendations for minor or stylistic changes are contained in the spreadsheet and reflected in the revised proposed rules.

Proposed new rule 4731-37-01

Definition of asynchronous communication technology in 4731-37-01(A)(3)

Comments (ATA, Bon Secours, Cleveland Clinic, Dr. Gelles, hims & hers, MetroHealth, OHA, and OSU Wexner Medical Center) suggested revising the definition to expand the types of stored clinical information that may be transmitted through asynchronous communication. These comments differed on what should be included. **Recommendation:** define asynchronous communication technology by reference to the definition of the term in 42 CFR § 410.78 for consistency with federal law.

Add definition for formal consultation in 4731-37-01(A)(7) to clarify other parts of rule

OHA comment suggested defining formal consultation to clarify other parts of the rule in which formal consulting or consultation are referenced. University Hospital commented that inclusion of “formal” before consulting adds ambiguity to definition of telehealth services.

Recommendation: Add definition suggested by OHA except for portion involving billing:

(7) “Formal consultation” means when a health care professional seeks the professional opinion of another health care professional regarding the diagnosis or treatment recommended for the patient’s medical condition presented, transfers the relevant portions of the patient’s medical record to the consulting health professional, and documents the formal consultation in the patient’s medical record.

Out of State Practice (4731-37-01(B) and (F))

R.C. 4743.09(C)(5) states that a health care professional who is a physician, physician assistant (PA), or advance practice registered nurse (APRN) may provide the following: (a) “telehealth services to a patient located outside of this state if permitted by the laws of the state in which the patient is located” and (b) “telehealth services through the use of medical devices that enable remote monitoring, including such activities as monitoring a patient’s blood pressure, heart rate, or glucose level.” Based on this additional authority specifically granted to physicians and PAs and not granted to other health care professionals, the proposed telehealth rules include the following provisions:

(B) A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:

(F) A health care professional that is a physician or physician assistant may provide the following additional telehealth services:

(1) A physician or physician assistant may provide telehealth services to a patient located outside of this state if permitted by the laws of the state in which the patient is located. The physician or physician assistant shall confirm and document in the medical record the location of the patient.

(2) A physician or physician assistant may provide telehealth services through the use of remote monitoring devices provided that:

Thirty-three comments (from licensed dietitians, OAND, OSRC, and Kroger Health) suggested revising the language in 4731-37-01(B) to allow dietitians, respiratory care professionals, and genetic counselors to provide telehealth services to patients located out of state.

Comments from OSMA and OPPA stated that 4731-37-01(F)(1) should be deleted as unnecessary and stated that “we do not feel the State Medical Board of Ohio’s telehealth rules should consider whether other state’s telehealth rules support an Ohio physician practicing telehealth in that state.”

Dr. Gelles’ comment raised the following questions/concerns with (F)(1): “Does the allowability of out-of-state care extend to a physician and patient dyad that does not have a pre-existing relationship? Is there a limit to how many visits across state lines can be done before an in person visit is required? There should be some restrictions on this so that corporate entities like amazon don’t start competing with Ohio physicians and try to take over the care of their patients. Also, unlimited telemedicine care across state lines (without some in person care required) can enable a patient who has moved not to establish care with a new primary care physician in their new home state. If you are providing care to a patient located in another state, is there an easy way to tell that this is allowed by law in the state where the patient is located?”

Recommendation: After consideration of the diverse comments, it is recommended to remove paragraph (F)(1) for clarity and consistency regarding the proposed rule’s regulation of telehealth services provided to patients located in this state.

Referral provisions in 4731-37-01(B)(4)

Comments (from Bon Secours, OHA, ATA, Teladoc, OSU Wexner Medical Center, and hims & hers) requested revision of the referral provisions to provide additional flexibility to whom a health care professional can refer, particularly as to the referral provision in (B)(4)(a). These comments oppose the current referral provisions because: (1) they are overly complicated; (2) impose unreasonable barriers that would limit patient access and make it difficult for some providers to offer telehealth services; and/or (3) hold telehealth services to a higher standard than in-person services.

Comments (from the OSMA and OPPA) stated that paragraph (B)(4)(b) needs to be clarified to allow a health care professional to refer the patient to another health care professional in the same specialty when the patient needs non-immediate care.

A comment from the Ohio American College of Emergency Physicians supported the provision in 4731-37-01(B)(4)(d) requiring the health care professional to notify the emergency room of a patient's potential arrival, while several other comments suggested this provision was overly burdensome and may cause confusion.

Comments (OneFifteen and Ms. Melvin) inquired about the inclusion of APRNs in the telehealth rules. We also received additional input from the Nursing Board regarding the various types of APRNs involved in telehealth, cross coverage agreements, and standard care arrangements.

Recommendation: After balancing all comments on the various components of this issue, the following changes are recommended:

- (1) 4731-37-01(A)(8) define advanced practice registered nurse for purposes of this rule to include clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.
- (2) 4731-37-01(B)(4)(a) – add APRNs as health care professionals that patients can be referred to via cross-coverage agreement or standard care arrangement.
- (3) Revise 4731-37-01(B)(4)(b)-(d) as follows:

(b) If the patient does not need to be seen immediately, the health care professional shall **do one of the following:**

(i) schedule the patient for an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented; or

(ii) **refer the patient to a health care professional in the same specialty to conduct an in-person visit within an amount of time that is appropriate for the patient and their condition.**

(c) If the patient must be seen by a specialist other than the health care professional, the health care professional shall make a referral to a specialist, licensed in this state, whom the healthcare professional knows has an appropriate scope of practice **for the medical condition of the patient** and ~~is capable of~~

~~conducting an in-person visit appropriate for the diagnosis and treatment of the patient's condition and ensure that all necessary medical files are shared upon request.~~

(d) If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency room and, if necessary, in the health care professional's discretion, provide notification to the emergency room of the patient's potential arrival.

Consent for treatment (4731-37-01(A)(6) and (C))

Comments (OPPA, Bon Secours) suggested limiting consent for telehealth treatment to initial visits or revising telehealth consent to an annual requirement rather than for each visit. University Hospitals commented that consent for treatment is not needed for a formal consultation if the patient has already consented to treatment.

No change recommended - Other stakeholder input obtained in stakeholder meetings has viewed informed consent as a valuable part of each telehealth visit that does not impose an undue burden.

Cleveland Clinic requested deleting risk discussion in the definition of consent for treatment because that requires more than is required for in-person consent for treatment.

No change recommended – this consent for treatment language is in current rule 4731-11-09 and exists for patient protection.

OHA offered several suggestions for revising paragraphs related to consent for treatment including: (a) change the term “consent for treatment” to “consent for telehealth treatment”; (b) replace the term “consent for treatment” for consultation in 4731-37-01(D)(1) with the term “acknowledge”; and (c) revise the language throughout the rule for simplicity and clarity from the term “patient, parent, guardian or person designated under the patient’s health care power of attorney” to the term “patient or legal representative of the patient.”

Recommendation: Revise rule to change terms to “consent for telehealth treatment” and “patient or patient’s legal representative” in paragraph (A)(6) and references throughout the rule. **No change recommended** regarding (b) changing the term “consent for telehealth treatment” to the term “acknowledge” in paragraph (D)(1).

Standard of Care Requirements – 4731-37-01(C)

Communication of Licensure Information (4731-37-01(C)(1))

Cleveland Clinic suggested changing the requirement for a health care professional to always communicate licensure information to the patient to only requiring this when the patient requests it. Dr. Levy commented that the requirement to communicate licensure information may only be necessary in situations where patient contacts a telehealth service provider who then connects the patient with a physician unknown to the patient. OHA requested clarification that the name and location of the patient can be verified verbally.

Recommendations – In situations where the telehealth provider is unknown to the patient, the benefit of the health care professional providing their name and type of active Ohio license outweighs the minimal burden. **Revise paragraph (C)(1) to state:**

The health care professional shall verify the patient's identity and location in Ohio, and communicate the health care professional's name and licensure information type of active Ohio license held to the patient if the health care professional has not previously treated the patient. This may be done verbally as long as it is documented by the health care professional in the patient's medical record.

Transmission of Patient's Medical Records (4731-37-01(C)(4))

OHA, University Hospitals, and the Ohio Department of Mental Health and Addiction Services suggested revisions to (C)(4) to reflect current practice and for consistency with the HIPAA Privacy Rule. **Recommendation:** revise (C)(4) as follows:

If applicable, the health care professional shall request the patient's, or if applicable, the patient's parent, guardian, or person designated under the patient's health care power of attorney, authorization and, if granted, forward the medical record to the patient's primary care provider, or other health care provider designated by the patient or the patient's legal representative, or refer the patient to an appropriate health care provider or healthcare facility to whom the patient is referred as provided in paragraph (B)(4) of this rule."

Remote Monitoring (4731-37-01(A)(4) and (F))

Ms. Collins' comment asked would the Medical Board allow a clinical research exemption to the requirement that a remote monitoring device be FDA approved, cleared, or authorized.

No change recommended - paragraphs include cleared, approved, or authorized by FDA to allow for the health care professional to utilize any existing FDA pathways for clinical research.

OSU Wexner Medical Center's comment suggested that the definition of remote monitoring devices be expanded to include digital therapeutics, digital software, and digital algorithms. MetroHealth systems commented that FDA approved algorithms should be included in the definition.

No change recommended: R.C. 4743.09(C)(5) allows telehealth through the use of medical devices that enable remote monitoring." The definition of remote monitoring device in 4731-37-01(A)(4) is tied to the FDA's definition of medical device. While some software and algorithms are included under the FDA definition of medical devices, not all software and algorithms are FDA approved, cleared, or authorized medical devices.

OSRC's comment requested that RCPs be permitted to provide telehealth services through the use of remote monitoring devices.

No change recommended – R.C. 4743.09(C)(5) only authorizes a physician, PA, or APRN to provide this care through telehealth.

4731-11-09

Defining new patient

Dr. Miller suggested substituting “new patient to the practice” for “new patient” in 4731-11-09(D) so that a doctor who is covering for another doctor in the same practice group can prescribe a schedule II substance to a patient that is new to the covering physician, but not new to the practice without an in-person visit.

No change recommended - the rule follows the text of R.C. 4743.09 which already allows a significant portion of controlled substance prescribing to occur without an in-person visit.

In-person visit requirements and exceptions to that requirement

Comments by Dr. Berkowski and Dr. Reynolds objected to the in-person visit requirements. **No change recommended:** The initial in-person visit for prescribing a schedule II controlled substance to a new patient is authorized by R.C. 4743.09(B)(2).

Comments (Dr. Barker, Cleveland Clinic, OSU Wexner Medical Center, and OHA) requested additional exceptions to the in-person visit requirement.

No change recommended: The exceptions in 4731-11-09(E) are authorized by R.C. 4743.09(B)(2). The additional exceptions requested in the comments are not among those listed in the statute. Further, other exceptions requested are covered under the requirement in 4731-11-09(B) that the prescribing must comply with federal law governing prescription drugs that are controlled substances.

Other changes made to this rule for clarity include: (1) updating the definition of mental health condition in paragraph (A)(4) to reflect the recent publication of the "Diagnostic and Statistical Manual of Mental Disorders Fifth Edition Text Revision" (DSM-5-TR) and (2) removing paragraph (J) “For purposes of this rule, "patient" means a person for whom the physician or physician assistant provides healthcare services or the person's representative.” This provision is recommended to be removed because it relates to the consent for telehealth treatment provisions which are in proposed rule 4731-37-01.

Rules incorporating the new telehealth rule OAC 4731-37-01

There were no comments made to these rules and there are no changes proposed to the following rules which incorporate OAC 4731-37-01 into the respective chapters for physician assistants, dietitians, respiratory care professionals, and genetic counselors: Rule 4730-1-07 Miscellaneous provisions, 4730-2-07 Standards for Prescribing, Rule 4759-11-01 Miscellaneous Provisions, Rule 4761-15-01 Miscellaneous provisions, and Rule 4778-1-06 Miscellaneous provisions.

Other comments:

Other comments received (Carter, Craven, Lenchitz, Khan, Koznek, Melvin, West, Runyon, Neurocrine Biosciences, and Hernandez) do not require changes for at least one of the following reasons:

the comment was positive or did not suggest changes; the comment did not address the substance of the proposed rules, the comments proposed stylistic changes, and the comments requested changes that either the rules already allow or the authorizing statute (R.C. 4743.09) does not permit.

Actions Requested:

- (1) Discuss and approve revised proposed rules (4731-37-01, 4731-11-09, 4730-1-07, 4730-2-07, 4759-11-01, Rule 4761-15-01, and 4778-1-06) for filing with CSI.

4731-37-01

Telehealth.

(A) As used in Chapters 4730, 4731, 4759, 4761, and 4778 of the Administrative Code:

(1) "Telehealth services" means health care services provided through the use of information and communication technology by a health care professional licensed in Ohio, within the professional's scope of practice, who is located at a site other than the site where the patient is receiving the services or the site where another health care professional with whom the provider of the services is formally consulting regarding the patient is located.

(2) "Synchronous communication technology" means audio and/or video technology that permits two-way, interactive, real-time electronic communication between the health care professional and the patient or between the health care professional and the consulting health care professional regarding the patient.

(3) "Asynchronous communication technology", also called store and forward technology, has the same meaning as asynchronous store and forward technologies as that term is defined in 42 C.F.R. 410.78 (effective January 1, 2022).

(4) "Remote monitoring device" means a medical device cleared, approved, or authorized by the United States food and drug administration for the specific purpose which the health care professional is using it and which reliably transmits data electronically and automatically.

(5) "Health care professional" means any of the following:

(a) A physician assistant licensed under Chapter 4730. of the Revised Code;

(b) A physician licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(c) A dietitian licensed under Chapter 4759. of the Revised Code;

(d) A respiratory care professional licensed under Chapter 4761. of the Revised Code; or

(e) A genetic counselor licensed under Chapter 4778. of the Revised Code.

(6) "Consent for telehealth treatment" means a process of communication between a patient or, if applicable, the patient's legal representative and the health care professional discussing the risks and benefits of, and alternatives to, treatment through a remote evaluation that results in the agreement to treatment that is documented in the medical record or signed authorization for the patient to be treated through an evaluation conducted through appropriate technology, as

specified in this rule, when the health care professional is in a location remote from the patient.

(7) "Formal consultation" means when a health care professional seeks the professional opinion of another health care professional regarding the diagnosis or treatment recommended for the patient's medical condition presented, transfers the relevant portions of the patient's medical record to the consulting health care professional, and documents the formal consultation in the patient's medical record.

(8) As used in this rule, "advanced practice registered nurse" means an individual who holds a current, valid license issued under Chapter 4723. of the Revised Code that authorizes the practice of nursing as an advanced practice registered nurse and is designated as any of the following: clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

(B) A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:

(1) The standard of care for a telehealth visit is the same as the standard of care for an in-person visit.

(2) The health care professional shall follow all standard of care requirements which include but are not limited to the standard of care requirements in paragraph (C) of this rule.

(3) The health care professional may provide the telehealth services through the use of synchronous or asynchronous communication technology provided that the standard of care for an in-person visit can be met for the patient and the patient's medical condition through the use of the technology selected. Telephone calls, as a synchronous communication technology, may only be used for telehealth services when all of the elements of a bona fide health care visit meeting the standard of care are performed. Telephone calls that are routine or simply involve communication of information do not constitute a telehealth service.

(4) If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall do the following:

(a) If the patient must be seen immediately but not in an emergency department, the health care professional shall immediately schedule the patient for an in-person visit with the health care professional and promptly conduct that visit or refer the patient for an in-person visit with one of the following licensed health care professionals who can

provide the services in-person that are appropriate for the patient and the condition for which the patient presents:

(i) Another health care professional or an advanced practice registered nurse with whom the health care professional has a cross-coverage agreement.

(ii) In the case of a physician, a physician assistant with whom the physician has a supervision agreement or an advanced practice registered nurse with whom the physician has a standard care arrangement; or

(iii) In the case of a physician assistant, a physician with whom the physician assistant has a supervision agreement.

(b) If the patient does not need to be seen immediately, the health care professional shall do one of the following:

(i) Schedule the patient for an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented; or

(ii) Refer the patient to a health care professional in the same specialty to conduct an in-person visit within an amount of time that is appropriate for the patient and their condition.

(c) If the patient must be seen by a specialist other than the health care professional, the health care professional shall make a referral to a specialist, licensed in this state, whom the healthcare professional knows has an appropriate scope of practice for the medical condition of the patient.

(d) If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency department and, if necessary, in the health care professional's discretion, provide notification to the emergency department of the patient's potential arrival.

(e) The health care professional shall document the in-person visit or the referral in the patient's medical record.

(f) All referrals must be made in an amount of time that is appropriate for that patient and their condition presented.

(C) A health care professional must comply with all standard of care requirements to provide telehealth services to a patient including but not limited to:

(1) The health care professional shall verify the patient's identity and physical

location in Ohio, and communicate the health care professional's name and type of active Ohio license held to the patient if the health care professional has not previously treated the patient. This may be done verbally as long as it is documented by the health care professional in the patient's medical record;

- (2) The health care professional shall document the consent for telehealth treatment of the patient or, if applicable, the patient's legal representative;
- (3) The health care professional shall provide the telehealth services in a manner that complies with the privacy and security requirements for the patient and their protected health information required by the law of this state and federal law. Also, the health care professional shall ensure that any username or password information and any electronic communications between the health care professional and the patient are securely transmitted and stored;
- (4) If applicable, the health care professional shall forward the medical record to the patient's primary care provider, other health care provider, or to an appropriate health care provider to whom the patient is referred as provided in paragraph (B)(4) of this rule;
- (5) The health care professional shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care for an in-person visit, which may include portions of the evaluation having been conducted by other Ohio licensed healthcare providers acting within the scope of their professional license;
- (6) The health care professional shall establish or confirm, as applicable, a diagnosis and treatment plan, which for those health care professionals designated as prescribers in section 4729.01 of the Revised Code, includes documentation of the necessity for the utilization of a prescription drug. The diagnosis and treatment plan shall include the identification of any underlying conditions or contraindications to the recommended treatment;
- (7) The health care professional shall promptly document in the patient's medical record the patient's or, if applicable, the patient's legal representative, consent for telehealth treatment, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;
- (8) The health care professional shall provide appropriate follow-up care or recommend follow-up care with the patient's primary care provider, other appropriate health care provider, or health care facility in accordance with the minimal standards of care;
- (9) The health care professional shall make the medical record of the visit available

to the patient or if applicable, the patient's legal representative, upon request.

(D) A health care professional must comply with the following requirements to provide telehealth services that involve a formal consultation with another health care professional:

(1) The referring health care professional who seeks a formal consultation shall document the consent for treatment of the patient or if applicable, the patient's legal representative, before seeking the telehealth services formal consultation with the consulting health care professional;

(2) The consulting health care professional must meet the licensure or certification requirements in division (C) of section 4743.09 of the Revised Code; and

(3) The health care professionals involved in the formal consultation must have received and reviewed all medical records of the patient relevant to the medical condition which is the subject of the consultation before the formal consultation occurs, unless this is not possible due to an emergency situation.

(E) While providing telehealth services, a health care professional that is a physician or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority shall comply with the following requirements regarding prescription drugs:

(1) The physician or physician assistant may only prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is not a controlled substance to a patient through the provision of telehealth services by complying with all requirements of this rule;

(2) The physician or physician assistant may only prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug to a patient that is a controlled substance through the provision of telehealth services by complying with the following requirements:

(a) Federal law governing prescription drugs that are controlled substances;

(b) The requirements of this rule; and

(c) The requirements in rule 4731-11-09 of the Administrative Code.

(F) A physician or physician assistant may provide telehealth services through the use of remote monitoring devices provided that:

(1) The patient or, if applicable, the patient's legal representative, gives consent for treatment to the use of remote monitoring devices;

(2) The medical devices that enable remote monitoring have been cleared,

approved, or authorized by the United States food and drug administration for the specific purpose for which the physician or physician assistant are using it for the patient, and the remote monitoring devices otherwise comply with all federal requirements.

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

(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; or

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

(2) For a physician assistant:

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

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

(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.

(3) For a dietitian:

(a) "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 or the rules adopted by the board," as that clause is used in

division (A)(1) of section 4759.07 of the Revised Code; or

(b) "A departure from, or 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 (A)(11) of section 4759.07 of the Revised Code.

(4) For a respiratory care professional:

(a) "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 or the rules adopted by the board," as that clause is used in division (A)(7) of section 4761.09 of the Revised Code; or

(b) "A departure from, or 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 (A)(10) of section 4761.09 of the Revised Code.

(5) For a genetic counselor:

(a) "Failure to comply with the requirements of this chapter, Chapter 4731. of the Revised Code, or any rules adopted by the board." as that clause is used in division (B)(2) of section 4778.14 of the Revised Code;

(b) "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 4778.14 of the Revised Code; or

(c) "A departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances whether or not actual injury to the patient is established," as that clause is used in division (B)(4) of section 4778.14 of the Revised Code.

4731-11-09

Controlled substance and telehealth prescribing.

(A) As used in this rule:

- (1) "Hospice care" means the care of a hospice patient as that term is defined in section 3712.01 of the Revised Code.
- (2) "Palliative care" has the same meaning as in section 3712.01 of the Revised Code.
- (3) "Medication assisted treatment" and "substance use disorder" have the same meanings as in rule 4731-33-01 of the Administrative Code.
- (4) "Mental health condition" means any mental health condition, illness, or disorder as determined by the diagnostic criteria in the "Diagnostic and Statistical Manual of Mental Disorders Fifth Edition Text Revision" (DSM-5-TR). This is a well-known and readily available text. It may be found at libraries, bookstores, or on the internet at www.psychiatry.org.
- (5) "Emergency situation" means a situation involving an "emergency medical condition" as that term is defined in section 1753.28 of the Revised Code.

(B) A physician or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority must comply with federal law governing prescription drugs that are controlled substances to prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is a controlled substance to a person.

(C) When the physician or physician assistant, who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority, prescribes, personally furnishes, otherwise provides, or causes to be provided a prescription drug that is a controlled substance during the provision of telehealth services, the physician or physician assistant must comply with all requirements in rule 4731-37-01 of the Administrative Code.

(D) The physician or physician assistant shall conduct a physical examination of a new patient as part of an initial in-person visit before prescribing a schedule II controlled substance to the patient except as provided in paragraph (E) of this rule.

(E) As an exception to paragraph (D) of this rule, a physician or physician assistant may prescribe a controlled substance to a new patient as part of the provision of telehealth services for any of the following patient medical conditions and situations:

- (1) The medical record of a new patient indicates that the patient is receiving hospice or palliative care;
- (2) The patient has a substance use disorder, and the controlled substance is FDA

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approved for and prescribed for medication assisted treatment or to treat opioid use disorder.

(3) The patient has a mental health condition and the controlled substance prescribed is prescribed to treat that mental health condition; or

(4) The physician or physician assistant determines in their clinical judgment that the new patient is in an emergency situation provided that the following occurs:

(a) The physician or physician assistant prescribes only the amount of a schedule II controlled substance to cover the duration of the emergency or an amount not to exceed a three-day supply whichever is shorter;

(b) After the emergency situation ends, the physician or physician assistant conducts the physical examination as part of an initial in-person visit before any further prescribing of a drug that is a schedule II controlled substance.

(F) When prescribing a controlled substance through the provision of telehealth services under one of the exceptions in paragraph (E) of this rule, the physician or physician assistant shall document one of the reasons listed in paragraph (E) for the prescribing in the medical record of the new patient in addition to the documentation already required to meet the standard of care in rule 4731-37-01 of the Administrative Code.

(G) Nothing in this rule shall be construed to imply that one in-person physician examination demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice.

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

(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; or

(c) "A departure from or the failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is

used in division (B)(6) of section 4731.22 of the Revised Code.

(2) For a physician assistant:

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

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

(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.

(I) This rule shall not apply to any prescribing situations specifically authorized by the Revised Code or Administrative Code.

4731-11-09

Prescribing to persons not seen by the physician.

TO BE RESCINDED

- (A) Except as provided in paragraph (D) of this rule, a physician shall not prescribe, personally furnish, otherwise provide, or cause to be provided, any controlled substance to a person on whom the physician has never conducted a physical examination.
- (B) Except as provided in paragraph (C) of this rule, a physician shall not prescribe, personally furnish, otherwise provide, or cause to be provided, any prescription drug that is not a controlled substance to a person on whom the physician has never conducted a physical examination.
- (C) A physician may prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is not a controlled substance to a person on whom the physician has never conducted a physical examination and who is at a location remote from the physician by complying with all of the following requirements:
 - (1) The physician shall establish the patient's identity and physical location;
 - (2) The physician shall obtain the patient's informed consent for treatment through a remote examination;
 - (3) The physician shall request the patient's consent and, if granted, forward the medical record to the patient's primary care provider or other health care provider, if applicable, or refer the patient to an appropriate health care provider or health care facility;
 - (4) The physician shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care, which may include portions of the evaluation having been conducted by other Ohio licensed healthcare providers acting within the scope of their professional license;
 - (5) The physician shall establish or confirm, as applicable, a diagnosis and treatment plan, which includes documentation of the necessity for the utilization of a prescription drug. The diagnosis and treatment plan shall include the identification of any underlying conditions or contraindications to the recommended treatment;
 - (6) The physician shall document in the patient's medical record the patient's consent to treatment through a remote evaluation, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any

contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;

- (7) The physician shall provide appropriate follow-up care or recommend follow-up care with the patient's primary care provider, other appropriate health care provider, or health care facility in accordance with the minimal standards of care;
 - (8) The physician shall make the medical record of the visit available to the patient;
 - (9) The physician shall use appropriate technology that is sufficient for the physician to conduct all steps in this paragraph as if the medical evaluation occurred in an in-person visit.
- (D) A physician may prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is a controlled substance to a person on whom the physician has not conducted a physical examination and who is at a location remote from the physician in any of the following situations:
- (1) The person is an active patient, as that term is defined in paragraph (D) of rule 4731-11-01 of the Administrative Code, of an Ohio licensed physician or other health care provider who is a colleague of the physician and the drugs are provided pursuant to an on call or cross coverage arrangement between them and the physician complies with all steps of paragraph (C) of this rule;
 - (2) The patient is physically located in a hospital or clinic registered with the United States drug enforcement administration to personally furnish or provide controlled substances, when the patient is being treated by an Ohio licensed physician or other healthcare provider acting in the usual course of their practice and within the scope of their professional license and who is registered with the United States drug enforcement administration to prescribe or otherwise provide controlled substances in Ohio.
 - (3) The patient is being treated by, and in the physical presence of, an Ohio licensed physician or healthcare provider acting in the usual course of their practice and within the scope of their professional license, and who is registered with the United States drug enforcement administration to prescribe or otherwise provide controlled substances in Ohio.
 - (4) The physician has obtained from the administrator of the United States drug enforcement administration a special registration to prescribe or otherwise provide controlled substances in Ohio.

- (5) The physician is the medical director, hospice physician, or attending physician for a hospice program licensed pursuant to Chapter 3712. of the Revised Code and both of the following conditions are met:
 - (a) The controlled substance is being provided to a patient who is enrolled in that hospice program, and
 - (b) The prescription is transmitted to the pharmacy by a means that is compliant with Ohio board of pharmacy rules.
- (6) The physician is the medical director of, or attending physician at, an institutional facility, as that term is defined in rule 4729-17-01 of the Administrative Code, and both of the following conditions are met:
 - (a) The controlled substance is being provided to a person who has been admitted as an inpatient to or is a resident of an institutional facility, and
 - (b) The prescription is transmitted to the pharmacy by a means that is compliant with Ohio board of pharmacy rules.
- (E) Nothing in this rule shall be construed to imply that one in-person physician examination demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice.
- (F) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:
 - (1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;
 - (2) "Selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; or
 - (3) "A departure from or the failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

- (G) For purposes of this rule, "informed consent" means a process of communication between a patient and physician discussing the risks and benefits of, and alternatives to, treatment through a remote evaluation that results in the patient's agreement or signed authorization to be treated through an evaluation conducted through appropriate technology when the physician is in a location remote from the patient.
- (H) This rule shall not apply to any prescribing situations specifically authorized by the Revised Code or Administrative Code.
- (I) For purposes of this rule, "patient" means a person for whom the physician provides healthcare services or the person's representative.

4730-1-07

Miscellaneous provisions.

For purposes of Chapter 4730. of the Revised Code and Chapters 4730-1 and 4730-2 of the Administrative Code:

- (A) An adjudication hearing held pursuant to the provisions of Chapter 119. of the Revised Code shall be conducted in conformance with the provisions of Chapter 4731-13 of the Administrative Code.
- (B) The provisions of Chapters 4731-4, 4731-11, 4731-13, 4731-14, 4731-15, 4731-16, 4731-17, 4731-18, 4731-23, 4731-25, 4731-26, 4731-28, 4731-29, ~~and~~ 4731-35, [and 4731-37](#) of the Administrative Code are applicable to the holder of a physician assistant license issued pursuant to section 4730.12 of the Revised Code, as though fully set forth in Chapter 4730-1 or 4730-2 of the Administrative Code.

4730-2-07

Standards for prescribing.

- (A) A physician assistant who holds a prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician may prescribe a drug or therapeutic device provided the prescription is in accordance with all of the following:
- (1) The extent and conditions of the physician-delegated prescriptive authority, granted by the supervising physician who is supervising the physician assistant in the exercise of the authority;
 - (2) The requirements of Chapter 4730. of the Revised Code;
 - (3) The requirements of Chapters 4730-1, 4730-2, 4730-4, 4731-11, ~~and 4731-35.~~ [and 4731-37](#) of the Administrative Code; and
 - (4) The requirements of state and federal law pertaining to the prescription of drugs and therapeutic devices.
- (B) A physician assistant who holds a prescriber number who has been granted physician-delegated prescriptive authority by a supervising physician shall prescribe in a valid prescriber-patient relationship. This includes, but is not limited to:
- (1) Obtaining a thorough history of the patient;
 - (2) Conducting a physical examination of the patient;
 - (3) Rendering or confirming a diagnosis;
 - (4) Prescribing medication, ruling out the existence of any recognized contraindications;
 - (5) Consulting with the supervising physician when necessary; and
 - (6) Properly documenting these steps in the patient's medical record.
- (C) The physician assistant's prescriptive authority shall not exceed the prescriptive authority of the supervising physician under whose supervision the prescription is being written, including but not limited to, any restrictions imposed on the physician's practice by action of the United States drug enforcement administration or the state medical board of Ohio.

- (D) A physician assistant holding a prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician to prescribe controlled substances shall apply for and obtain the United States drug enforcement administration registration prior to prescribing any controlled substances.
- (E) A physician assistant holding prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician shall not prescribe any drug or device to perform or induce an abortion.
- (F) A physician assistant holding prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician shall include on each prescription the physician assistant's license number, and, where applicable, shall include the physician assistant's DEA number.

4759-11-01

Miscellaneous provisions.

For purposes of Chapter 4759. of the Revised Code and rules promulgated thereunder:

- (A) An adjudication hearing held pursuant to the provisions of Chapter 119. of the Revised Code shall be conducted in conformance with the provisions of Chapter 4731-13 of the Administrative Code.
- (B) The provisions of Chapters 4731-4, 4731-8, 4731-13, 4731-15, 4731-16, 4731-26, ~~and~~ 4731-28, and 4731-37 of the Administrative Code are applicable to the holder of a license or limited permit issued pursuant to Chapter 4759. of the Revised Code, as though fully set forth in agency 4759 of the Administrative Code.

4761-15-01

Miscellaneous provisions.

For purposes of Chapter 4761. of the Revised Code and rules promulgated thereunder:

- (A) An adjudication hearing held pursuant to the provisions of Chapter 119. of the Revised Code shall be conducted in conformance with the provisions of Chapter 4731-13 of the Administrative Code.
- (B) The provisions of Chapters 4731-4, 4731-8, 4731-13, 4731-15, 4731-16, 4731-17, 4731-26, ~~and~~ 4731-28, and 4731-37 of the Administrative Code are applicable to the holder of a license or limited permit issued pursuant to Chapter 4761. of the Revised Code, as though fully set forth in agency 4761 of the Administrative Code.

4778-1-06

Miscellaneous provisions.

For purposes of Chapter 4778. of the Revised Code and rules promulgated thereunder, the provisions of Chapters 4731-13, 4731-16, 4731-26, ~~and~~ 4731-28, [and 4731-37](#) of the Administrative Code are applicable to the holder of a license to practice as a genetic counselor issued under Chapter 4778. of the Revised Code, as though fully set forth in Chapter 4778-1 or Chapter 4778-2 of the Administrative Code.

Comments on Initial Circulation of Telehealth Rules

Name & Med Bd license Type (if applicable)	Email	Organization	Comments	Disposition of Comments
Miller, Laverne MD	drmilller@cmhosp.com		The term "new patient" in 4731-11-09 should be defined. She suggests substituting "new patient to the practice" because, when a doctor is covering for another doctor in the same practice group, the covering doctor can safely prescribe controlled substances by consulting the medical record and checking OARRS for a patient that is new to the covering doctor, but not new to the practice group.	No change recommended. The proposed rule directly implements R.C. 4743.09(B)(2) which only allows the Board to require "an initial in-person visits prior to prescribing a schedule II controlled substance to a new patient" with several exceptions.
Zebley, Kyle	kzebley@ataaction.org	ATA Action	(1) 4731-37-01(A)(3) - Definition of asynchronous communication is restrictive and could cause confusion among telehealth providers. Specifically, the transmission of stored clinical data should not be limited to video clips, sound/audio files, or photo images. This could exclude things like the transmission of patient medical histories and lab results from qualifying as asynchronous communication. (2) 4731-37-01(B)(4) - Referral provisions are impractical, restrict providers' ability to deliver telehealth services in Ohio, and hold telehealth services to a higher standard than in-person services. The provision in (B)(4)(d) requiring a telehealth provider to help the patient identify the closest emergency room and provide notification to the emergency room of the patient's potential arrival could risk patient safety by delaying their arrival to the emergency room.	(1) considered comment in revision to definition of asynchronous communication technology; (2) considered comment in revision of referral provisions.
Barker, Bruce, MD	Bruce.Barker@ohiohealth.com		4731-11-09(E) - This language is overly prescriptive and will result in the more complex patient being treated for obesity not being able to continue on treatment Anorectic therapy should be added to the list of exceptions. Also, under the proposed rule, prescribing sedative hypnotics, such as low level sleep aides like Ambien or Lunesta, during a telehealth visit is prohibited.	No changes recommended. The exceptions in 4731-11-09(E) are authorized by R.C. 4743.09(B)(2). The exceptions requested in the comment are not among those listed in the statute. As Ambien is a schedule IV drug, it is subject to the requirements of proposed 4731-11-09 (B) and (C), but is not prohibited by the proposed rule.
Berkowski, Andy, MD	BERKOWJ@ccf.org		4731-11-09(D)-(E) - opposed to these paragraphs because they require an initial in-person visit and that will be a barrier to many of his patients as he states that over 80% of his patients being treated for Restless legs syndrome (RLS) require schedule II and III opiates, are seen virtually, and live more than an hour from a Cleveland Clinic facility.	No changes recommended. The initial in-person visit for prescribing a schedule II controlled substance to a new patient is authorized by R.C. 4743.09 (B)(2)
Bestic, Anna, LD	BESTICA@ccf.org		Proposed 4731-37-01(B) restricts dietitians from providing telehealth out of state and may have negative effect on patient access to care. Requests revising 4731-37-01(B) to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Bon Secours Mercy Health	jpfishpaw@mercy.com	Bon Secours Mercy Health	(1) 4731-37-01(A)(3)- Definition of asynchronous communication should include written communication through a patient portal as part of the definition of stored clinical data or clarify that E-visits may be delivered by practitioners. (2) 4731-37-01(B)(4) - the referral provisions should include the ability to refer the patient for an in-person visit with a health care professional who is not in a cross-coverage relationship with the referring health care professional. This would prevent delays in care. (3) Consent for telehealth treatment provisions in 4731-37-01 - change these provisions to only require annual telehealth consent. As drafted this requires additional time that detracts from time spend delivering care. Suggested change would be consistent with CMS annual consent requirement for telehealth services such as e-visits and virtual check-ins.	(1) considered comment in revised definition of asynchronous communication; (2) considered comment in revised referral provisions; (3) no change recommended - stakeholder input obtained in stakeholder meetings indicates obtaining consent for treatment is a valuable part of each telehealth visit that does not impose an undue burden.
Bury, Christan, LD	BURYC@ccf.org		Proposed 4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Requests revising 4731-37-01(B) to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.

Butscher, Heather, LD	Heather.Butscher@UHHospitals.org		Proposed 4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and may have negative effect on patient care and access to care. Requests revising 4731-37-01(B) to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Cleveland Clinic - Blair Barnhart and Dr. Steven Shook	barnhab@ccf.org	Cleveland Clinic	(1) 4731-37-01(A)(3)- Definition of asynchronous communication - suggests revising the language as: "Asynchronous communication also includes bi-directional text-based communication between a provider and an established patient which is both (1) communicated via a HIPPA compliant digital platform, and (2) reviewed and responded to by a licensed medical professional for the purpose of providing medical care. Asynchronous also includes remote patient monitoring where physiologic data is reviewed by a provider who then makes a recommendation for continuing care. It does not include telephone calls, images transmitted via facsimile machines, or unidirectional text messages communicated via a non-HIPPA compliant digital platform." (2) 4731-37-01(A)(7) Definition of consent for treatment: requests deleting risk discussion in telehealth consent for treatment because that requires more than is required for in-person consent for treatment. (3) Strongly supports revised language in 4731-37-01(B)(3); (4) 4731-37-01(C)(1) - suggests revising requirement to upon request, the health care professional communicate licensure information. (5) 4731-11-09(E)(4)- urges adding two new exceptions to in-person visit requirement for prescribing schedule II controlled substances to a new patient: "patients currently being treated as inpatients in other facilities and residents of nursing home."	(1) considered comment in revised definition of asynchronous communication; (2) no change recommended - this language is in current OAC 4731-11-09 and exists for patient safety; (3) no change requested - positive comment; (4) considered comment in revising 4731-37-01(C)(1); (5) no changes recommended - the exceptions in 4731-11-09(E) are authorized by R.C. 4743.09(B)(2) and the exceptions requested in the comment are not among those provided in the statute.
Collins, Aileen	Aileen.Collins@nationwidechildrens.org	Nationwide Children's Hospital	4731-37-01 (F)(2)(b): would the Medical Board allow a clinical research exemption to requirement that remote monitoring device be FDA cleared, approved, or authorized.	No change recommended - language includes cleared, approved, or authorized by FDA to allow for health care professional to utilize any existing FDA pathways for clinical research or trials.
Craven, Deborah	debcraven06@yahoo.com		Reviewed the proposed rules and states "I am in favor."	No changes requested.
Culbertson, Gillian	CULBERG@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could negatively effect the health of her patient population. Requests rule to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
DiMarino, Anthony, LD	dimaria@ccf.org		4731-37-01(B) restricts dietitians from providing telehealth out of state and may negatively impact my patient population and our clinic . Requests revising paragraph to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements: "	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Gelles, Ellen, MD	egelles@metrohealth.org		(1) 4731-37-01(A)(3) clarification needed on whether back and forth messaging over a secure patient portal is included in the definition of asynchronous communication. (2) 4731-37-01(F)(1) questions and comments include: does allowability of out of state care extend to a new patient being seen by a physician for the first time?; "is there a limit to how many visits across state lines can be done before an in-person visit is required?; There should be some restrictions on this so that corporate entities like amazon don't start competing with Ohio physicians and try to take over the care of their patients. Also, unlimited telemedicine care across state lines (without some in person care required) can enable a patient who has moved not to establish care with a new primary care physician in their new home state. If you are providing care to a patient located in another state, is there an easy way to tell that this is allowed by law in the state where the patient is located? Education might be needed so that physicians know which states don't allow this." Are you allowed to do a telehealth visit with a patient located outside of the U.S.?	(1) Comment considered in revision of definition of asynchronous communication technology. (2) Comment considered in removal of 4731-37-01(F)(1).

Goldian, Kristen Welch, LD	kgoldian@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Allowing patients full access to healthcare regardless of what state we are in is better for patient care. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Pitts, Dartesia	dpitts@forhims.com	hims & hers	(1) 4731-37-01(A)(3) definition of asynchronous communication is too restrictive in its limits on types or stored clinical data allowed. This limits patient access and does not allow providers to exercise professional discretion when determining the best modality to treat patients. (2) 4731-37-01(B)(4) - referral obligations impose unreasonable barriers that would limit patient access. Also, the barriers would make it impractical for most providers to offer any telehealth services as they would not be able to comply with the required referrals to in-person care.	(1) Comment considered in revision of definition of asynchronous communication technology. (2) Comment considered in revisions of referral provisions in 4731-37-01(B)(4).
Homan, Elyse, LD	HOMANE@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Allowing out of state patients to have access to nutrition therapy via telehealth optimizes time spent receiving adequate nutrition and also allows for more equitable health care to people in remote areas. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Kennel, Julie, LD	kennel.3@osu.edu		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Telehealth improves access to nutrition services. Limiting access to nutrition services worsens outcomes. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Kerner, Jennifer, LD	jennifer.n.kerner@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could negatively impact patients due to the travel involved in attending in-person visits. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Khan, Mukarram, DO	khan@aspm.com		Audio only calls need to be made permanent.	No change recommended - 4731-37-01(B)(3) allows for synchronous communication including audio telephone calls under conditions described in that paragraph.
Korsberg, Jane, LD	nutritionrealityllc@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could negatively affect the health of my patients who have relocated and significantly restrict my practice. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements: "	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction regulating telehealth.
Koznek, K, DO	bakerkoznek@roadrunner.com		The explosion of telemedicine would not have been necessary if pharmacies, hospitals, and state medical agencies not interfered with practice of medicines such as physician off-label prescribing.	No change requested - comment does not address proposed telehealth rules.
Lindholz, Colleen	taylor.newman@kroger.com	Kroger Health	4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and would disrupt current patient continuity of care and future opportunities to serve new patients. This provision would also limit our business opportunities. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements: "	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Lenchitz, Bernard, MD	lenchib@ucmail.uc.edu		Supports proposed rule 4731-11-09.	No change requested.
Loch, Laura, LD	Laura.Loch@thechristhospital.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and may hinder her ability to provide care to immunocompromised patients in Northern Kentucky, who prefer telehealth visits during the ongoing pandemic.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.

Ludy, Dr. Mary-Jon	mludy@bgsu.edu		4731-37-01(B) will likely affect a dietitian faculty member at Bowling Green who is involved in a pilot study about food allergy education with another dietitian in North Carolina because the faculty member is not licensed in North Carolina. Requests that wording of rule be changed to give dietitians, respiratory therapists, and genetic counselors the same telehealth practice permissions as physician and physician assistants.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Luis, Maria Garcia	GARCIA29@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and significantly impacts the patients and the services we provide. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Jamieson-Petonic, Amy, LD	Amy.Jamieson-Petonic@Uhhospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and may negatively impact my patients' health. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Match, Alie, LD	Alie.Match@UHealth.com		4731-37-01(B) - worried that this rule would significantly hinder ability to provide equal care to patients in Indiana and Kentucky who seem to prefer a telehealth option with the ongoing pandemic.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
McKnight, Pat LD	mcknightp@aol.com		4731-37-01(B) restricts dietitians from using telehealth for patients living in states bordering Ohio and those who temporarily leave Ohio to go to Florida and Arizona for the winter. Requests removal of this limitation.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Melvin, Kelli	doxie1967@gmail.com		Inquires whether certified nurse practitioners working under the supervision of a physician are allowed to see patients via telehealth and whether that will be reflected in the rules.	Revised 4731-37-01(A)(7) and (B)(4)(a) to clarify referrals to APRN in cross coverage agreement or standard care arrangement. Proposed rules do not focus on telehealth by APRNs because they are licensed by the Nursing Board.
Menapace, Jeanette, LD	jmcourt15@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could negatively affect the health of her clients and limit their access to the care and convenience of telehealth. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Nageotte, Emily, LD	Emily.Nageotte@Uhhospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Tierney, Jodie	JTierney@neurocrine.com	Neurocrine Biosciences	4731-37-01 - the proposed rule does not contemplate that telehealth visits may never be the same as in-person care for certain diseases and health conditions. Recommend aligning rules with federal policies by amending rule to state that for patient with mental health conditions, and specifically those at risk of developing a drug-induced movement disorder (DIMD) such as tardive dyskinesia, the provider and patient must meet in person at least once in the six months prior to delivering the first telehealth service, and at least once annually thereafter. For subsequent visits, the in-person visit could be waived if a documented consultation between the patient and provider which concluded that an in-person visit was not necessary occurred.	No change recommended - R.C. 4743.09 does not authorize rules to mandate in-person visits for specific medical conditions or rules to require periodic in-person visits.
Nishnick, Amy, LD	nishnia@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. As a practicing dietitian, she treats patients from all over the country. These patients seek out the Cleveland Clinic and are not financially able to visit in person. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
West, Jared	acucleveland@gmail.com	Ohio Association of Acupuncture and Oriental Medicine	4731-37-01 - requests that licensed acupuncturists be included as a telehealth provider in the rule. Telehealth allows acupuncturists to perform wellness checks as well as instruct patients on how to perform self-care techniques such as acupressure and mind-body interventions.	No change recommended - acupuncturists are not authorized by R.C. 4743.09 as health care professionals allowed to provide telehealth services.

Runyon, Randy	kcarey@ohiohc.org	Ohio Association of Community Health Centers	OAHC greatly appreciates the Board's consideration to allow telemedicine and increasing access to care, and strongly supports the ability to use telehealth to serve Ohio's communities and most vulnerable populations.	No changes requested.
Mavko, Kay, LD	kmavko@columbus.rr.com	Ohio Academy of Nutrition and Dietetics	4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. OAND believes that "all health care professionals deserve continuing access to patients under the care of Ohio based providers - whether the patient lives in Ohio or outside the state." Further, "Ohio has many regional, national, and internationally renowned medical centers that provide highly specialized care to patients and once treatment is complete aftercare at home should be seamless and be provided by the team of professionals who are most familiar with the patient and the patient's treatment plan." OAND requests revising this paragraph to "A health care professional may provide telehealth services to a patient located outside of this state if permitted by the laws of the state in which the patient is located, and if they comply with the following requirements:".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
McGlone, Sean	Sean.McGlone@ohiohospitals.org	Ohio Hospital Association	(1) 4731-37-01(A)(1) - telehealth necessarily includes the term "formally consulting"; suggests defining "formal consultation" as "when a health care professional seeks the professional opinion of another health care professional regarding the diagnosis or treatment recommended, transfers the relevant portions of the medical record to the consulting health professional, documents the consult in the medical record, and the consulting health care professional bills for such consult." (2) 4731-37-01(A)(3) definition of asynchronous communication is too restrictive of the types of stored clinical data that can be transmitted; suggests revising definition to be more inclusive of other types of stored clinical data. (3) 4731-37-01(A)(7) change "consent for treatment" to "consent for telehealth treatment"; (4) 4731-37-01(D)(1) replace "consent for treatment" with "acknowledgement" - it is common for patient's to acknowledge that a consult may occur during their discussion with the health care professional rather than consent for treatment. (5) Revise language throughout from "patient or parent or guardian" to "patient or a legal representative of a patient"; (6) 4731-37-01(B)(4) - suggests revisions to provide the referring provider with greater flexibility to refer the patient and eliminating the requirement to notify the emergency room in (B)(4)(d) provision; (7) 4731-37-01(C)(1) - clarify language so that verbal verification of patient identity and physical location is sufficient; (8) 4731-37-01(C)(4) suggests eliminating the requirement for authorization of the patient before transferring record to another provider; (9) 4731-37-01(D)(3) - delete "all" in the requirement that health care professional involved in the consultation must have received and reviewed all medical records of the patient relevant to the medical condition which is the subject of the consultation before the consultation occurs, unless this is not possible due to an emergency situation"; (10) 4731-11-09 - the current version of the rule allows additional exceptions for prescribing controlled substances to patients via telehealth that are not covered by the proposed rule. Suggest revising the rule to include current exceptions in 4731-11-09(D)(1)-(4).	(1) Revised except for billing portion suggested. (2) considered comment in revised definition of asynchronous communication. (3) revised relevant paragraphs; (4) No change recommended - patient consent should be obtained; (5) revised relevant paragraphs; (6) considered comment in revising referral provisions; (7) considered comment in revising (C)(1); (8) considered comment in revising (C)(4); (9) No change recommended - the modifying phrase "relevant to the medical condition" and the inclusion of an emergency exception sufficiently address the concerns; (10) no change recommended - these additional exceptions in current 4731-11-09 are covered by the requirement that the controlled substance prescribing comply with federal law in proposed 4731-11-09(B).
Hernandez, Soley	hernandez@theohiocouncil.org	The Ohio Council of Behavioral Health and Family Service Providers	4731-37-01(A)(2) - the definition of synchronous communication should specifically include telephone calls.	No change recommended - 4731-37-01(B)(3) already states that telephone calls may be used as synchronous communication under certain circumstances.
Taylor, Marti	martit@verily.com	OneFifteen	(1) Suggests revising OBOT rules (OAC Chapter 4731-33) prior to the scheduled revision date of 2024 by clarifying that an appropriate physical exam may be conducted via telehealth with a synchronous audiovisual connection. (2) We believe that the Medical Board rules should cross-reference the categories of APRNs that the Board of Nursing approves for the practice of telehealth and include them in the definition of health care professional.	(1) No change recommended at this time - the OBOT rules will be addressed once these general telehealth rules are further along in the rulemaking process; (2) comment considered in revisions to 4731-37-01(A)(8) and (B)(4)(a).

Opher, Abigail	ado20@case.edu		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Expanding telehealth services outside of Ohio could be beneficial for my patients, including those with eating disorders who move out of state for college. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Shaw, Janet	jshaw@oppa.org	Ohio Psychiatric Physicians Association	(1) 4731-37-01(B)(4)(b) - the rule should include the situation in which a patient does not need emergency care nor to be seen by a specialist, but needs an in-person visit with a physician of the same specialty as the physician that conducted the telehealth visit. (2) 4731-37-01(C)(2) - suggests limiting the consent for treatment through telehealth to only at the initial telehealth visit. (3) 4731-37-01(F)(1) should be deleted because it is unnecessary and "we do not believe that the State Medical Board of Ohio's telehealth rules should consider whether telehealth rules from other states support a physician in Ohio practicing telehealth in another state."	(1) Considered comment in revision of referral provisions. (2) No change recommended - other stakeholder input obtained in stakeholder meetings indicated consent for telehealth treatment is a valuable part of each telehealth visit that does not impose an undue burden; (3) Removed 4731-37-01(F)(1).
Hayhurst, Jennifer	jhayhurst@osma.org	Ohio State Medical Association in consultation with the Ohio Dermatological Association and the Ohio Psychiatric Physicians Association	(1) 4731--37-01(A)(2) Definition of synchronous communication technology is not clear whether a telephone call is included. (2) 4731-37-01(B)(4)(b) - the rule fails to incorporate a scenario in which the patient does not require emergency care or care by a different specialist, but needs an in-person visit with a provider of the same specialty. (3) 4731-37-01(F)(1) should be deleted because it is unnecessary and "we do not feel that the State Medical Board of Ohio's telehealth rules should consider whether other state's telehealth rules support an Ohio physician practicing telehealth in that state."	(1) No change recommended - 4731-37-01(B)(3) allows for synchronous communication including audio telephone calls under conditions described in that paragraph; (2) comment considered in revising referral provisions; (3) Deleted 4731-37-01(F)(1).
Ciarlariello, Sue , RCP and David Corey	dpc@pacainc.com	Ohio Society for Respiratory Care	(1) 4731-37-01(B) and (F) - The OSRC believes that all health care professionals need access to patients under the care of Ohio based providers whether the patient lives in Ohio or outside the state. This rule "will prevent RCPs involved in regional programs or those working in border cities from reaching their out-of-state patients" and will "restrict the RCP's ability to use 'standard of care' remote equipment and physiologic monitoring in all patients."	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth. No change recommended for remote monitoring as R.C. 4743.09 does not authorize RCPs to provide this.
Thomas, Andrew, MD and L. Arick Forrest, MD	William.Hayes@osumc.edu	The Ohio State University Wexner Medical Center	(1) 4731-37-01(A)(3) - the definition of asynchronous communication is unnecessarily restrictive of the types of stored clinical data that may be transmitted. (2) 4731-37-01(B)(4) is overly complicated and should be simplified into one section describing the choice to see the patient in-person or make an appropriate referral. (3) 4731-37-01(C)- seek clarification that the rule allows for delegation of standard of care tasks such as obtaining consent for treatment or verifying the patient's identify and physical location. (4) 4731-37-01(F)(2) - recommend expanding the use of remote monitoring devices approved by the FDA by adding digital therapeutics, digital software, and digital algorithms. (5) 4731-11-09 - request clarifications on when an in-person visit has to occur, whether a sickle cell crisis would be captured under the emergency medical condition exception, and why this rules does not mention nurse practitioners.	(1) considered comment in revising the definition of asynchronous communication; (2) considered comment in revising referral provisions; (3) No change recommended - the current delegation rules cover this. (4) No change recommended - R.C. 4743.09(C)(5) allows telehealth through the use of medical devices that enable remote monitoring. The definition of remote monitoring device in 4731-37-01(A)(4) is tied to the FDA's definition of medical device. Not all software and algorithms are FDA approved, cleared, or authorized. (5) No change recommended - the exceptions in the rule mirror the exceptions provided in R.C. 4743.09(B)(2).
Pehling, Victoria, LD	PEHLINV@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and will significantly impact my practice and limit the care I can provide to our patients. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Poland, Laura, LD	laura@dietitianinyourkitchen.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and may have negative effect on client care and access to care. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.

Reed, Kelly	Reedk2@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could hinder patient care. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Reynolds, Thomas Lee, MD	doc@4kidhelp.com		4731-11-09 - requests to exempt children with Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) from requiring in-person sessions to receive stimulants.	No change recommended - the rule requires initial in-person visit of a new patient before prescribing a schedule II controlled substance consistent with R.C. 4743.09(B)(2).
Rodich, Melanie, LD	Melanie.Rodich@UHhospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Rood, Robin, LD	rroodrd@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. She is a dietitian that works for Teladoc and sees patients "within Ohio, but also from Maryland, Virginia, California, and Michigan to name a few." Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Shawhan, Stacy, LD	Stacy.Shawhan@UCHealth.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and would limit my ability to provide adequate care to my patients in Kentucky.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Sowa, Agnieszka, LD	SOWAA@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. The ability to see our patients virtually who live outside of Ohio borders is imperative in order to be able to provide continuity of care and ensure best outcomes. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Sullivan, Lauren, LD	sullivl2@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and would limit health care to our patients who live in New York, Pennsylvania, Michigan, and West Virginia. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Carter, Tracy	cartert@summahealth.org	Summa Health	(1) clarify when an in-person visit should be conducted - is there a specific timeframe? (2) clarify how to handle non-controlled drug prescription refills for patient. (3) recommend that healthcare professionals who provide cross-coverage should not be required to see the patient in-person first before prescribing non-controlled drugs.	(1) No change recommended - 4731-37-01(B)(3)-(4) and 4731-11-09(D),(E) are consistent with R.C. 4743.09. (2) and (3) No changes recommended - 4731-37-01(E)(1) addresses the prescribing of non-controlled drugs through telehealth.
Teague, Erin, LD	Erin.Teague@UHhospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.

Tucker, Claudia Duck	ctucker@teladochealth.com	Teladoc Health	(1) 4731-37-01(A)(1) - Definition of telehealth "does not track with the statutory definition in R.C. 4743.09. (2) 4731-37-01(A)(3) - Definition of asynchronous technology arbitrarily limits the types of clinical data that may be transmitted. (3) 4731-37-01(B)(4) - referral provisions place a significant burden on health care providers and may limit patient's choice of health care provider. The referral provisions for telehealth services are beyond what is required for in-person service referrals. (4) 4731-37-01(B)(4)(d) - this provision regarding referrals to the emergency room is overly prescriptive and does not reflect current best practice. (5) 4731-37-01(C)(7) - there is no definition provided for what constitutes "prompt" documentation of the patient record. (6) 4731-37-01(D)(3) - it is unreasonable to expect any health care professional to know at the time of diagnosis or treatment that they have received all the medical records of the patient relevant to the medical condition of the patient which is the subject of the consultation before the consultation occurs.	(1) No change recommended - definition is consistent with statutory definition; (2) considered comment in revising definition of asynchronous communication; (3) and (4) considered comments in revising referral provisions; (5) no change recommended; (6) no change recommended - paragraph allows for relevant medical records and provides an exception to the requirement in an emergency situation.
Sines, Amanda	amanda@gov-advantage.com	Ohio American College of Emergency Physicians	(1) 4731-37-01(A)(1) - clarify definition to include situation where physician could be on the same campus, but in a different part of the health care facility providing telehealth. (2) 4731-37-01(B)(4)(d) - "[w]e support this provision and believe it increases patient care by creating a more formalized handoff for when the patient arrives at the emergency department. (3) change references from "emergency room" to "emergency department".	(1) No change recommended; (2) positive comment - no change requested; (3) revised (B)(4)(a),(d)
Jolliff, Kinsey	kjolliff@metrohealth.org	The MetroHealth System	(1) 4731-37-01(A)(3) - the definition of asynchronous communication is unnecessarily restrictive of the types of stored clinical data that may be transmitted. (2) 431-37-01(A)(4) - definition of remote monitoring advice should be expanded to include FDA approved algorithms in the definition. (3) 4731-37-01(B)(4) - We applaud the steps the Board has taken in this section "to ensure that patients who receive telehealth services are best served when their care must be transitioned to being seen in person." Further, the rule "prioritizes the care of patients, the citizens of Ohio, rather than providers who may have no connection to Ohio who only provide care at a singular point of time." (4) 4731-37-01(B)(4)(d) - suggests revising to: If the patient needs the emergency care, the health care professional shall help the patient identify the closest emergency room."	(1) considered comment in revising the definition of asynchronous communication; (2) No change recommended - definition is tied of FDA definition of medical devices. Not all software and algorithms are FDA approved, cleared, or authorized; (3) positive comment - no change requested; (4) considered comment in revising the referral provisions.
DiBlasio, Carla	Carla.DiBlasio@UHHospitals.org	University Hospitals	(1) 4731-37-01(A)(1) - including the word "formal" before consulting adds some ambiguity in the definition of telehealth services. (2) 4731-37-01(D)(1) - does not believe that a patient needs to consent to a formal consultation if the patient has already consented to treatment. (3) We generally agree with ATA's comment letter.	(1) considered comment in adding definition for formal consultation in 4731-37-01(A)(7). (2) No change recommended - a formal consultation should have patient consent for treatment. (3) No change requested.
Wise, Julie, LD	Julie.Wise@UHHospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could be harmful to patients with eating disorders who rely on weekly telehealth visits regardless of their location. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Comments on January 20, 2022 Preliminary Draft of Telehealth Rules				
Trevino, Justin, MD	Lisa.Frederick@mha.ohio.gov	Ohio Department of Mental Health and Addiction Services	(1) 4731-37-01(C)(4) - suggest "forward the medical documentation created in conjunction with performance of the telehealth service to the patient's primary care provider..." (2) 4731-37-01(C)(5) - suggest "that meets the minimal standards of care for an in-person visit, which may include the use of medical information and data gathered by other Ohio licensed healthcare providers acting within the scope of their professional license." (3) 4731-37-01(C)(7) - suggest "evaluation findings", "any contraindications to standard/indicated treatments for the identified condition(s)". (4) 4731-11-09(D) - Because there are schedule III controlled substances used for MAT that have significant abuse liability, I would consider specifying both schedules II and III in this provision.	(1) Considered comment in paragraph (C)(4) revision. (2) and (3) No changes recommended - comments suggest stylistic changes. (4) No change recommended - R.C. 4743.09 only allows for the initial in-person visit for schedule II controlled substances.

O'Reilly, Kelly	gblazer@oahp.org	Ohio Association of Health Plans	OAHp cautions implementing telehealth rules that could threaten access. Many times, a consumer will utilize telehealth because that is how they can access care. However, if a follow-up in-person appointment is required immediately after the telehealth visit it directly undermines the utility of telehealth. We believe the intent of HB 122 was to bridge access, therefore requiring an in-person visit immediately after a telehealth visit runs counter to this intent.	No changes recommended - the proposed telehealth rules do not require an in-person visit immediately after a telehealth visit. Provisions in 4731-37-01(B)(3),(4) and 4731-11-09(D),E) are consistent with R.C. 4743.09.
DiBlasio, Carla	Carla.DiBlasio@UHHospitals.org	University Hospitals	(1) 4731-37-01(C)(1) - request removal of requirement that health care professional communicate their licensure information to the patient; (2) 4731-37-01(C)(4) - remove the requirement to obtain the patient's consent to share the medical record with another health care provider; (3) concerns with the consent to consultation requirement in 4731-37-01(D)(1) articulated in the initial circulation comment above.	(1) Comment considered in paragraph (C)(1) revision; (2) revised paragraph (C)(4) consistent with comment; (3) No change recommended.
Duck Tucker, Claudia	ctucker@teladochealth.com	Teladoc	concerns with referral provisions 4731-37-01(B)(4) articulated in the initial circulation comment above.	Comment considered in changes made to referral provisions.
Levy, Alan, MD	conveyed by OSMA		(1) 4731-37-01(B)(4) - suggests another subparagraph (iv) to read "another health care professional, or medical institution, capable of conducting an in-person visit appropriate for the diagnosis and treatment of the patient's medical condition." (2) 4731-37-01(C)(1) - requirement to communicate licensure information may only be necessary in situations where patient contacts a telehealth service provider who then connects the patient with a physician unknown to the patient; (3) 4731-37-01(C)(4)-add "if applicable" to beginning of paragraph; (4) 4731-37-01(D)(3) - begin sentence with "if possible"; (5) 4731-37-01(F)(1)- it is unnecessary for the Medical Board to establish the standard of care for on Ohio provider who is providing services to a patient in another state. (6) happy with the prescribing provisions in the rules.	(1) Comment considered in revisions to referral provisions; (2) Comment considered in paragraph (C)(1) revisions; (3) and (4) changes made for initial circulation draft; (5) removed this paragraph; (6) No change requested - positive comment.
Zebley, Kyle	kzebley@ataaction.org	ATA Action	(1) 4731-37-01(A)(3) definition of asynchronous communication and 4731-37-01(B)(4) referral provisions concerns articulated in the initial circulation comment above. (2) 4731-37-03(C)(3) - "This language puts the onus of ensuring the secure username and password on the provider during patient-provider communications. ATA Action believes that this responsibility should fall on the facility or health care entity, not the provider."	(1) Comment considered in revisions made to definition of asynchronous communication and referral provisions. (2) No change recommended.
McGlone, Sean	Sean.McGlone@ohiohospitals.org	Ohio Hospital Association	(1) 4731-37-01 - the language in rule needs to appropriately differentiate between consent for treatment and informed consent. (2) Also, the rule should differentiate between "formal" consults and "informal consults". (3) 4731-37-01(B)(4) - there are differences in perspective on this issue, even within our membership - it seems the trick will be striking a balance between ensuring patient access to care and continuity of care. Some situations may not be conducive to immediately scheduling as the provider may not have control over the scheduling system. (4) Certain references to the medical record throughout the draft need to be narrowed to the relevant telehealth encounter instead of all medical records.	(1) and (2) changes were included in initial circulation draft of the rules; (3) Comment considered in revisions to referral provisions. (4) No change recommended.



March 1, 2022

Ms. Stephanie Loucka
Executive Director, State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

RE: ATA ACTION COMMENTS ON PROPOSED TELEHEALTH RULES

Dear Ms. Loucka:

On behalf of ATA Action, I am writing to comment on and express our concerns about language in proposed new rule 4731-37-01 relating to telehealth.

ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, advances policy to ensure all individuals have permanent access to telehealth services across the care continuum. ATA Action supports the enactment of state and federal telehealth coverage and fair payment policies to secure telehealth access for all Americans, including those in rural and underserved communities. ATA Action recognizes that telehealth and virtual care have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

Our organization appreciates the Medical Board's attention to advancing telehealth policy that increases access to care while ensuring patient safety. We believe that many of the provisions in the proposed rules – including its recognition of both synchronous and asynchronous modalities as acceptable modes for delivering virtual care and the removal of an in-person mandate for controlled substances via telehealth – are steps in the right direction for Ohio's telehealth regulation. We also want to thank the Board for being receptive to our comments and working alongside us to craft telehealth regulations that will optimize the telehealth experience for Ohio patients.

With that said, ATA Action still has several concerns with the Board's latest draft of its proposed rules. We believe that these areas of concern will significantly limit access to telehealth services in Ohio if left unaddressed.

Definition of Asynchronous Communication Technology

Our first issue with the proposed rules comes with the definition of asynchronous communication technology found at 4731-37-01(A)(3). ATA Action believes that this definition is unnecessarily restrictive and could cause confusion among telehealth providers.

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First, the definition suggests that an asynchronous communication between a patient and provider **must always** involve the transmission of “stored clinical data” in the form of video clips, sound/audio files, or photo images. This unnecessarily excludes other types of clinical data – such as vital signs, lab test results, patient medical histories, and/or patient descriptions of symptoms – that are often part of asynchronous telehealth visits. Indeed, providers in Ohio – as well as at major health systems throughout the country such as Mayo Clinic, Mercy Hospital, and Intermountain Health – often rely on robust and appropriate asynchronous online visits that may not incorporate videos or images to treat conditions like colds, seasonal allergies, UTIs, and sexual health conditions. The current definition of asynchronous communication technology should be revised so as not to create uncertainty for providers who are otherwise using asynchronous communication consistent with the standard of care.

Secondly, the definition singles out particular modalities – including “text messages, such as electronic mail, without either visual or audio files of the patient included with the text message” – from qualifying as asynchronous care. ATA Action believes licensed providers should be able to use whichever telehealth technologies they wish so long as those technologies are sufficient to meet the standard of care for the condition presented by the patient and to meet the security standards outlined in the rule. Instead of favoring certain modalities over others, the Board should promulgate regulations that tie providers’ decisions as to which telehealth technologies are appropriate to diagnose and treat patients directly to the standard of care. Such a provision would ensure that the full range of telehealth technologies could be utilized in the delivery of virtual health care without sacrificing the quality of that care. As enacted with an effective date of March 23, 2022, H.B. 122 sought to make the maximum choice of technology available to patients and enable licensed providers to decide which modalities are appropriate to meet the standard of care for the condition presented by the patient.

For these reasons, ATA Action recommends the Board revise the definition of asynchronous communication technology as follows:

*Asynchronous communication technology, also called store and forward technology, means the transmission of a patient’s stored clinical data from an originating site to the site where the healthcare professional is located. The health care professional at this distant site can review the stored clinical data at a later time from when the data is sent and without the patient being present. Stored clinical data that may be transmitted via asynchronous communication technology **includes but is not limited to** video clips, sound/audio files, and photo images that may be sent along with electronic records and written records about the patient’s medical condition. Asynchronous communication technology in a single media format does not include telephone calls, images transmitted via facsimile machines, and text messages, such as in electronic mail, without visualization of the patient. Photographs or video images that are visualized by a telecommunications system must be both specific to the patient’s medical condition and sufficient for furnishing or confirming a diagnosis and/or a treatment plan.*

Referral to In-Person Care

Our next several concerns are with proposed new rule 4731-37-01(B)(4), which includes four different referral obligations depending on the needs of the particular patient. We believe the referral requirements, as drafted, undermine a central premise of telehealth and HB122: ensuring patients can connect to available providers to receive quality and affordable care when and where they need it. The language reads:

(4) If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall do the following:

(a) If the patient must be seen immediately but not in an emergency room, the health care professional shall immediately schedule the patient for an in-person visit with the health care professional and promptly conduct that visit or refer the patient for an in-person visit with one of the following licensed health care professionals who can provide the services in-person that are appropriate for the patient and the condition for which the patient presents:

- (i) another health care professional with whom the health care professional has a cross-coverage agreement,*
- (ii) in the case of a physician, a physician assistant with whom the physician has a supervision agreement or a certified nurse practitioner with whom the physician has a standard care arrangement; or*
- (iii) in the case of a physician assistant, a physician with whom the physician assistant has a supervision agreement.*

(b) If the patient does not need to be seen immediately, the health care professional shall schedule the patient for an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented.

(c) If the patient must be seen by a specialist other than the health care professional, the health care professional shall make a referral to a specialist, licensed in this state, whom the healthcare professional knows has an appropriate scope of practice and is capable of conducting an in-person visit appropriate for the diagnosis and treatment of the patient's condition and ensure that all necessary medical files are shared upon request.

(d) If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency room and provide notification to the emergency room of the patient's potential arrival.



(e) The health care professional shall document the in-person visit or the referral in the patient's medical record.

(f) All referrals must be made in an amount of time that is appropriate for that patient and their condition presented.

When a provider starts a telehealth interaction, it is unknown whether the patient will ultimately require care beyond what can be provided via telehealth. Thus, under the Board's proposed rule, any Ohio-licensed provider who seeks to deliver telehealth services would need to be prepared to meet the referral standard for each potential scenario (immediate non-emergency care, non-immediate care, specialty care, and emergency care).

Yet, two of these scenarios – immediate non-emergency care (a) and non-immediate care (b) – seem to mandate that Ohio-licensed providers have a physical location to conduct an in-person visit with the patient or formalized cross-coverage relationships with providers nearby any potential patient.

Practically speaking, insisting that the patient see the specific provider with which he or she interacted virtually would preclude Ohio-licensed providers from rendering care to any patient who is not located within that provider's vicinity unless the provider somehow had cross coverage relationships throughout every part of the state. This would make it substantially more difficult for patients and providers to interact, restricting patient access to care in the process. For example, a family physician in Toledo would not be able to continue to treat through telehealth his or her college-age patients who attend Ohio State in Columbus unless that physician has a relationship with other providers in Columbus or the patient was willing to travel back home. Moreover, these provisions would cause confusion in terms of compliance. Would it be sufficient for telehealth providers who have established referral relationships with providers in the Cleveland area to refer Cincinnati-based patients for an in-person visit with those providers?

Not only are these proposed referral requirements impractical and limiting in terms of providers' ability to deliver telehealth services in Ohio, but they also hold telehealth services to a higher standard than in-person care settings. When Ohio patients go to a provider's office in person and the provider determines that the patient needs more specialized care, the provider is not required to "schedule" an appointment with a specialist in person or provide the patient with a referral to a *specific specialist* who "is capable of conducting an in-person visit appropriate for the diagnosis and treatment of the patient's condition," as is complicated in (C). Rather, current practice – as noted in the last Board meeting by a Board member – is for a provider to say, "you need to see a [insert type of] specialist." If the Board intends to hold telehealth providers to heightened referral obligations, ATA Action questions whether similar guidance will be issued for in-person care settings.



Finally, we are concerned with language in point (d) relating to patients who need emergency care. We agree that health care professionals – whether delivering care through telehealth technologies or other tools – have in place appropriate protocols to deal with emergency situations if and when they occur. In some situations, that would include immediately notifying emergency services. The proposed rule, however, would require telehealth providers to help patients identify the closest emergency room and provide notification to the emergency room of the patient’s potential arrival. In addition to placing a specific responsibility on telehealth providers that are not placed on providers at physical locations under current practice, this provision could potentially put patients’ lives at risk in delaying a patient getting to emergency care as soon as possible. It would not help patients experiencing a heart attack or stroke to have their providers spend time walking them through which emergency room is closest and calling that emergency room in advance. In such situations, it is absolutely vital that the patient gets to a health care facility as soon as possible. Any provision related to patients requiring emergency services should mandate that health care professionals have in place appropriate protocols to deal with emergency situations if and when they occur. Most often, that would include immediately notifying emergency services.

ATA Action agrees with the State Medical Board that the standard of care must be the same for all health care services – regardless of whether providers render that care in person or virtually – in the interest of patient safety. We also recognize that there are some health care services which can only be addressed properly via a face-to-face interaction between a patient and his or her provider. Accordingly, our members have protocols in place to ensure that telehealth providers who determine that telehealth technologies are not sufficient to meet the standard of care can connect patients with in-person providers.

We recommend the Board revise 4731-37-01(B)(4) to provide clear guidance as to telehealth providers continuity of care obligations:

“If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or that additional in-person care is necessary, the health care professional shall provide or refer a patient to appropriate in-person health care services.”

Thank you for the opportunity to comment. We encourage the Board to amend the proposed rules for the sake of expanding Ohio patients’ access to the health care they want, need, and deserve. Please let us know how we can be helpful in your efforts to adopt common-sense telehealth policy in Ohio. If you have any questions or would like to discuss further the telehealth industry’s perspective, please contact me at kzebley@ataaction.org.

Kind regards,

ATA ACTION

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Kyle Zebley
Executive Director
ATA Action

ATA ACTION

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2/24/2022

State Medical Board of Ohio

Attn: Nathan Smith

30 E. Broad St., 3rd Floor

Columbus, Ohio 42315

(614) 466-3934

www.med.ohio.gov

Dear members of the Ohio Medical Board:

Thank you for the opportunity to review proposed rule 4731-37-01 and 4731-11-09. In opening, I would like to thank the medical board for taking steps to treat obesity as a chronic progressive disease. Obesity has been recognized as a chronic disease by the American Medical Association in 2013, to be treated the same as other diseases such as hypertension and type 2 diabetes. The AMA members have pursued legislation to help remove barriers to treatment so that physicians can practice the current standard of care with regards to the treatment of obesity without fear of reprisal. The use of telehealth in the treatment of obesity has helped numerous individuals decrease their risk particularly in light of the COVID-19 pandemic.

I appreciate the State's concerns regarding mis-use of medications that are controlled substances; however, as you review your rules, please consider the following question – would you have the same rule in place for a patient in person? Also, will the rule improve the care the patient receives, or will it be a barrier for them to receive treatment?

With that in mind, this proposed rule represents a good step in the right direction. In particular, establishing the rule for telehealth treatment opportunities improves access to care for individuals in Ohio and in my opinion, improves compliance as it removes the barriers of leaving work, driving to office and waiting to be seen that patients commonly cite for not following up as instructed. The standard of care to be provided for many more Ohio patients living with obesity can be met with the proposed telehealth rules. This population is particularly venerable due to mobility issues related to fat mass disease.

That being said, I do have several concerns with the proposed language where I think it is overly prescriptive and will still represent a barrier to care for many patients, particularly with those with difficult to treat obesity.

4731-11-09 Item E This language is overly prescriptive and will result in the more complex patient not being able to continue on treatment. The proposed rule for anorectic management (4731-11-04) allows after 3 in person visits for patients to have medication refilled without an in person visit for 3 months. Patients struggling with obesity are commonly seen every 1-4 weeks, often by telehealth and adjustments in appetite suppressants such as dosing changes due to metabolic adaptation or needs to

change within the class should be allowed with subsequent in person follow up the following month. With validated home based blood pressure monitoring and remote monitoring such as blue tooth scales, the standard of care as provided in an in person visit is easily reproduced. I would advocate that anorectic therapy be added to the exemption list as well. Certainly, requiring in person visit to follow up on telehealth visit for adverse reactions to anorectic therapy is warranted but that is already addressed earlier in this proposal.

The other concern in this proposal is related to sedative hypnotics, particularly low level sleep aides such as Ambien and lunesta. There are individuals that require short term use of such agents for circadian rhythm disorders that utilize these for sleep induction. Under the proposed rule, prescribing these during a telehealth visit would be prohibited. That again, seems overly prescriptive. Some compromise where an in-person visit and exam has established need for these agents and subsequent follow up and adjustments over telehealth services would be more reasonable approach. Sleep disorders are common in the obese population and contribute significantly to the burden of disease due to the adverse effects of sleep deprivation on the appetite regulatory mechanisms.

Thank for the opportunity for comments on this very important piece of legislation that will potentially affect the care of up to 70% of Ohioans. As a native Ohioan, I look forward to seeing patients struggling with the chronic progressive disease of obesity to be able to enjoy the ability to obtain treatment that is consistent with the current science without bias or ostracization. Helping eliminate barriers to care access through telehealth with appropriate monitoring will markedly improve the opportunity to impact the significant disease burden of Obesity in Ohio.

Sincerely,

Bruce Barker MD

OhioHealth Weight Management

Diplomate American Board of Obesity Medicine

Diplomate American Board of Family Medicine

801 OhioHealth Blvd Ste.160

Delaware Ohio 43015

From: [Berkowski, Joseph Andrew](#)
To: [Smith, Nathan](#)
Subject: Comments on Controlled Substances and Telehealth
Date: Saturday, February 19, 2022 6:23:37 AM
Attachments: [2021-Silber-Management of RLS An Updated Algorithm.pdf](#)

Dear Mr. Smith:

On behalf of many of my colleagues at the Cleveland Clinic, particularly in the specialty of sleep medicine, I write to you with complete opposition to Rule 4731-11-09 sections D & E. The rapid adoption of telemedicine by the medical field in early 2020 due to the pandemic has been a tremendous boon to our field and access to high quality care for many citizens of Ohio. This bill is highly regressive and would have a devastating impact as it highly discriminates against Ohio residents who live in rural communities, those with physical and intellectual disabilities, and people with low income who have transportation barriers or inflexibility with their work or family schedule to make in person appointments. Speaking for the field of sleep medicine, there is minimal advantage to seeing a patient in person and aside from sleep apnea, nearly all sleep conditions are treated with controlled substances. Restless legs syndrome (RLS) is treated first-line with seizure medications (schedule V) and second line opiates (schedule III-IV). Insomnia often requires hypnotics (schedule IV). Circadian rhythm disorders like shift work disorder and conditions of daytime sleepiness like narcolepsy are treated with wake-promoting agents (schedule IV) and stimulants (schedule II). Parasomnia disorders often need benzodiazepines (schedule IV), and so on. When a patient discusses their sleepiness, restless legs, difficulty sleeping, acting out dreams, excessive daytime sleepiness, and even pain, these are all subjective experiences. How would seeing them in person versus a synchronous video platform be advantageous to the patient or affect whether we prescribe controlled substances? These patients can still sign controlled substance agreements electronically, submit urine drug screens at their local lab, and will continue to have prescriptions monitored through OARRS/PDMP as usual. Passing this legislation would create a huge obstacle, and many of these patients would not obtain care from us in the first place without the access from telemedicine.

Specifically for my patients, I am one of the few regional specialists in restless legs syndrome (RLS) in the entire Midwest. As above, controlled substances have become the standard first and second line of treatment, particularly for severe cases that represent up to 3% of the general US population (see attach treatment guidelines). A physical exam is not part of the diagnosis and treatment so virtual care has become a mainstay for this group that require frequent visits for medication adjustments. More than 80% of my RLS patients are seen virtually, more than 80% have such severe symptoms they require opiates (schedule II-III), and more than 80% do not live within an hour of a Cleveland Clinic facility. Passing this legislation would devastate this practice and exclude a large portion of disadvantaged Ohioans from the care that is now within their reach due to technological advancements in the delivery of medicine.

Please reach out to me through the email or phone below if I can provide any more information on this perspective.

Best regards,

Andy Berkowski, MD

Staff Physician
Sleep Disorders Center
Cleveland Clinic Neurological Institute
9500 Euclid Ave / S73
Cleveland, OH 44195
Email: berkowj@ccf.org
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The Management of Restless Legs Syndrome: An Updated Algorithm



Michael H. Silber, MBChB; Mark J. Buchfuhrer, MD;
Christopher J. Earley, MBBCh, PhD; Brian B. Koo, MD; Mauro Manconi, MD;
and John W. Winkelman, MD, PhD, for the Scientific and Medical Advisory Board
of the Restless Legs Syndrome Foundation

Abstract

Restless legs syndrome (RLS) is a common disorder. The population prevalence is 1.5% to 2.7% in a subgroup of patients having more severe RLS with symptoms occurring 2 or more times a week and causing at least moderate distress. It is important for primary care physicians to be familiar with the disorder and its management. Much has changed in the management of RLS since our previous revised algorithm was published in 2013. This updated algorithm was written by members of the Scientific and Medical Advisory Board of the RLS Foundation based on scientific evidence and expert opinion. A literature search was performed using PubMed identifying all articles on RLS from 2012 to 2020. The management of RLS is considered under the following headings: General Considerations; Intermittent RLS; Chronic Persistent RLS; Refractory RLS; Special Circumstances; and Alternative, Investigative, and Potential Future Therapies. Nonpharmacologic approaches, including mental alerting activities, avoidance of substances or medications that may exacerbate RLS, and oral and intravenous iron supplementation, are outlined. The choice of an alpha₂-delta ligand as first-line therapy for chronic persistent RLS with dopamine agonists as a second-line option is explained. We discuss the available drugs, the factors determining which to use, and their adverse effects. We define refractory RLS and describe management approaches, including combination therapy and the use of high-potency opioids. Treatment of RLS in pregnancy and childhood is discussed.

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Restless legs syndrome (RLS) is characterized by an urge to move the legs, usually in association with limb discomfort.¹ The symptoms occur at rest, are relieved by movement, and are worse in the evening and at night. They should not be solely accounted for by other conditions, such as arthritis, leg cramps, positional discomfort, or myalgia.² RLS is usually associated with involuntary, rhythmic brief contractions of the legs during sleep (and at times during relaxed wakefulness) known as periodic limb movements. The severity and frequency of symptoms vary widely. For symptoms occurring at least twice a week and resulting in moderate or severe distress, the prevalence is 1.5% to 2.7%.^{3,4} For many patients, RLS is a cause

of disabling sleep-onset or maintenance insomnia and may result in reduced quality of life,⁵ depression, and increased risk of suicide.^{6,7} RLS is familial in about 50% of patients⁸ but may be related to acquired conditions, especially iron deficiency, pregnancy, and chronic renal failure. Several predisposing candidate genes have been identified through genome-wide association studies.⁹ Evidence suggests that RLS is associated with low intracerebral iron stores due to as yet unclear defects in iron homeostatic mechanisms and downregulation of striatal dopamine receptors.^{10,11} Increased cerebral glutamate and decreased adenosine may also play a role in the pathophysiologic mechanism of the disorder.¹² Dopamine agonists, alpha₂-delta calcium channel ligands,



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ARTICLE HIGHLIGHTS

- Iron status should be assessed in all patients with restless legs syndrome (RLS) and appropriate oral or intravenous iron therapy considered.
- Unless contraindicated, alpha₂-delta ligands are first-line agents for treatment of chronic persistent RLS, with dopamine agonists second-line drugs.
- Low-dose opioid therapy is indicated for the management of refractory RLS with appropriate precautions.

and opioids are effective therapies, but understanding of the mechanisms through which they work will depend on better elucidation of the underlying disease pathogenesis.

The high prevalence of RLS requires that primary care physicians familiarize themselves with the condition and take a leading role in its management. The Medical Advisory Board of the nonprofit RLS Foundation constructed an algorithm for the management of RLS in 2004 that was revised in 2013, with both papers published in *Mayo Clinic Proceedings*.^{13,14} In the past 8 years, advances have been made in the management of the disorder, including the following developments: the long-term risks of chronic dopaminergic therapy, especially augmentation, have been better understood; large controlled trials of pregabalin¹⁵ and oxycodone¹⁶ have been published; in the setting of the overuse of prescription opioids for the management of chronic pain, consensus recommendations on their responsible use for refractory restless legs have been developed¹⁷; the use of intravenous iron and its methods of administration have been better delineated through controlled trials¹⁸; more attention has been paid to RLS management in pregnancy, lactation, and childhood; and active research is exploring other novel RLS therapies. As a result of these developments, the RLS Foundation Scientific and Medical Advisory Board decided the time was right for the issuing of an updated algorithm of treatment for RLS.

Many rigorous evidence-based reviews of the treatment of RLS have been published, including several since publication of the 2013 revised algorithm. These include updates from the American Academy of Neurology¹⁹ and the International Parkinson and Movement Disorder Society²⁰ and a guideline paper on first-line treatments and management of dopaminergic augmentation jointly produced by the International RLS Study Group, the European RLS Study Group, and the RLS Foundation.²¹ Although evidence-based reviews are valuable, they may not in isolation be helpful for the primary care physician trying to determine the optimal therapy for a particular patient. Conclusions from such reviews are constrained by the breadth and quality of the published peer-reviewed literature. The highest level of evidence usually requires large multicenter studies that are almost always funded by the manufacturer of the drug to be tested. Thus, the degree of evidence to support a specific medication may depend on whether a pharmaceutical manufacturer has been willing to fund large studies. For similar reasons, very few large comparative studies of different drugs have been published. Whereas large controlled trials are essential, they usually test short-term use of drugs. Long-term studies generally provide lower levels of evidence, being either uncontrolled prospective or retrospective studies. Nevertheless, such data on continued use of medication in the community are highly relevant for medical practice for a disease that is often lifelong. For many of these reasons, evidence-based reviews of specific disorders generally make authoritative statements on the degree of evidence for each medication. They are, however, not always conducive to the development of practical algorithms for the management of disorders of varying severity and a lengthy natural history. For relatively rare conditions that are managed predominantly by specialists with considerable experience and a reasonable knowledge of the published literature, evidence-based reviews may be adequate. However, for primary

care physicians seeking a practical approach to common disorders, evidence-based reviews alone may be insufficient.

To prepare the updated algorithm, the RLS Foundation Scientific and Medical Advisory Board established a task force from among its members who produced and revised a draft that was submitted for approval to the other members of the board. The authors have had many years of experience in the treatment of RLS and have conducted original research on this disorder. Some have been members of task forces that have produced the previously discussed evidence-based reviews. The effort was supported by the Board of Directors and Executive Director of the RLS Foundation, but this article is entirely the work of the physicians and scientists on the Scientific and Medical Advisory Board. It is based on both a detailed knowledge of the literature, including evidence-based assessments, and expert opinion from practical experience. A literature search was performed using PubMed identifying all articles on RLS from 2012 (the year before the publication of the previous algorithm) to 2020. Relevant studies of RLS management were included in our recommendations. We recognize that a different group of specialists might have produced a somewhat different algorithm, but we believe that our approach reflects current thinking about the management of RLS. We expect that the development of new medications and further research on existing ones may alter clinical approaches in the future. Of note, the US Food and Drug Administration (FDA) has approved pramipexole, ropinirole, rotigotine patch, and gabapentin enacarbil for the treatment of RLS, and thus all other drugs discussed are being used “off label.” Although we have attempted to produce an accurate document, it is the responsibility of individual physicians to familiarize themselves with all aspects of the medications they prescribe and to decide whether a specific drug is appropriate for a particular patient.

Box 1. Road Map to the Algorithm

General Considerations

- Assess systemic iron status and consider appropriate iron replacement if needed, especially in patients with refractory restless legs syndrome (RLS).
- Consider and manage any coexisting sleep disorders.
- Consider the role of medications in causing or exacerbating RLS.

Intermittent RLS

- Use nonpharmacologic strategies, including mental alerting and a trial of abstinence from caffeine and alcohol.
- Consider intermittent use of carbidopa/levodopa, low-potency opioids, or benzodiazepine agonists.

Chronic Persistent RLS

- Use α_2 -delta calcium channel ligands, unless contraindications exist.
- Use a nonergot dopamine agonist if α_2 -delta calcium channel ligands are contraindicated or ineffective.
- If dopamine agonists are being used, monitor for augmentation and impulse control disorders and modify treatment accordingly.

Refractory RLS

- Consider combination therapy with α_2 -delta calcium channel ligands, dopamine agonists, or benzodiazepines.
- Consider opioid monotherapy.

Box 1 presents a “road map” to the algorithm; each section is discussed in more detail in the following sections.

GENERAL CONSIDERATIONS

Iron Therapy

There is substantial clinical research demonstrating that patients with RLS have lower than normal iron stores in some regions of the brain and that iron therapy can be beneficial, even if the patient is not anemic or does not have a systemic iron deficiency (Box 2).^{10,18,22,23} However, because there is currently no accepted method to assess a patient's brain iron stores, clinicians should evaluate iron status in all patients with RLS, even in the absence of typical factors associated with iron deficiency, such as menorrhagia, gastrointestinal blood loss, or frequent blood donations. A full iron assessment should include serum iron, ferritin, total iron-binding capacity, and percentage transferrin saturation and should be measured in the early morning after an overnight fast.

On the basis of a consensus of RLS experts,¹⁸ it is recommended that all RLS

Box 2. Iron Therapy

- Determine the patient's iron status (early morning, fasting iron panel: serum ferritin, iron, total iron-binding capacity, and percentage transferrin saturation).¹⁸
- If serum ferritin concentration is ≤ 75 $\mu\text{g/L}$ and transferrin saturation is $< 45\%$, administer an oral iron preparation (elemental iron 65 mg) with 100 to 200 mg of vitamin C every 1 or 2 days on an empty stomach. (Note that in the presence of inflammation or malignant disease, serum ferritin concentration may be misleadingly high, and thus transferrin saturation $< 20\%$ may be a more accurate measure of iron deficiency.)
- Consider intravenous administration of iron if transferrin saturation is $< 45\%$ and (1) serum ferritin concentration is < 100 $\mu\text{g/L}$ and a more rapid response is desired than is possible with oral iron; (2) oral iron cannot be adequately absorbed because of disorders of the gastrointestinal system, bariatric surgery, or chronic inflammatory conditions; (3) oral iron is not tolerated; and (4) restless legs symptoms do not improve despite an adequate (3-month) trial of oral intake of iron.

patients with serum ferritin concentration of 75 $\mu\text{g/L}$ (to convert to pmol/L , multiply by 2.247) or less and transferrin saturation below 45% should receive a trial of oral iron therapy. Serum measures of systemic iron status, however, do not consistently predict those who will respond to iron treatment. If serum ferritin concentration is below the lower limit of normal based on the patient's sex and age, a cause for iron deficiency should also be pursued. Of note, serum ferritin is an acute phase reactive protein and may take up to 6 weeks after recovery from an inflammatory or infective event before returning to normal. In the presence of acute or chronic inflammation or malignant disease, serum ferritin concentration can be misleadingly high. In those situations, transferrin saturation below 20% may be a more accurate measure of systemic iron deficiency.

A common oral iron regimen is 325 mg of ferrous sulfate (65 mg elemental iron) in combination with 100 to 200 mg of vitamin C with each dose to enhance absorption once daily or once every second day. More frequent administration of iron may reduce absorption. There are data from nonhuman primate studies that iron is taken up by the brain from the blood at higher rates at night than in the morning.²⁴ Because the treatment object is to increase specifically brain iron concentrations, the use of oral iron at night may be more advantageous.

Iron tablets should ideally be taken on an empty stomach to enhance absorption, but if gastrointestinal symptoms develop, they can be taken with food (not with substances high in calcium). Iron should not be prescribed empirically because it may result in iron overload, especially in patients with previously unsuspected hemochromatosis. Follow-up ferritin determinations are needed, initially after 3 to 4 months and then every 3 to 6 months until the serum ferritin level is greater than 100 $\mu\text{g/L}$.¹⁸ If there is not an ongoing cause for iron deficiency, oral iron therapy can be stopped, but treatment should recommence if RLS worsens unless serum ferritin concentration is 300 $\mu\text{g/L}$ or higher, the usually accepted safe upper limit.

Intravenous administration of iron should be first-line iron therapy if moderate to severe chronic persistent or refractory RLS is present (see later for definitions) and either serum ferritin concentration is between 76 $\mu\text{g/L}$ and 100 $\mu\text{g/L}$ or a more rapid response is desired than is possible with oral iron. (Intravenous administration of iron is recommended as first-line iron therapy if serum ferritin concentration is between 76 $\mu\text{g/L}$ and 100 $\mu\text{g/L}$ because absorption of oral iron at these higher ferritin levels is likely to be minimal.) Intravenous iron therapy is also recommended if oral iron cannot be adequately absorbed because of disorders of the gastrointestinal system or bariatric surgery, oral iron is not tolerated, and RLS symptoms do not improve despite an adequate (3-month) trial of oral intake of iron. According to a consensus of RLS experts,¹⁸ the base requirement for any use of intravenous iron therapy in RLS is that the serum ferritin concentration should be less than 100 $\mu\text{g/L}$ (and not affected by inflammation) and transferrin saturation less than 45%.

All of the intravenous iron formulations that are currently FDA approved for treatment of iron deficiency anemia may be of value in treatment of RLS. The majority of the class I clinical trials for intravenous iron therapy in RLS used, however, ferric carboxymaltose.²⁵⁻²⁷ This has been shown

to be effective at doses of 1000 mg administered as a single dose of 1000 mg or as 2 doses of 500 mg at 5- to 7-day intervals, but the clinical response to treatment is rarely immediate and may be delayed for 4 to 6 weeks or longer. The percentage of patients responding ranges between 37% and 59%. Intravenous ferric carboxymaltose causes hypophosphatemia in up to 39% of patients.²⁸ The clinical significance of this finding is uncertain, but repeated use may possibly contribute to osteopenia. Other intravenous iron preparations that can be considered are low-molecular-weight iron dextran (1000 mg) and ferumoxytol (1020 mg), both as single infusions. Although low-molecular-weight iron dextran has a lower risk of life-threatening allergic reactions (estimated at 1 per 300,000 uses) compared with the older high-molecular-weight iron dextran, a test dose (25 mg) should be given first. Pretreatment with diphenhydramine is unnecessary and may exacerbate restless legs. Use of any other iron formulations for RLS should follow the clinical guidelines recommended for treatment of iron deficiency anemia. If there has been an adequate response to an intravenous iron infusion but symptoms recur, repeated infusions can be given in at least 12-week intervals as long as serum ferritin concentration is below 300 µg/L and transferrin saturation is less than 45%. In patients with a questionable response, a second infusion can be considered, especially if the serum ferritin concentration is still less than 100 µg/L.

Role of Medications in Causing or Worsening RLS

Clinical experience and open-label studies suggest that administration of most antidepressants may be associated with initiation or worsening of RLS (Box 3).²⁹ An exception is bupropion,³⁰ which should be considered for management of depression in RLS patients. However, if other antidepressants are deemed necessary to treat a mood disturbance, they should be introduced and the effects on RLS monitored. The mechanisms by which antidepressants and antihistamines

Box 3. Role of medications in causing or worsening RLS

Consider whether antidepressants, neuroleptic agents, dopamine-blocking antiemetics such as metoclopramide, or sedating antihistamines (including those found in nonprescription medications) may be contributing and whether discontinuation is possible without causing the patient harm.

might worsen RLS are uncertain. Dopamine-blocking agents presumably act by exacerbating the effect of downregulation of dopamine receptors characteristic of RLS.

Assessment for Other Sleep Disorders

See Box 4.

INTERMITTENT RLS

Intermittent RLS is defined as restless legs symptoms that are troublesome enough to require treatment but occur on average less than twice per week (Figure 1).

Nonpharmacologic Strategy

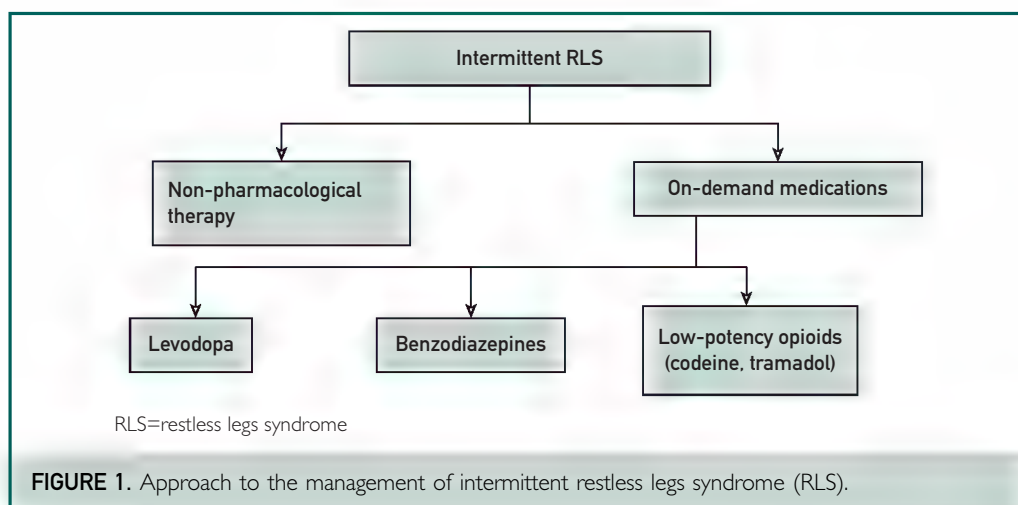
Nonpharmacologic therapies may obviate the need for medications in mild cases of RLS and may allow a reduction in dosage in patients with moderate or severe disease (Box 5). Mental alerting activities and abstinence from caffeine and alcohol are based on empirical observations, and the mechanisms by which they may be effective are uncertain.

Medication

Intermittent use of the medications listed in Box 6 may be helpful. Carbidopa/levodopa, 25 mg/100 mg ($\frac{1}{2}$ -1 tablet), can be used for RLS that occurs intermittently in the evening, at bedtime, or on waking during the night or for RLS associated with specific activities, such as airplane or lengthy car rides or theater attendance. Controlled-release

Box 4. Assessment for Other Sleep Disorders

Concurrent sleep disorders, sleep fragmentation, or insufficient sleep may exacerbate RLS. Clinicians should especially inquire about symptoms of obstructive sleep apnea and pursue appropriate testing as indicated; in some cases, sleep apnea treatment results in improvements in RLS, eliminating the need for medications. Patients with RLS may have other causes of insomnia, including depression, anxiety, or behavioral (eg, excessive caffeine intake), and these may need independent treatment.



carbidopa/levodopa, 25 mg/100 mg (1 tablet), can be used alternatively before bed for RLS that awakens the patient during the night. Even the controlled-release form has a relatively short duration of action and may not produce sustained efficacy if RLS persists throughout much of the night. Controlled trials have shown efficacy of both preparations.³¹ For maximal absorption, levodopa should not be taken with high-protein foods.

Problems with levodopa treatment include augmentation and rebound. Augmentation (drug-induced worsening of RLS, which is discussed in more detail later) may occur in up to 70% of patients taking levodopa daily, and the risk increases with daily doses of 200 mg or more.³² As a result, levodopa should be prescribed only for intermittent use, such as 3 or fewer times a week, although a lower risk of augmentation with

such use has not been firmly established. Rebound, the recurrence of RLS in the early morning, occurs in 20% to 35% of patients taking levodopa.³³ (Because the action of dopamine agonists generally commences 90 to 120 minutes after ingestion, these agents are less helpful once symptoms have started and are rarely prescribed for intermittent RLS.)

Intermittent use of low-potency opioids usually before bed can be effective. Doses of 30 to 90 mg of codeine, in combined preparations with acetaminophen, or 50 to 100 mg of tramadol can be taken before bed or during the night. Constipation or nausea may occur. Tramadol can rarely induce seizures and is the only nondopaminergic drug associated occasionally with the development of augmentation.

Intermittent use of benzodiazepines or benzodiazepine receptor agonists before sleep may be considered, especially if the patient has another cause of poor sleep in addition to RLS, such as insomnia associated with psychophysiologic factors. Short-acting agents, such as zolpidem (5-10 mg) or zaleplon (5-10 mg), may be helpful for sleep-onset insomnia caused by RLS; intermediate-acting agents, such as temazepam (15-30 mg) or eszopiclone (1-3 mg), may be helpful for RLS that awakens the patient later in the night. Lower doses should be used in women and in older patients. Adverse effects include risk of falls during

Box 5. Non-pharmacological Strategy

- Determine the patient's iron status and replace iron as indicated (see General Considerations).
- Recommend mental alerting activities, such as video games or crossword puzzles, to reduce symptoms at times of boredom.
- Consider a trial of abstinence from caffeine and alcohol.
- Consider the possibility of other co-occurring sleep disorders, most importantly obstructive sleep apnea.
- Consider the role of medications in causing or exacerbating restless legs (see General Considerations).

Box 6. Medications for Intermittent RLS

Intermittent use of the following medications may be helpful:

- Carbidopa/levodopa, 25 mg/100 mg, or controlled release, 25 mg/100 mg
- Low-potency opioids, such as codeine or tramadol
- Benzodiazepines or benzodiazepine agonists, such as temazepam, zolpidem, zaleplon, or eszopiclone

the night and cognitive difficulties, especially in the elderly. The fast-onset, short-acting agents, especially zolpidem, may cause sleepwalking and sleep-related eating disorder, with RLS patients especially predisposed to these effects.^{34,35} Long-acting agents, such as clonazepam, may result in more adverse effects, such as unsteadiness during the night and drowsiness or cognitive impairment in the morning, and should generally be avoided unless used for comorbid psychiatric conditions with careful monitoring for adverse effects. There are no adequate controlled trials of benzodiazepines for RLS,³¹ and it is likely that the drugs act by treating the associated insomnia or concurrent anxiety rather than the sensory or motor symptoms of the disorder.

CHRONIC PERSISTENT RLS

Chronic persistent RLS is defined as restless legs symptoms that are frequent and

troublesome enough to require daily treatment, usually occurring on average at least twice a week and resulting in moderate or severe distress (Figure 2).

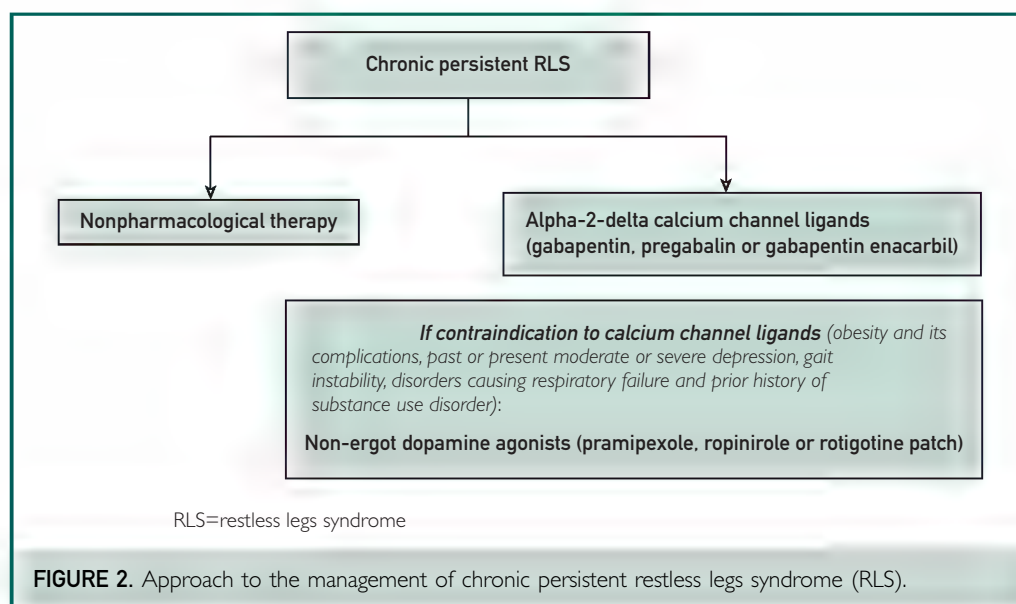
Nonpharmacologic Strategy

The nonpharmacologic approach for chronic persistent RLS is the same as for intermittent RLS. Iron stores should be checked in all patients.

Medication

Dopamine agonists are an effective treatment option for RLS and were formerly used for first-line treatment of RLS. However, because of increasing awareness of the high incidence of dopamine agonist–induced worsening of RLS symptoms known as augmentation and the risk for development of impulse control disorders, alpha₂-delta ligands should, when not contraindicated, be tried first (Box 7). Regular follow-up of RLS patients receiving medications long term is important. The frequency depends on the response to treatment; initially, this should be at least every 3 months, with stable patients reassessed at least every year.

Gabapentin and pregabalin (Table 1) are usually administered as once- or twice-daily doses in the late afternoon or evening or before sleep. It is recommended to start treatment 1 to 2 hours before usual onset



Box 7. Management of Chronic Persistent RLS

- Treatment should start with an α_2 -delta ligand (gabapentin, pregabalin, or gabapentin enacarbil) unless patient factors suggest that a nonergot dopamine agonist (pramipexole, ropinirole, or rotigotine patch) would be safer.
- Factors favoring a dopamine agonist as initial treatment include obesity and its complications, past or present moderate or severe depression, gait instability, disorders causing respiratory failure, and previous history of substance use disorder. α_2 -delta ligands can worsen these conditions.
- If untreated RLS is present for much of the day and night, consider the use of slow-release preparations (gabapentin enacarbil, unless a contraindication exists, then use the rotigotine patch).
- If α_2 -delta ligands are ineffective or poorly tolerated, change to a dopamine agonist.

of symptoms. Treatment should commence at 300 mg of gabapentin (100 mg in patients older than 65 years) or 75 mg of pregabalin daily (50 mg in patients older than 65 years) and be increased every few days as needed. Most RLS patients require 1200 to 1800 mg of gabapentin daily, but doses up to 3600 mg daily can be used. Because of nonlinear kinetics and substantial interindividual variability, the gabapentin dose often does not always reflect serum level, especially at single doses above 600 mg. For this reason, multiple doses of gabapentin, spaced at least 2 hours apart, may be necessary to enhance absorption and efficacy. Effective pregabalin doses are usually in the range of 150 to 450 mg daily. Gabapentin enacarbil is a pro-drug of gabapentin, converted to gabapentin after absorption, and thus avoids the nonlinear pharmacokinetics of gabapentin. It is administered as a single daily dose of

600 mg (300 mg in patients older than 65 years) at 5 PM to target adequate therapeutic levels at bedtime. Doses of 1200 mg have been used. Class adverse effects include daytime drowsiness, dizziness, unsteadiness, and cognitive disturbances, all of which may be more frequent in older patients, as well as edema, weight gain, and depression, including suicidal ideation. The drugs have been reported to occasionally cause respiratory depression when they are used in patients with underlying pulmonary disease or in combination with opioids. Increased abuse potential has been reported in patients with a history of substance use disorder.³⁶ The development of adverse effects should be carefully monitored, especially if higher doses are used. Note that the α_2 -delta ligands may provide additional benefit to RLS patients who have comorbidities of chronic pain, insomnia, or anxiety.

When dopamine agonists (Table 2) are used, nonergot agents should be prescribed because ergot agonists such as cabergoline and pergolide are associated with cardiac valvular fibrosis and other fibrotic reactions. Doses used are lower than approved for treatment of Parkinson disease because higher doses are associated with increased risk of augmentation. Pramipexole is usually commenced as 0.125 mg once daily, taken 2 hours before major RLS symptoms start. The dose is increased by 0.125 mg every 2 to 3 days until relief is obtained. The acceptable maximum daily dose is 0.5 mg in most

TABLE 1. Comparison of α_2 -Delta Ligands Used to Treat Restless Legs Syndrome

	Gabapentin	Pregabalin	Gabapentin enacarbil
Time to maximum blood level	2 h	1.5 h	7-9 h
Elimination half-life	5-7 h	6 h	Relatively stable plasma levels during 18-24 h (elimination half-life, 6 h)
Metabolism and excretion	Renal	Renal	Intestinal metabolism; renal excretion
Initial daily dose	300 mg ^a	75 mg ^a	600 mg ^a
Maximum daily dose	3600 mg	450 mg	600 (-1200) ^b mg

^aDoses should be adjusted for renal dysfunction. In patients older than 65 years, initial daily dose should be reduced (gabapentin, 100 mg; pregabalin, 50 mg; gabapentin enacarbil, 300 mg).

^bValue in parentheses differs from Food & Drug Administration—approved value.

TABLE 2. Comparison of Dopamine Agonists Used to Treat Restless Legs Syndrome

	Pramipexole	Ropinirole	Rotigotine patch
Time to maximum blood level	2 h	1-1.5 h	Stable plasma levels during 24 h
Elimination half-life	8-12 h (increases with decreasing glomerular filtration rate and age)	6 h	Stable plasma levels during 24 h (elimination half-life biphasic, 3 h and 6 h)
Metabolism and excretion	Renal	Hepatic metabolism; renal excretion	Hepatic metabolism; renal excretion
Initial daily dose	0.125 mg	0.25 (-0.5) ^a mg	1 mg
Maximum daily dose	0.5 mg	(2-) ^a 4 mg	3 mg

^aValues in parentheses differ from Food & Drug Administration–approved values.

patients. Ropinirole is usually commenced as 0.25 to 0.5 mg taken 1.5 hours before major symptoms start and is increased by 0.25 to 0.5 mg every 2 to 3 days. Most patients require 2 mg or less (note that 4 times higher equivalent doses are needed compared with pramipexole), but total daily doses up to 4 mg are FDA approved. Some patients require twice-daily doses of oral dopamine agonists, with an earlier dose in the late afternoon or early evening and a second dose 1 to 2 hours before bed. The rotigotine patch is applied once daily, commencing at 1 mg and increasing if necessary to 2 to 3 mg. Minor adverse effects of the agonists include nausea and light-headedness that usually resolve within 10 to 14 days. Daytime sleepiness may occur with higher doses, presenting as either sleep attacks closely following doses of the drug or continuous daytime sleepiness. Nasal stuffiness, constipation, insomnia, and leg edema occur less frequently and are reversible with cessation of treatment. Application site reactions commonly occur with the rotigotine patch.

Two major problems often limit the use of dopamine agonists, which is why they are not recommended as first-line agents

unless there are contraindications to α_2 -delta ligands. The single and by far most common problem is disease augmentation³⁷ (onset of RLS symptoms earlier in the day after an evening dose of medication, spread of symptoms to the arms, paradoxical worsening of symptoms with dose increase, and shorter effect of each dose of medication; Table 3). For pramipexole and ropinirole, this occurs in about 40% to 70% of patients during a 10-year period^{38,39} or at an annual rate of 8% per year for at least the first 8 years of use. Augmentation frequency with the rotigotine patch may be slightly lower at 36% after 5 years.⁴⁰ The risk of augmentation is dose dependent, thus the great importance of not exceeding recommended maximum doses.

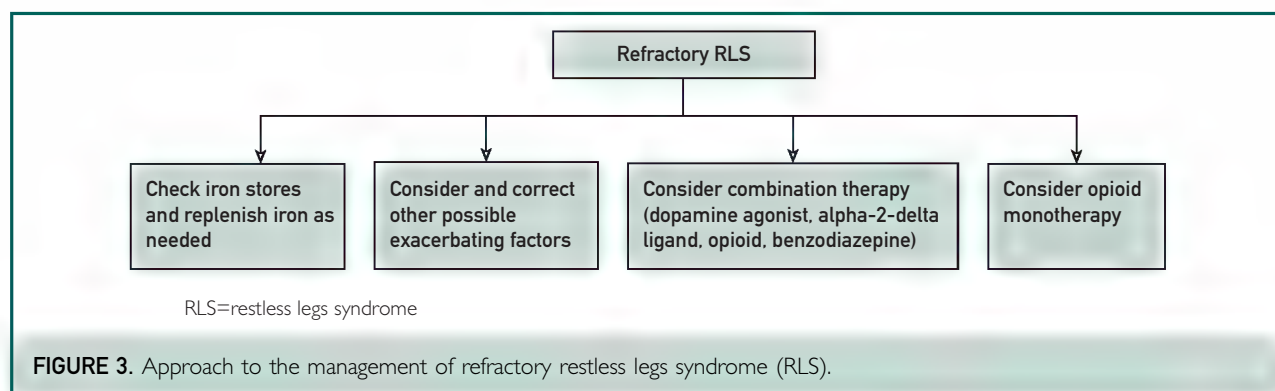
A second common adverse effect of long-term dopamine agonist use is impulse control disorder, with rate of occurrence estimated to be between 6% and 17%.⁴¹ Before dopamine agonist therapy is commenced, patients should be questioned about a history of impulse control disorder, although the disorder may occur for the first time on starting the drugs. An impulse control disorder, which may be manifested as pathologic

TABLE 3. Diagnosis of RLS Augmentation With Dopaminergic Medication

1. Do RLS symptoms appear earlier than when the drug was first started?
2. Are higher doses of the drug now needed, or do you need to take the medicine earlier, to control the RLS symptoms compared with the original effective dose?
3. Has the intensity of symptoms worsened since starting the medication?
4. Have symptoms spread to parts of the body (eg, the arms) since starting the medication?

RLS, restless legs syndrome.

From Sleep Med,²¹ with permission.



gambling, impulsive shopping, or hypersexuality,⁴¹ commences an average of 9 months after introduction of the drug. Both these serious adverse effects should be assessed at every follow-up visit.

If augmentation is mild (predominantly manifested by symptoms starting less than 2 hours earlier in the day), consider initially splitting the dose with some of the drug administered at an earlier time. Use of extended-release pramipexole or ropinirole can be considered, generally without increasing the total daily dose, although limited data are available on their use in RLS. If an increase in total dose of dopamine agonist is deemed necessary, careful monitoring is essential to detect progressive augmentation. If augmentation progresses after the second increase in dose, another increase should not be made. Subsequent

choices include maintaining the dose, replacing oral agents with the rotigotine patch, adding another agent from a different class, and discontinuing the drug.

Discontinuation of dopamine agonists because of severe augmentation or other adverse effects and substitution of a drug of a different class (such as an α_2 -delta ligand) can be achieved in 2 ways. The initial drug can be reduced slowly after the new agent is introduced with an overlap period when the patient is taking both medications. Alternatively, the initial drug can be reduced and discontinued with a drug holiday before the new agent is introduced. Higher doses of dopamine agonists should never be discontinued abruptly as serious withdrawal effects can occur, characterized by severe RLS, sleep disturbance, and depression. Rates of reduction should not exceed 0.25 mg (pramipexole) or 0.5 mg (ropinirole) every 3 days. Whereas a drug holiday can allow a new symptom baseline to be established, many patients with augmentation from dopamine agonists find it difficult to tolerate a period free of any medication, with exacerbation of RLS and profound insomnia lasting sometimes a week or longer after complete discontinuation.⁴²

Box 8. Management of Refractory RLS

- Iron stores should be rechecked. If the serum ferritin level is less than 100 $\mu\text{g/L}$ and symptoms are severe, intravenous iron therapy should be considered (see General Considerations).
- Other exacerbating factors should be sought. These include the use of medications that can worsen restless legs (see General Considerations); change in lifestyle, such as more sedentary behavior or shift work; and other causes of sleep disturbance, such as sleep apnea or chronic insufficient sleep.
- Consider combination therapy with drugs of different classes, taking into account adverse effects experienced during previous drug trials. Add a second agent and try to reduce the dose of the initial drug. Second agents may include a dopamine agonist for patients treated with an α_2 -delta ligand or vice versa, a benzodiazepine (if RLS is present mainly at night with resulting insomnia), or a low- or high-potency opioid.
- Consider substituting an opioid such as oxycodone, hydrocodone, morphine, or methadone. In particular, consider low-dose methadone for severe refractory RLS resistant to other treatments.³⁹

REFRACTORY RLS

Refractory RLS is restless legs unresponsive to monotherapy with tolerable doses of first-line agents due to reduction in efficacy, augmentation, or adverse effects (Figure 3; Box 8). (If apparent RLS has *never* responded to adequate doses of dopamine agonists

TABLE 4. Suggested Doses for Opioids in Restless Legs Syndrome

Drug	Starting total daily dose	Usual effective total daily dose
Tramadol (immediate release or ER)	50 mg (100 mg ER)	100-200 mg
Codeine	30 mg	60-180 mg
Morphine CR	10-15 mg	15-45 mg
Oxycodone (immediate release or ER)	5-10 mg	10-30 mg
Hydrocodone (immediate release or ER)	10-15 mg	20-45 mg
Methadone	2.5-5 mg	5-20 mg
Buprenorphine hydrochloride/naloxone (sublingual film or tablet)	0.5-1 mg	0.5-6 mg

CR, controlled release; ER, extended release.

administered at appropriate times, the accuracy of the diagnosis should be questioned.)

Opioids are highly effective in the management of refractory RLS,^{16,43,44} reducing daytime tiredness and improving sleep and quality of life,^{43,44} and thus should not be withheld from appropriately screened patients because of a fear of potential development of tolerance or dependence.¹⁷ When opioids are used appropriately for RLS, escalation of dose is uncommon, and misuse is infrequent in the absence of a history of substance abuse. Nausea, constipation, and urinary retention are not uncommon but either resolve with time or can be managed symptomatically. Itch may be a problem as a result of mast cell degranulation rather than allergy. Daytime drowsiness, cognitive dysfunction, and unsteadiness resulting in falls, especially at night, are potential adverse effects. Opioids can suppress gonadotropin-releasing and luteinizing hormones, and symptoms related to low testosterone, such as lowered mood, increased sweating, and sexual dysfunction, may occur. Secondary adrenal insufficiency may be due to suppression of the hypothalamic-pituitary-adrenal axis. Opioids can induce central sleep apnea and may possibly precipitate or worsen obstructive sleep apnea. Testing for sleep apnea should be considered for RLS patients receiving opioids if there is a suspicion of sleep disordered breathing. In general, however, these medications are well tolerated at the low total daily recommended doses.

The choice of drug depends on physician preference, patient factors, and cost, and providers should familiarize themselves with the different characteristics of the various available medications. Initial use of short-acting agents is reasonable, but most patients transitioning to opioids will have augmented symptoms present for more than 12 hours per day, and thus long-acting drugs or extended-release formulations are most appropriate to avoid interdose rebound and to maintain benefit. Table 4 summarizes the doses of recommended opioids. The low total daily doses of opioids used for RLS rarely approach the higher doses used for the management of chronic pain.

Reasonable precautions should be taken in light of the opioid epidemic in the United States, and state regulations should be followed.¹⁷ Patients should be questioned about risk factors for opioid abuse, including personal and family history of substance use

Box 9. Management of RLS During Pregnancy

- Nonpharmacologic therapies are strongly preferred, with special attention to moderate exercise and correction of iron stores by oral or, if necessary, intravenous administration of iron during the second or third trimester.
- Medications at lowest effective doses, used on demand if possible, should be reserved for severe RLS, preferably only in the second or third trimester to reduce any risk of inducing congenital abnormalities, and physicians should work closely with the patient's obstetric provider. The risk-benefit ratios of drugs in pregnancy should be carefully considered and discussed with each patient. Recommendations are based on 2 consensus publications.^{45,46}

disorders, and an opioid contract should be signed by the patient. This should include information about drug adverse effects, the need for regular (usually every 3-6 months) follow-up visits, a notification that early prescription refill will generally not occur, and an understanding by the patient that prescriptions will be received from only a single provider and the dose will not be altered without permission. A urine drug screen should be considered at the start of therapy and at least yearly thereafter. State prescription drug monitoring databases should be regularly reviewed.

SPECIAL CIRCUMSTANCES

Pregnancy and Lactation

RLS may start or worsen during pregnancy, with a peak of incidence and severity in the third trimester. In general, symptoms improve or resolve around delivery, but women with pregnancy-related RLS have an increased risk for development of RLS in future pregnancies or later in life (Box 9).

Pregnancy. Clonazepam 0.25 to 0.5 mg before bed can be considered in the second and third trimesters. This drug should not be combined with antihistamines or anticonvulsants in pregnancy. Carbidopa/levodopa 25 mg/100 mg or 50 mg/200 mg controlled release can be considered. The alternative dopa decarboxylase inhibitor to carbidopa, benserazide, should not be used because of the risks of congenital malformations. Augmentation is common with levodopa, and patients should be monitored for this adverse effect. Oxycodone 5 to 10 mg before

bed can be considered for severe, refractory RLS in the second and third trimesters, but the neonate would need to be monitored for symptoms of opioid withdrawal.

Lactation. Clonazepam 0.25 to 0.5 mg and gabapentin 300 to 900 mg are possible options. For severe, refractory RLS, tramadol 50 to 100 mg can be considered. Dopamine inhibits prolactin production, and therefore levodopa and dopamine agonists should not be used during lactation.

Childhood

RLS is more difficult to diagnose in childhood, and careful attention should be paid to the child's own words in describing symptoms (Box 10). A strong family history in first-degree relatives may be helpful in doubtful cases. The presence of periodic limb movements during sleep on polysomnography may provide supportive diagnostic information. A relationship between RLS, periodic limb movements of sleep, and attention-deficit/hyperactivity disorder has been proposed.

Iron stores are lower in adolescents than in adults because of an increase in red cell mass during growth periods and, in women, the onset of menstruation. Thus, serum ferritin concentration is usually lower than in adults. Although optimal levels are uncertain, iron supplementation should be considered if the serum ferritin concentration is below 50 µg/L.⁴⁷ Oral ferrous sulfate 3 to 5 mg/kg in either tablet or liquid form should be administered once daily before breakfast. Constipation and abdominal discomfort are possible adverse effects. Serum ferritin concentration should be checked in 3 months to ensure that the level has risen above 50 µg/L.

If oral iron therapy is not tolerated or is not accompanied by a satisfactory rise in serum ferritin concentration, consideration can be given to intravenous administration of iron. Iron sucrose, 5 mg/kg to a maximum of 200 mg during 2 hours, has been reported effective in a case series.⁴⁸ Alternatively, ferric carboxymaltose, 10 mg/kg to a maximum of 1000 mg during 1 hour, may

Box 10. Management of RLS in Childhood

- Nonpharmacologic approaches, including a consistent bedtime routine, avoidance of sleep deprivation, and elimination of caffeine, should be tried. If possible, selective serotonin reuptake inhibitors should be avoided.
- The mainstay of RLS treatment in children is iron replacement. Serum ferritin concentration should be measured; iron supplementation should be prescribed if levels are <50 µg/L.
- As in adults, first-line drug therapy in children should be alpha₂-delta ligands.
- Other drugs that can be considered include clonazepam, dopaminergic agents, and clonidine, but potential side effects should be carefully considered.

be used. Potential side effects of intravenous administration of iron include subcutaneous extravasation with brownish skin discoloration, abdominal discomfort, and hypersensitivity reactions.

There are no large controlled trials of pharmacologic agents in childhood and no drugs approved by the FDA for RLS treatment in children. The following recommendations are therefore based on anecdotal experience and case series.^{49,50} Gabapentin (5-15 mg/kg) and pregabalin (2-3 mg/kg) are first-line agents if iron is not needed or is ineffective. Second-line agents include clonazepam (0.1-1 mg), noting sedation and paradoxical hyperactivity as possible adverse effects. Dopamine agonists used in children include pramipexole (0.0625-0.25 mg), ropinirole (0.25-0.5 mg), and the rotigotine patch (1-3 mg), but they should preferably be avoided in adolescents because of the risk of precipitating schizophrenia in predisposed patients. If long-term therapy is contemplated, there is a significant risk for augmentation, and monitoring for impulse control disorders is important. Clonidine, an α_2 -adrenergic agonist, can be considered in children (0.05-0.4 mg) who also have an anxiety disorder or attention-deficit/hyperactivity disorder. Its use may be limited by adverse effects including sedation, irritability, depression, and orthostatic hypotension.

Chronic Renal Insufficiency

RLS is common in patients with chronic renal insufficiency,^{19,20} especially those undergoing hemodialysis. Iron status should be checked and managed with intravenous administration of iron or erythropoietin. Nonpharmacologic therapies, including aerobic exercise and the use of vitamins C and E, may be beneficial. Ropinirole and rotigotine, both with hepatic metabolism, can be used. Gabapentin and pregabalin are also effective, but owing to renal metabolism, doses should be kept low and patients carefully monitored for adverse effects, such as mental confusion and falls.⁵¹ RLS often improves or resolves after renal transplant.

ALTERNATIVE, INVESTIGATIVE, AND POTENTIAL FUTURE THERAPIES

Many other therapies, usually based on anecdotes, open-label series, or small controlled trials, have been proposed.⁵² In assessing the efficacy of such therapies, the strong effect of placebos in improving RLS should be carefully weighed.

Mechanical Devices

Limited evidence in support of the use of pneumatic compression devices is based on a single small controlled trial.⁵³ Vibration devices do not improve RLS symptoms but may enhance the quality of sleep in RLS patients.

Electrical and Magnetic Stimulation

Case reports have suggested partial benefit of spinal cord stimulation by implanted electrodes, mainly in patients with chronic pain in addition to RLS. Transcutaneous spinal cord stimulation with direct current showed improved RLS symptoms compared with sham stimulation up to an hour after 15 minutes of treatment in one series.⁵⁴ Transcranial and local leg electrical stimulation has not been effective. Deep brain stimulation targeting various regions, largely for control of Parkinson disease, has produced variable effects on RLS. Transcranial magnetic stimulation has also produced variable results.

Botulinum Toxin

There are conflicting reports on the effects of botulinum toxin injection into leg muscles, with no convincing evidence of long-term benefit.^{55,56}

Cannabis

No controlled clinical trials have evaluated the use of cannabis for RLS. A case series from a single center and patient anecdotes suggest the possibility of some benefit,⁵⁷ but the formulation, dosage, and mode of administration that might be beneficial are unclear. Anecdotal experience suggests that ingested cannabis (brownies, cookies, or other edibles) is ineffective, whereas inhaled cannabis (cannabis cigarette or vaporizer)

may, in some patients, provide rapid but short-lived relief of RLS symptoms.

Cannabis can interact both pharmacokinetically and pharmacodynamically with multiple other drugs that are used to treat RLS, including dopamine agonists, α_2 -delta ligands, and benzodiazepines, potentially increasing adverse effects from these agents.⁵⁸ Inhaled cannabis may be harmful in patients with lung disorders, such as asthma or chronic obstructive pulmonary disease. The long-term adverse effects or complications of cannabis are unknown. Despite that cannabis is legal in many states, it is still illegal under federal law in the United States.

Minerals and Vitamins

Other than for iron, there is no evidence that supplemental minerals or vitamins relieve idiopathic RLS. Specifically, there is no evidence to support magnesium supplementation.⁵⁹ A single controlled trial suggested benefit of vitamin C and vitamin E in uremic RLS patients.⁶⁰

In summary, the management of RLS continues to evolve as new treatment modalities become available and older ones are prescribed less frequently. Basic science studies to better understand the pathophysiologic mechanism of RLS will, with time, lead to the exploration of novel therapeutic agents.⁶¹ Further research is needed to understand the augmentation phenomenon associated with dopaminergic agents and to determine how best to reduce or to avoid it. Long-term follow-up studies of the α_2 -delta ligands and opioids are needed. Older studies suggested the efficacy of carbamazepine, but antiseizure medications, other than the α_2 -delta ligands, are not commonly used in clinical practice. Studies of newer anticonvulsants should be undertaken. Further studies of clonidine would help delineate its role in RLS.⁶² Controlled studies of drugs that increase adenosine⁶³ or decrease glutamine⁶⁴ might open up new approaches to RLS therapy. Because serum measurements of iron status do not correlate with brain iron concentrations, markers of intracerebral iron deficiency

associated with response to intravenous iron therapy, such as quantitative transcranial sonography of the substantia nigra,⁶⁵ need to be developed and tested. Noninvasive electrical stimulation techniques need further exploration, especially transcutaneous spinal stimulation.

CONCLUSION

The management of RLS has steadily advanced during the past few decades, resulting in increased relief for patients with this distressing disorder. In the previous iterations of this algorithm, we stated that further revisions will be needed in the future as our understanding of RLS grows and new approaches to treatment are developed. This is undoubtedly again true in 2021.

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Abbreviations and Acronyms: FDA = Food and Drug Administration; RLS = restless legs syndrome

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From: [Bestic, Anna](#)
To: [Smith, Nathan](#)
Subject: HB 122-Telehealth
Date: Tuesday, March 1, 2022 2:38:59 PM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Like other dietitians at Cleveland Clinic, I work in a very unique specialty that sees complex patients from many different states. Preventing dietitians from seeing out of state patients limits access to care that these patients may otherwise not have available to them. Additionally, not all patients are able to afford travel and may be further limited by inclement weather in both their location and our location of practice. There are certainly patient scenarios that do warrant in person visits for evaluation, but the vast majority can be seen via telehealth. During the pandemic, telehealth has been able to provide ongoing care to patients across many specialties that otherwise would not have been seen due to COVID-19. If anything, continuing to ensure access to patients should be a priority.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Anna Bestic, MS, RD, LD, CNSC



Anna Bestic MS RD LD CNSC | Lead Dietitian, Center for Gut Rehabilitation and Transplant | Center for Human Nutrition | Cleveland Clinic | 9500 Euclid Ave. | Cleveland, OH 44195 | (216) 445-2090 office

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State Medical Board of Ohio

Comments to Proposed Rules 4731-37-01 and 4731-11-09

Bon Secours Mercy Health supports the recommendations of the Ohio Hospital Association and provides the following additional comments:

1. Asynchronous Communication Technology

For purposes of “asynchronous communication technology” definition, the term “stored clinical data” doesn’t include electronic visits via written communication (E-Visits) through a patient portal unless the transmitted information includes videos, photos, or audio files.

BSMH requests that Medical Board revise proposed rule OAC 4731-37-01 to include written communication through a patient portal as part of the definition of “stored clinical data” or clarify that E-Visits may be delivered by practitioners.

E-Visits bridge the gap between rural areas and health care providers based out of urban centers. In 2019, Medicare permanently covered “E-visits” which reimburses practitioners for providing patient services using an online patient portal without going to the doctor’s office.

During the pandemic, E-Visits became pivotal to patients for quick follow-up with established patients about ongoing issues with their care. According to Centers for Medicare and Medicaid Services (CMS), between March 1, 2022- Feb. 28, 2021, over 367,000 E-visits occurred.¹

2. Necessary In-Person Care Visit Scheduling

In cases where in-person care is necessary, proposed rule OAC 4731-37-01(B)(4) requires the health care professional to schedule the patient an in-person visit with the health care professional or with another health care professional with whom the professional has a cross coverage arrangements or specialist referral if applicable.

Due to limitations on appropriate health care professional referrals, this requirement may prevent the patient from receiving immediate care. In many cases, an urgent care or after-hours provider may be able to provide patient care immediately or faster than the health care practitioner or health care professional with whom the professional has a cross coverage arrangement.

BSMH requests that a health care professional providing telemedicine be able to schedule or refer the patient to in-person visits with other appropriately licensed health care practitioner that are not in cross-coverage relationships with practitioner. The ability to refer patient to health care practitioners immediately available may prevent delays in care that can occur with unavailable appointments.

¹ Centers for Medicare and Medicaid Services, Medicare Telemedicine Snapshot Medicare Claims and Encounter Data: March 1, 2020 to February 28, 2021, available at <https://www.cms.gov/files/document/medicare-telemedicine-snapshot.pdf> (Last Visited 2/25/2022)

3. Consent for Telehealth Treatment

For purposes of telehealth, proposed rule OAC 4731-37-01(C)(2),(D)(1),(F)(2)(A) requires that the health care professional patient's document consent.

BSMH requests that telehealth consent language be updated to require annual telehealth consent. Providers have additional time and burden with obtaining telehealth consent at every visit which takes valuable time away from delivering necessary care. This will align with federal requirements related to communication technology-based services such as virtual check-ins and e-visits.

CMS has identified such burden on practitioners and made Medicare consent annual for telehealth services such as remote evaluation of patient images/video, virtual check-ins and interprofessional consultations.² CMS stated the change was in relation to continue to hear from stakeholders that requiring advance beneficiary consent for each of these services is burdensome.³

Bon Secours Mercy Health Contact Information:

Jon Fishpaw

Chief Advocacy & Government Relations Officer

jpfishpaw@mercy.com

Jeffrey Gill

Vice President, Virtual Health

jmgill@ads.bshsi.com

² Centers for Medicare and Medicaid Services, CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies at 84 FR 62699 (11/15/2019), available at <https://www.federalregister.gov/documents/2019/11/15/2019-24086/medicare-program-cy-2020-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other> (Last Visited 2/25/2022)

³ Id. at 62699

From: [Bury, Christan](#)
To: [Smith, Nathan](#)
Subject: Telehealth
Date: Tuesday, March 1, 2022 10:28:55 AM
Attachments: [Outlook-ehleqtwk.png](#)

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic. As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Christan Bury



Christan Bury, MS, RD, LD, CNSC

Advanced Practice II

Nutrition Support Team, ICU

Digestive Disease and Surgery Institute

9500 Euclid Avenue, M17

Cleveland, OH 44195

Phone: 216-444-3644

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From: [Butscher, Heather A](#)
To: [Smith, Nathan](#)
Cc: [Butscher, Heather A](#)
Subject: Telehealth administrative rule 4731-37-01 comment
Date: Thursday, February 24, 2022 11:45:33 AM
Attachments: [image003.png](#)

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov
Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"
Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Many patients at the hospital has and do receive services remotely throughout the pandemic. Without being able to provide services remotely, patients will be affected. Patients who have difficulty with mobility and with transportations may not be seen. Pts who obtained care in Cleveland but live several hours away would not be able to continuously receive services remotely once returning home and this can impede on care.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:
4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.
Sincerely,

Heather Butscher, MS, RDN, LD, FAND
Outpatient Clinical Dietitian Specialist
University Hospitals Cleveland Medical Center
Digestive Health Institute

Heather.butscher@uhhospitals.org

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March 1, 2022

Nathan Smith
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Telehealth Rules 4731-37-01 and 4731-11-09

Submitted electronically via: Nathan.Smith@med.ohio.gov

Dear Mr. Smith:

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching and research. With a footprint in Northeast Ohio, Florida and Nevada, Cleveland Clinic Health System operates 18 hospitals with approximately 6,000 staffed beds, 21 outpatient Family Health Centers, 11 outpatient surgery locations and numerous physician offices. Cleveland Clinic employs over 4,600 salaried physicians and scientists. Last year, our system cared for 2.4 million unique patients, including 10 million outpatient visits and 273,000 hospital admissions and observations. Below are our comments to the proposed telehealth rules.

4731-37-01(A)(3)

Proposed Language

Asynchronous communication technology, also called store and forward technology, means the transmission of a patient's stored clinical data from an originating site to the site where the health care professional is located. The health care professional at this distant site can review the stored clinical data at a later time from when the data is sent and without the patient being present. Stored clinical data that may be transmitted via asynchronous communication technology means video clips, sound/audio files, and photo images that may be sent along with electronic records and written records about the patient's medical condition. Asynchronous communication technology in a single media format does not include telephone calls, images transmitted via facsimile machines, and text messages, such as in electronic mail, without visualization of the patient. Photographs or video images that are visualized by a telecommunications system must be both specific to the patient's medical condition and sufficient for furnishing or confirming a diagnosis and/or a treatment plan.

Cleveland Clinic Comments

We urge the Medical Board to expand the definition of Asynchronous. We are concerned that the current definition would not allow certain types of care that we have found to be safe and effective for patients, such as eVisits and remote patient monitoring. An example of the effective use of an eVisit would be a patient suffering with a sinus infection. In this type of visit, the patient completes a questionnaire regarding their symptom history and a provider responds with a diagnosis and treatment instructions within one business day. If medication is prescribed, the order is sent to the patient's

preferred pharmacy. While eVisits are not covered by insurance, they are a low cost, out of pocket expense. This is just one example of how technology can be used effectively and efficiently to evaluate and care for patients in a safe and timely manner.

We suggest the Medical Board provide additional clarification around this definition by revising the language to read “Asynchronous communication also includes bi-directional text-based communication between a provider and an established patient which is both (1) communicated via a HIPPA compliant digital platform, and (2) reviewed and responded to by a licensed medical professional for the purpose of providing medical care. Asynchronous also includes remote patient monitoring where physiologic data is reviewed by a provider who then makes a recommendation for continuing care. It does not include telephone calls, images transmitted via facsimile machines, or unidirectional text messages communicated via a non-HIPPA compliant digital platform.”

4731-37-01 (A)(7)

Proposed Language

"Consent for treatment" means a process of communication between a patient or, if applicable, the patient's parent, guardian, or person designated under the patient's health care power of attorney and the health care professional discussing the risks and benefits of, and alternatives to, treatment through a remote evaluation that results in the agreement to treatment that is documented in the medical record or signed authorization for the patient to be treated through an evaluation conducted through appropriate technology, as specified in this rule, when the health care professional is in a location remote from the patient.

Cleveland Clinic Comments

We appreciate that the Medical Board addressed our concern regarding a prior version of this rule by removing the wording “informed consent” from this section. However, we are concerned that the description of “consent” in the current proposed rule still imposes a consent requirement for telehealth visits that goes beyond that required for in-person services. We question why this is needed, as that telehealth is not a different kind of care but merely an alternative medium to provide the care. In fact, the legislature intended, and the Medical Board has agreed, that the standard for in-person and virtual care is the same. Thus it is not clear why providers would be required to undertake a risk discussion with the patient if the service is the same but merely the delivery mechanism is different. A telehealth appointment does not carry with it an inherent risk or invasiveness necessitating a heightened consent process, and therefore we would argue that the risk discussion is unnecessary and should be eliminated from the definition.

4731-37-01(B)(3)

Proposed Language

The health care professional may provide the telehealth services through the use of synchronous or asynchronous communication technology provided that the standard of care for an in-person visit can be met for the patient and the patient's medical condition through the use of the technology selected. Telephone calls, as a synchronous communication technology, may only be used for telehealth services when all of the elements of a bona fide health care visit meeting the standard of care are performed. Telephone calls that are routine or simply involve communication of information do not constitute a telehealth service.

Cleveland Clinic Comments

We strongly support this revised language.

4731-37-01 (C)(1)**Proposed Language**

The health care professional shall verify the patient's identity and physical location in Ohio and communicate the health care professional's name and licensure information to the patient;

Cleveland Clinic Comments

During a routine in-person visit, a healthcare professional does not describe their licensure status to a patient. Therefore, we suggest the language be changed to “The health care professional shall verify the patient's identity and physical location in Ohio and communicate the health care professional's licensure information upon request of the patient.”

4731-11-09 (E)(4)**Proposed Language**

As an exception to paragraph (D) of this rule, a physician or physician assistant may prescribe a controlled substance to a new patient as part of the provision of telehealth services for any of the following patient medical conditions and situations:

(4) The physician or physician assistant determines in their clinical judgment that the new patient is in an emergency situation provided that the following occurs:

- (a) the physician or physician assistant prescribes only the amount of a schedule II controlled substance to cover the duration of the emergency or an amount not to exceed a three-day supply whichever is shorter;
- (b) after the emergency situation ends, the physician or physician assistant conducts the physical examination as part of an initial in-person visit before any further prescribing of a drug that is a schedule II controlled substance.

Cleveland Clinic Comments

We urge the Medical Board to include at least two exceptions to this section that we have seen in other states, including Florida. Specifically, we think there should be an exception for patients currently being treated as inpatients in other facilities and residents of nursing homes.

Thank you for conducting a thoughtful process that allows us to provide input on such important issues. Should you need any further information, please don't hesitate to contact me.

Sincerely,



Steven Shook, MD, MBA
Lead for Virtual Health

From: [Collins, Aileen](#)
To: [Smith, Nathan](#)
Cc: [Reardon, Jill](#)
Subject: 4731-37-01 Telehealth Proposed New Rule Comment
Date: Tuesday, March 1, 2022 8:57:37 AM

Nathan,

Thank you for allowing us to review the new telehealth rules. Below is a comment/request for clarification.

I would like to seek clarification on Section (F)(2)(b):

(b) the medical devices that enable remote monitoring have been cleared, approved, or authorized by the United States food and drug administration for the specific purpose for which the physician or physician assistant are using it for the patient, and the remote monitoring devices otherwise comply with all federal requirements.

We would like to understand how this applies to remote monitoring devices that are used for clinical research. For example, we may wish to conduct research with a device that has not been fully approved by the FDA.

Would the Board allow an exemption to this clause for clinical research?

Thank you.

Aileen Collins

Government Relations Manager
Nationwide Children's Hospital
Cell: 330-285-3872



[Nationwide Children's Hospital](#)
[The Collaboratory for Kids and Community Health](#)

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From: [deborah craven](#)
To: [Smith, Nathan](#)
Subject: Proposed new Telehealth Rules Comment
Date: Saturday, February 19, 2022 8:47:24 AM

Good Morning Mr. Smith,

I received the email with the proposed updated Telehealth Rules changes and have to say I am in favor. It will enable me to maintain the medical relationship I have with my doctor, regardless of where I live. If my condition shows no changes, it makes sense that an in-person visit for a chronic condition would be unnecessary. Telehealth enables the patient to avoid germ laden waiting rooms, saves the commute and waiting times and is more efficient all around. It benefits practitioners as well, enabling them to service several patients in a row without the necessary down time for sanitization etc.

Thanks for your time.

Sincerely,
Debbie Craven
440-567-3156

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From: [Culbertson, Gillian](#)
To: [Smith, Nathan](#)
Subject: Access to Care, telehealth
Date: Tuesday, March 1, 2022 10:06:17 AM

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

The language could negatively affect the health of our patient population.

Cleveland Clinic provides world class care and as a dietitian we consistently see patients outside of Ohio . Virtual visits have been a valuable tool in reaching our patients.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Gillian Culbertson, MS RD, LD
Clinical Dietitian
Cleveland Clinic
9500 Euclid Ave,
Cleveland, OH 44195

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From: [DIMARINO, ANTHONY](#)
To: [Smith, Nathan](#)
Subject: In Response to Draft Rule 4731-37-01
Date: Thursday, February 24, 2022 10:46:47 AM

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Dear Mr. Smith,
I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

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The narrow language of this legislation may negatively impact my patient population and our clinic. I work for the Cleveland Clinic Bariatric and Metabolic Center. We are a certified center of excellence specializing in bariatric surgery and obesity medicine. Due to our experience, expertise, and documented outcomes, patients seek us out for treatment from surrounding states. Patients typically travel for their first round of visits to complete testing and get to know the program.

We usually request that our patients follow up with their dietitians before surgery and for post operative care. Due to the number of follow ups and logistics for travel, it would not make sense for patients to cross state lines to complete their continued care.

The narrow wording of this legislation may impede our ability to provide quality care to our patients. In addition, our department would be hurt financially from the loss of a potential patient population.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Anthony DiMarino RD, LD | Clinical Outpatient Dietitian
Digestive Disease Institute Center for Human Nutrition | Cleveland Clinic
9500 Euclid Avenue/ M61 | Cleveland, OH 44195
P: 216-445-3136 | F: 216-636-1588 | E: dimaria@ccf.org

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From: [Garcia Luis, Maria](#)
To: [Smith, Nathan](#)
Subject: 4731-37-01 Telehealth
Date: Tuesday, March 1, 2022 9:18:50 AM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Telehealth improves the monitoring, timeliness, and communications with the healthcare system and our patients. As we face the Covid19 pandemic, telehealth has become a more prominent mode of providing healthcare, especially when patients and providers sought to decrease in-person contact for routine visits.

Telehealth also gives the opportunity for patients to continue care with the same provider they trust despite any major life events (Ex moving to another state for a job, or family emergencies). This really has an impact on the patient's health. Limiting telehealth services to only the state would significantly impact not only the patients, but also the services we provide. Chronic illnesses are rising within the worldwide population, and being able to provide our services through telehealth to anybody who needs it (even if outside Ohio) for disease prevention can decrease the burden that we are currently facing in the healthcare system.

I respectfully request that the State Medical Board of Ohio revise the Telehealth

rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

*Maria Garcia Luis MS, RDN, LD
Clinical Registered Dietitian
Cleveland Clinic Marymount Hospital
12300 McCracken Rd, Garfield Heights, OH 44125*

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From: [Ellen Gelles](#)
To: [Smith, Nathan](#)
Subject: Comments on telehealth bill 122
Date: Sunday, February 27, 2022 10:20:02 PM

Hello,

My name is Dr. Ellen Gelles, and I am involved with strategy, implementation, and physician/advanced practice providers' education regarding telehealth matters. I am also the chairperson for the Health and Public Policy Committee for the Ohio Chapter of the American College of Physicians—a group of over 5000 internists and medical trainees throughout Ohio.

I have the following questions/comments on the 4731-37-01 portion of HB 122:

Section A, 3) regarding asynchronous telehealth care:

I am unclear if back-and-forth messaging over a secure patient portal (like MyChart) is allowed. What I have been told is that providing and billing for care via back and forth messaging is allowed as long as it is initiated by the patient, is a certain timeframe away from another type of in person or telehealth visit, and exceeds a certain amount of time. This needs clarification.

Section F 1) regarding care for a patient out of state

Questions:

Does the allowability of out-of-state care extend to a physician and patient dyad that does not have a pre-existing relationship? Is there a limit to how many visits across state lines can be done before an in person visit is required? There should be some restrictions on this so that corporate entities like Amazon don't start competing with Ohio physicians and try to take over the care of their patients. Also, unlimited telemedicine care across state lines (without some in person care required) can enable a patient who has moved not to establish care with a new primary care physician in their new home state.

If you are providing care to a patient located in another state, is there an easy way to tell that this is allowed by law in the state where the patient is located? Education might be needed so that physicians know which states don't allow this.

re

Are you allowed to do a telehealth visit in someone outside the US? Case example: my patient is in Costa Rica and tested positive for COVID. 1 week later, they are asymptomatic and need a "letter of recovery". Can I do a video visit with them to assess them for appropriateness of this document?

Please feel free to reach out to me if you need more comments/perspectives on telehealth in Ohio. I am happy to be a resource for this very important part of our health care system.

Ellen J. Gelles, MD,FACP

Director of Medical Informatics, Provider User Experience

MetroHealth System

Associate Professor of Medicine, Case Western Reserve University School of Medicine

Co-Chair, Health and Public Policy Committee, American College of Physicians, Ohio Chapter

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From: [Kristen Goldian](#)
To: [Smith, Nathan](#)
Subject: Comments on telehealth rule
Date: Thursday, February 24, 2022 5:03:52 PM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Allowing my patients full access to health care regardless of what state we are in, is better for patient care. Removing barriers to service is always better.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns.

Kristen Welch Goldian, MS RD LDN CLS
Clinical Dietitian
MetroHealth Medical Center
Cleveland OH 44108

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VIA EMAIL: Nathan Smith, State Medical Board of Ohio, Nathan.Smith@med.ohio.gov

March 1, 2021

Hon. Betty Montgomery
President, State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dr. Sherry Johnson
Vice-President, State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Ms. Stephanie Loucka
Executive Director, State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

RE: Hims & Hers' Comments on Proposed Telehealth Rules

Dear President Montgomery, Vice-President Johnson and Executive Director Loucka:

Per notice for public comments on the Ohio Medical Board's proposed telehealth rules, Hims and Hers offers input on the drafted language of the new rules (473-37-01) for the Board's review.

Hims & Hers, a direct-to-consumer digital health company, was founded to make it easier for patients to access quality, affordable healthcare. Our telehealth platform allows our customers to gain access to qualified health care providers licensed in their home state. Via this connection, customers are able to receive a remote clinical assessment and, when medically appropriate and in accordance with the standard of care, a diagnosis and treatment from a qualified medical professional.

In early 2021, Hims & Hers opened a fulfillment center in New Albany, Ohio, which fulfills orders for non-prescription products for direct-to-consumer purchases and orders from Hims & Hers retail partners. When fully staffed, the fulfillment center will employ hundreds of Ohioans with good paying jobs ranging from pharmacists to sales representatives. We are committed to the Buckeye State for the long-term.

As it relates to the proposed telehealth rules, we respectfully raise two concerns.

First, the definition for asynchronous communication in the proposed rule 4731-37-01(A)(3) restricts a patient's access to this modality by limiting the transmission of acceptable stored clinical data to photo images, video clips, or sound/audio files. This definition not only limits patient access,

but also does now allow providers to exercise professional discretion when determining the best modality to treat patients. We respectfully request the Board consider revising the definition to ensure clarity and incorporate all varied telehealth technologies used by providers to exchange stored clinical data, thereby allowing consistent communication between providers and patients in alignment with the standard of care.

Second, the referral obligations in the rules, as delineated in 4731-37-01(B)(4), impose unreasonable barriers to patients' access to telehealth care services in Ohio. As written, such barriers would make it impractical for most providers to offer any telehealth services as they would not be able to comply with the required referrals to "in-person" care as mandated by the rule. We respectfully suggest that the Board revise the language to allow the provider to determine the appropriate "in-person" health care service when a telehealth visit is deemed not sufficient to meet the standard of care for the patient.

Hims & Hers has built quality and safety into our processes from the very beginning to ensure providers delivering services via the platform are able to appropriately diagnose and treat patients conveniently without compromising on quality or safety. We have designed a number of systems to safeguard medical quality assurance at every step of the process.

We also believe providers should always be held to the highest standard of care regardless of the mode of delivery they use, which is why providers furnishing services via our platform are licensed, credentialed, and held to evidence-based clinical standards. Our suggested modifications to the telehealth rules are in alignment with the language of HB 122 which benefits all residents of Ohio as it addresses and expands telehealth access for all regardless of location, income, or background.

Thank you for your service and the opportunity to provide feedback throughout this process. If you would like to further discuss, please do not hesitate to contact us with any questions.

Sincerely,

Dartesia Pitts

Dartesia Pitts
Government Relations Manager

Hims & Hers

dpitts@forhims.com

forhims.com

forhers.com

About Hims & Hers

Hims & Hers is a direct-to-consumer, digital health company. We connect patients to licensed healthcare providers for telemedicine consultations and treatment across all 50 states. Since our launch in 2017, we've powered millions of digital healthcare visits¹ across a variety of conditions

¹ Defined as the creation of a consultation ID in the medical.

From: [Homan, Elyse](#)
To: [Smith, Nathan](#)
Subject: Letter of Concern in regards to 4731-37-07 Telehealth Rule
Date: Tuesday, March 1, 2022 11:22:05 AM
Attachments: [image001.png](#)

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

I see many patients with complex digestive concerns that travel far to seek testing and treatment from specialized providers within the Cleveland Clinic. Allowing out of state patient's to have access to nutrition therapy via telehealth helps optimize time spent receiving adequate nutrition, especially for those requiring continuous nutrition support. It also allows more equitable health care to those in remote areas. I have seen an influx of patient's that suffered for many years prior to having access to providers that are experts in rare conditions.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

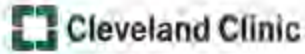
4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Elyse Homan



Elyse Homan, MS, RD, LD

Registered Dietitian

Cleveland Clinic

9500 Euclid Ave, Cleveland OH 44195

Tel/Appt: 440-519-6800

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From: [Jamieson-Petonic, Amy](#)
To: [Smith, Nathan](#)
Subject: PLEASE do not change the nature of Telehealth of Registered Dietitians in Ohio
Date: Thursday, February 24, 2022 4:37:06 PM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth": 4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

The language could negatively affect the health of your patients/clients. For my patients that are unable to make in-person visits due to their medical condition, this can significantly impact their health. I have a number of children and adult patients that have made huge strides with telehealth visits as they are unable to attend appointments in person due to the pandemic.

Only being able to provide telehealth in-state caused a patient problem (especially during the pandemic), for a patient that received surgery at University Hospitals in Cleveland, and would not be able to follow up at home with our providers as she lives out of state.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows: 4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Amy Jamieson-Petonic, MBA, MEd, RDN, CSSD, LD

Administrator II
Primary Care Institute
Phone: 440.590.1945
Fax: 216.201.6259
Amy.Jamieson-Petonic@UHhospitals.org



Visit us at www.UHhospitals.org.

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Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Feb 23, 2022

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the Covid 19 pandemic.

As a dietitian, educator, and interested party I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) " A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Telehealth improves access to nutrition services, in particular, the most vulnerable of populations. This is especially true during the pandemic but extends well beyond it. We know that limiting access to nutrition services worsens outcomes, especially related to chronic disease management. I see it with my clients, and it's something I talk about in my academic courses at Ohio State.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) " A health care professional may provide telehealth services and shall comply with all of the following requirements: "

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Julie Kennel, PhD, RDN, LD
Associate Professor of Clinical Practice
The Ohio State University
330 E. Torrence Road
Columbus, OH 43214

From: [Jennifer Kerner](#)
To: [Smith, Nathan](#)
Subject: Telehealth rule 4731-37-01
Date: Monday, February 28, 2022 9:51:52 PM

Hello Mr. Smith,

The Greater Cleveland Academy of Nutrition and Dietetics has brought to my attention that the State Medical Board of Ohio (SMBO) is seeking comments on the "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122, which recently became law in Ohio. This legislation permanently authorizes and expands access to telehealth services that have been successfully used by Ohioans during the COVID-19 pandemic.

As a dietitian, I am concerned about the limiting nature of the following language contained in the draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

I currently work as an outpatient dietitian at University Hospitals of Cleveland. I changed positions about two months ago, and previously worked in the Transplant Institute at University Hospitals of Cleveland. I specifically thought of some of the patients in transplant when I heard about this legislation, and how it could negatively impact them. Sometimes patients seeking transplant at our transplant center lived in other states (Pennsylvania, Michigan, New York, Washington D.C., West Virginia are examples that come to mind). The patients would become listed at our center in order to widen their chances of getting a transplant, and/or to be near adequate support people if their family and support system lived in Cleveland. I recall conducting visits virtually with those patients on a regular basis instead of making them drive, and it was a very effective way to tend to their health without adding the burden of extra visits to Cleveland. It would be very disappointing to require them to drive up for extra visits in-person if the dietitian could not provide them with telehealth, when they are already coping with the burden and stress of end stage organ failure. Sometimes patients would come to our center because some appointments were essential to be in-person (i.e. if they had an organ offer, or if they were coming for a surgeon appointment where their body habitus and frailty would be assessed). The patients waiting for a kidney transplant would need to schedule traveling between days at the dialysis center, the lung patients would need to pack an adequate supply of oxygen tanks for the car ride, and the liver patients would need to carefully plan their trips to make sure they could stop at the restroom enough along the way to have bowel movements. Taking a car ride for healthcare when you are feeling miserable can be a stressful experience. Part of the role of the dietitian is to provide education and counseling. I remember one husband and wife both looking exhausted and upset, and expressing to me what a poor night of sleep they had experienced the night before in a hotel that wasn't adequately accessible and equipped for his physical needs. They had come to the appointment that day in-person because they were seeing the surgeon in-person for a physical

evaluation, but I felt that my visit with them was spent on being a sounding board for their stress instead of providing Medical Nutrition Therapy. Since then, I had followed up with them multiple times using telehealth, and our conversations from his living room over telehealth were always a much more relaxed experience for he and his wife, and we completed much more effective education/counseling in that environment.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,
Jennifer Kerner, MS, RDN, LD, CCTD
Clinical Dietitian, Advanced Practice
University Hospitals of Cleveland
11100 Euclid Avenue, Cleveland Ohio 44106

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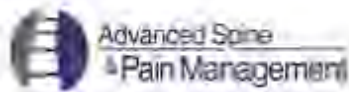
From: [Dr. Mukarram A. Khan, DO](#)
To: [Smith, Nathan](#)
Subject: telehealth
Date: Monday, February 21, 2022 11:19:42 AM
Attachments: [image001.png](#)

Mr. Smith:

I'm reaching out to you about the telehealth rules. In my opinion the audio only calls need to be made permanent. My only point is that some patients cannot do video conferencing on any device and they are going to be forced to come into the office. Unfortunately, the ones the patients that do not have the finances or social support to do video telehealth are being forced to come into the office. Its frustrating because they are the ones who would benefit the most. I can elucidate further but you get my point. Contact me if you have any questions.

Thank you.

Mukarram Khan DO



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From: [Jane Korsberg](#)
To: [Smith, Nathan](#)
Subject: Telehealth administrative rule 4731-37-01
Date: Thursday, February 24, 2022 9:01:19 AM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

This language could negatively affect the health of my patients who have relocated, as consistency of care is vital for long-term success in controlling many diseases/conditions and to guide behavior change. In addition, I am often asked to provide services to patients in other states due to my specialization. If telehealth is not allowed outside of Ohio, this would significantly restrict my practice. Since I lost my office space when COVID began and many people are still reluctant to meet in person, telehealth is vital to my business survival and not be limited to only our state.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Jane Korsberg, MS,RDN,LD,FAND

--

From: bakerkoznek@roadrunner.com
To: [Smith, Nathan](#)
Subject: Telemedicine
Date: Friday, February 18, 2022 2:53:13 PM

The explosion of telemedicine wouldn't have been necessary, had pharmacies, hospitals and state medical agencies not interfered with the practice of medicine. Off label drug use is at the discretion of the practitioner. Politicized suppression of appropriate early treatments(hcq and ivermectin) lead to needless complications and death. The medical field has much to atone for.
K Koznek DO

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Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

February 28th, 2022

Dear Mr. Smith,

It has come to Kroger's attention that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01, which implements portions of HB 122. As an Ohio-based business that values and relies on the expertise of healthcare providers, including registered dietitians, The Kroger Co. is concerned about the limiting nature of the following language contained in the draft rule around telehealth services: "A health care professional may provide telehealth services to a patient **located in this state**. The health care professional shall comply with all of the following requirements" [4731-37-01 (B)].

Kroger Health, the healthcare arm of Kroger, supports a dedicated, educated, and personalized approach to eating and enjoying food so we can live healthier lives and prevent illness before it starts. Kroger has a Telenutrition program (Medical Nutrition Therapy via telehealth for nutrition care) as part of our Food as Medicine strategy that relies on Kroger registered dietitians being able to support patients across the country. Kroger opposes restrictions to telehealth delivered by Ohio registered dietitians for the following reasons:

- We have many registered dietitians based in Ohio. Restricting Ohio registered dietitians from providing telehealth services to patients who live outside of Ohio's borders would disrupt current patient continuity of care and future opportunities to serve new patients who may not otherwise have access to nutrition care.
- Telehealth restrictions would limit our business opportunities. As a retailer with national scale, Kroger depends on being able to provide services like Telenutrition at scale to meet business to business needs from payors.
- There is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including registered dietitians licensed by SMBO) from providing telehealth services to individuals living outside of Ohio.
- The implications of the draft rule would ultimately become a burden for patients, as it would limit public access to expert nutrition professionals.
- Telenutrition has provided a safe and accessible opportunity to meet with a Kroger Health registered dietitian as COVID-19 continues to impact our daily lives. Further, given the data around the negative impact of diet-related disease on COVID-19 outcomes, we should be expanding access to nutrition care rather than limiting it.
- Telenutrition has been a key capability for Kroger to deliver care more equitably and to address health equity. Video-based appointments have helped alleviate typical barriers to in-patient care that disproportionately impact vulnerable populations, including addressing social determinants of health like a lack of access to reliable transportation. Our Telenutrition services have also provided a realistic, convenient digital opportunity to receive care for patients who don't have the luxury of leaving their workplace in the middle of the day for an appointment.

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in Ohio. Therefore, **Kroger respectfully requests that the State Medical Board of Ohio revise the Telehealth rule as follows:**

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

Thank you for considering Kroger's concerns and comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Colleen Lindholz".

Colleen Lindholz

President

Kroger Health

555 Race St, Cincinnati, OH 45202

From: [Lenchitz, Bernard \(lenchib\)](#)
To: [Smith, Nathan](#)
Subject: RE: February eNews from the State Medical Board of Ohio
Date: Wednesday, February 23, 2022 11:51:41 AM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)

My public comments:

I support the proposed rule.

Bernard Lenchitz MD FACP
Professor of Clinical Medicine
University of Cincinnati College of Medicine/Academic Health Center
231 Albert Sabin Way, Room 7559
ML 0535
Cincinnati, OH 45267-0535
Phone 513-558-7581
Fax 513-558-4399

Vice President, Primary Care Network
UC Health - University of Cincinnati Physicians
2830 Victory Parkway
Cincinnati, OH 45206

UCPhysicians
425 Walnut St.
Suite 200
Cincinnati Ohio 45202
Phone 513-475-7676 and fax 513-381-1830
Cell phone 513 909 5488

email:bernard.lenchitz@uc.edu

From: Nathan.Smith@med.ohio.gov <Nathan.Smith@med.ohio.gov>
Sent: Wednesday, February 23, 2022 11:48 AM
To: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Subject: RE: February eNews from the State Medical Board of Ohio

Dr. Lenchitz,

Proposed rule 4731-11-09 requires that a physician or physician assistant (as described in the rule) who is prescribing a drug that is a controlled substance must meet the following requirements:

(B) must comply with federal law governing prescription drugs that are controlled substances
(C) during the provision of telehealth services, the physician or physician assistant must comply with all requirements in rule 4731-37-01 of the Administrative Code.
(D) shall conduct a **physical examination of a new patient as part of an initial in-person visit before prescribing a schedule II controlled substance** to the patient except as provided in paragraph (E) of this rule.

Paragraph (E) provides the statutory exceptions to the in-person requirement stated in paragraph (D). Paragraph (E) states:

E) As an exception to paragraph (D) of this rule, a physician or physician assistant may prescribe a controlled substance to a new patient as part of the provision of telehealth services for any of the following patient medical conditions and situations:

- (1) The medical record of a new patient indicates that the patient is receiving hospice or palliative care;
- (2) The patient has a substance use disorder, and the controlled substance is FDA approved for and prescribed for medication assisted treatment or to treat opioid use disorder.
- (3) The patient has a mental health condition and the controlled substance prescribed is prescribed to treat that mental health condition; or
- (4) The physician or physician assistant determines in their clinical judgment that the new patient is in an emergency situation provided that the following occurs:
 - (a) the physician or physician assistant prescribes only the amount of a schedule II controlled substance to cover the duration of the emergency or an amount not to exceed a three-day supply whichever is shorter;
 - (b) after the emergency situation ends, the physician or physician assistant conducts the physical examination as part of an initial in-person visit before any further prescribing of a drug that is a schedule II controlled substance.

Thank you for your questions regarding controlled substances prescribing.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov





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From: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Sent: Friday, February 18, 2022 3:24 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: RE: February eNews from the State Medical Board of Ohio

Regarding the proposed telehealth rules, am I correct in interpreting them to allow telehealth for opiate management?

From: Nathan.Smith@med.ohio.gov <Nathan.Smith@med.ohio.gov>
Sent: Friday, February 18, 2022 3:15 PM
To: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Subject: RE: February eNews from the State Medical Board of Ohio

Dr. Lenchitz,

The requirements in the current rules regarding prescribing still exist. The Board is suspending its enforcement of the rules listed in the Telemedicine guidance until new telehealth rules are amended or adopted. As the telemedicine guidance states, providers must document their use of telemedicine and meet minimal standards of care.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
med.ohio.gov



State Medical Board of

Ohio

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From: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Sent: Friday, February 18, 2022 2:40 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: RE: February eNews from the State Medical Board of Ohio

Breaking it down – Is the requirement for in-person visits for established patients for opiate management indefinitely suspended at this point?

From: Nathan.Smith@med.ohio.gov <Nathan.Smith@med.ohio.gov>
Sent: Friday, February 18, 2022 2:20 PM
To: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Subject: RE: February eNews from the State Medical Board of Ohio

Dr. Lenchitz,

The Ohio General Assembly passed Substitute House Bill 122 Telehealth Services which was signed by Governor DeWine on December 22, 2021. I have attached a copy of the new telehealth law which will be effective on March 23, 2022. The most relevant sections to telehealth and the Board's proposed rules are on pages 10-14. The proposed rules are implementing this new telehealth law. There is a section on page 18 of the bill that states:

SECTION 6. Beginning on the effective date of this section, a health care professional licensing board, as defined in section 4743.09 of the Revised Code, may suspend the enforcement of any rules that the board has in effect on the effective date of this section regarding the provision of telehealth and in-person services by a health care professional under the board's jurisdiction, and requirements for the prescribing of controlled substances, while the board amends or adopts new rules that are consistent with the provisions of this act.

The Medical Board will continue to suspend enforcement of its telehealth related rules, including those involving in-person requirements, while the board amends or adopts new telehealth rules. Effective March 9, 2020, the Board had posted the following Telemedicine guidance:

<https://med.ohio.gov/Telemedicine-Guidance>

The new telehealth law provision that I quoted above allowed the Board to continue the suspension of the enforcement of these rules while the Board amends or adopts new rules, which the Board did on February 9th.

(2) The proposed 4731-11-09 rule implements the legislation's requirements in R.C. 4743.09. The proposed rule requires an initial in-person visit for a new patient before a physician or physician assistant prescribes a schedule II controlled substance with some exceptions (listed in paragraph E of the rule). The proposed rule also requires that controlled substance prescribing must also comply with federal law requirements regarding controlled substances as well as the telehealth requirements in proposed rule 4731-37-01 if the care is provided through telehealth.

I hope this addresses your questions.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
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by telephone.

From: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Sent: Friday, February 18, 2022 1:34 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: RE: February eNews from the State Medical Board of Ohio

Thanks for getting back to me

1. What does this mean?

In accordance with the new telehealth law, at its February 9th meeting, the Board voted to continue to suspend enforcement of its telehealth related rules, including those with in-person requirements, while the board amends or adopts new telehealth rules.

What “new telehealth law”?

Was there something new from State Medical Board that I missed?

Does this also mean that for now in-person requirements are suspended?

2. Would the 4731-11-09 Controlled substance and telehealth prescribing *Proposed New Rule* mean that, after an initial in person exam, opiates can be prescribed without an office visit every 90 days for example?

From: Nathan.Smith@med.ohio.gov <Nathan.Smith@med.ohio.gov>
Sent: Friday, February 18, 2022 1:19 PM
To: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Subject: RE: February eNews from the State Medical Board of Ohio

Dr. Lenchitz,

I would be happy to try to clarify the proposed rules. Is there a particular paragraph or paragraphs in the rules about which you have a question? If so, it may help to put your question or concern in writing so that I can give it a thoughtful response.

I look forward to receiving your comments and questions.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
med.ohio.gov



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From: Lenchitz, Bernard (lenchib) <lenchib@ucmail.uc.edu>
Sent: Friday, February 18, 2022 1:00 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: FW: February eNews from the State Medical Board of Ohio

Hi Mr. Smith

Would you have a few moments to clarify the proposals below:?

4731-37-01 Telehealth *Proposed New Rule*

4731-11-09 Controlled substance and telehealth prescribing *Proposed New Rule*

If so, what is best way to communicate?

Bernard Lenchitz MD FACP
Professor of Clinical Medicine
University of Cincinnati College of Medicine/Academic Health Center
231 Albert Sabin Way, Room 7559
ML 0535
Cincinnati, OH 45267-0535
Phone 513-558-7581
Fax 513-558-4399

Vice President, Primary Care Network
UC Health - University of Cincinnati Physicians
2830 Victory Parkway
Cincinnati, OH 45206

UCPhysicians
425 Walnut St.
Suite 200
Cincinnati Ohio 45202
Phone 513-475-7676 and fax 513-381-1830
Cell phone 513 909 5488

email:bernard.lenchitz@uc.edu

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From: [Loch, Laura R](#)
To: [Smith, Nathan](#)
Subject: Nutrition telehealth
Date: Monday, February 21, 2022 8:22:12 PM

This message was sent securely using Zix®

Hello,

My name is Laura and I am a licensed dietitian in the state of Ohio. I have been made aware of 4731-37-01(B) and its potential effect on the ability to provide nutrition counseling via telehealth across state lines. As a dietitian with the Christ Hospital Health Network, I am based in Cincinnati but do provide nutrition counseling to patients in Northern Kentucky at our satellite outpatient oncology location in Fort Wright. I am worried that this rule would significantly hinder my ability to provide equal care to immunocompromised cancer patients, many of which prefer telehealth visits during the ongoing pandemic. Please consider the effects of this new rule and its ability for a major healthcare system to provide ongoing care to our cancer patients.

Thank you,
Laura

Laura Loch, RDN, LD
Registered Dietitian, Cancer Center
The Christ Hospital Health Network
2139 Auburn Avenue
Cincinnati, OH 45219
513-585-4250
Laura.Loch@TheChristHospital.com



[TheChristHospital](#) [Facebook](#) [Twitter](#) [Instagram](#) [YouTube](#) [Linkedin](#) [Yammer](#)

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From: [Mary-Jon Ludy](#)
To: [Smith, Nathan](#)
Subject: Comment on Telehealth Rules / Dietitian / Across State Lines
Date: Tuesday, March 1, 2022 9:50:40 PM

Hi Nate:

It has been a long time since we've communicated.

I am writing to share concerns about the language in 4731-37-01(B). It appears to restrict dietitians (along with respiratory therapists and genetic counselors) to only providing telehealth in Ohio and not across state lines. In contrast, physicians and physician assistants are permitted to practice across state lines.

When I first read about this, I didn't think too much about this... but then a faculty member who I supervise reached out about a pilot study that she and a colleague in North Carolina are planning. Right now, it's fine. They'll deliver standard food allergy education that does not involve medical nutrition therapy. However, if the research keeps moving forward, it is possible (likely) that they will want to carry out an intervention that involves medical nutrition therapy. The dietitian who I supervise is licensed in Ohio, but not North Carolina (where the research is being conducted)... so, the inability to deliver telehealth across state lines would negatively impact her.

My hope is that the wording can be changed so that dietitians, respiratory therapists, and genetic counselors all have the same telehealth practice permissions as their physician and physician assistant colleagues.

Please feel free to reach out if you any questions or concerns.

Best regards,
Mary-Jon

Mary-Jon Ludy, PhD, RDN, FAND

Chair, Department of Public & Allied Health
Associate Professor, Food & Nutrition Program
135 Health & Human Services
Bowling Green State University
Bowling Green, Ohio 43403-0154
Email: mludy@bgsu.edu
Zoom: <https://bgsu-edu.zoom.us/my/mludy>
Phone: 419-372-6461 | Fax: 419-372-2881
[Pronouns](#): she/her/hers

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From: [Match, Alie](#)
To: [Smith, Nathan](#)
Subject: Re: 4731-37-01(B)
Date: Tuesday, February 22, 2022 12:13:35 PM
Attachments: [image004.png](#)
[image005.png](#)

This message was sent securely using Zix®

Hi Nathan,

I am emailing to voice my concerns over the changes to telehealth that would no longer allow RDs to provide telehealth services across state lines. I work in Cincinnati and regularly have patients who live in Indiana and Kentucky, if passed, I am worried this rule would significantly hinder my ability to provide equal care to oncology patients who seem to prefer a telehealth option with the ongoing pandemic.

Thank you for taking the time to hear my concerns.

Be well,

Alie



Alie Match, RD, CSO, LD (she/her/hers)
Registered Dietitian | Certified Specialist in Oncology Nutrition
University of Cincinnati Cancer Center | Barrett Center
📞 (513) 584-6987
✉ Alie.Match@UCHealth.com
🌐 www.uchealth.com/cancer

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From: [Mcknightp](#)
To: [Smith, Nathan](#)
Subject: telehealth
Date: Wednesday, February 23, 2022 7:13:59 PM

Nate -- I haven't seen you in a long while and I am sure your little one has grown to an independent child. I hope she is doing well.

I am writing related to the telehealth rules. Dietitians were so pleased that with the Covid issue telehealth expanded to include dietitians. We are pleased that HB 122 put this into legislation.

Our concern is for the statement in the proposed SMBO Rule -- A health care professional may provide telehealth services to a patient located in this state. This a problem for dietitians and we do not see anything in HB 122 that limits services to Ohio.

Central Ohio dietitians who provide telehealth services to patients may not be affected, EXCEPT if their patient goes to Florida or Arizona for the winter. The dietitians in Cincinnati have many patients who live in Kentucky. The same is true for dietitians who live near Michigan, Pennsylvania and West Virginia.

I am sure you will hear from other dietitians. We are asking the State Medical Board to remove this restriction from the proposed Rule. We would be most willing to discuss this with anyone you suggest.

Take Care. pat

Pat McKnight, MS,RDN, LD.

State Policy -- Ohio Academy of Nutrition and Dietetics

Assistant Professor, Nutrition Mt. Carmel College of Nursing mcknightp@aol.com

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From: [Smith, Nathan](#)
To: [Kelli Melvin](#)
Subject: RE: Telehealth rules
Date: Wednesday, February 23, 2022 10:21:00 AM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)

Dr. Melvin,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

The new telehealth law (effective on March 23, 2022), specifically R.C. 4743.09, does include advanced practice registered nurses as health care professionals allowed to provide telehealth services. The Medical Board's rules do not focus on APRTs because the Nursing Board licenses and regulates APRTs. If you have more specific questions regarding APRTs and telehealth you may want to contact the Nursing Board. Here is a link to their website: <https://nursing.ohio.gov/>

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov



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From: Kelli Melvin <doxielover1967@gmail.com>
Sent: Sunday, February 20, 2022 7:20 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: Telehealth rules

Are certified nurse practitioners working under the supervision of a physician allowed to see patients via telehealth? If so, will that language be adopted in the proposed rules? I don't see that in there now. It only refers to physician assistants.

Thank you,
Kelli Melvin MD
Springboro, OH

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From: [Jeanette Menapace](#)
To: [Smith, Nathan](#)
Subject: Telehealth Rule: 4731-37-01 Telehealth
Date: Thursday, February 24, 2022 8:42:52 AM

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

The language used could negatively affect the health of the clients I work with in that the clients would not benefit from the flexibility of telehealth professionals in other states.

Depending on the client's health status, this severely limits access to care and the convenience of telehealth to a patient.

Offering telehealth across state lines could benefit a patient who is seeking alternative care or more advanced care such as a cancer treatment. Other cities/states have state of the art care and this gives easier access to a patient who doesn't have access in the state they reside. It also makes follow up appointments easier since the patient doesn't have to travel for that, only for actual treatment.

There are already examples where this kind of service works well. The nurses' compact is a great example of this and currently used at my employer to speak to clients in those states within the compact.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

*Jeanette Menapace MPH, RDN, LDN, CHES
Health Education Specialist
WebMD Health Services
9229 Delegates Row
Suite 400, Building 81
Indianapolis, IN 46240*

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From: [Smith, Nathan](#)
To: [Dr. Laverne Miller](#)
Subject: RE: QUESTIONS Telehealth Prescribing
Date: Thursday, February 24, 2022 3:33:00 PM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)

Dr. Miller,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

There is not a definition of the term “new patient” in the proposed rule 4731-11-09. We will consider your comment and suggested edit.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov



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From: Dr. Laverne Miller <drmill@cmhosp.com>
Sent: Thursday, February 24, 2022 11:23 AM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: QUESTIONS Telehealth Prescribing

Dear Nathan Smith,

I am Laverne Miller MD, Family Medicine and Geriatrics.

I have a concern regarding some definitions in your proposed rules, namely how we define a “new patient”. (4731-11-09, Para (D) and following)

Especially when it comes to prescribing controlled medications for such a patient who I have never seen but is a patient of one of my group or partners who are covering and have the same employer. At least once during a coverage period which may last a week we are asked to give a controlled medication to a patient because their primary care physician of the group is out of town or unavailable.

Needless to say this is not simply a night off or a day off but usually a week off because otherwise they can wait and usually are taken care of.

If care is taken we can assure ourselves the medicine is given for the correct diagnosis because the record is available to us. OARRS can and should be consulted. All of that is part of the minimal standards that should not have to be taught to everyone over again.

Do you already have a definition for new patient that I have missed?

It would be very simple to substitute “new patient to the practice ” that would mean the record would not be available and the prescription would NOT be written except for the emergency provisions which are very stringent.

I appreciate your prompt answering to these questions and bringing them up before the board if necessary.

Sincerely,
Laverne Miller MD

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From: [Nageotte, Emily](#)
To: [Smith, Nathan](#)
Subject: Letter of Concern
Date: Thursday, February 24, 2022 3:07:46 PM

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Explain here how the language negatively could negatively affect the health of your patients/clients. Give an example here of how only being able to provide telehealth in-state caused a business or patient problem (especially during the pandemic), or how your business or patient could benefit from being able to provide telehealth across state lines.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Emily Nageotte, RDN, LD

She/Her

Clinical Dietitian

Cystic Fibrosis Center Peds UH Rainbow Babies & Children's Hospital University Hospitals Cleveland Medical Center

11100 Euclid Avenue, RBC 6302A

Cleveland, Ohio 44106

P: 216-844-8147

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12780 El Camino Real, San Diego, CA 92130 (858) 617-7600

SUBMITTED ELECTRONICALLY to Nathan Smith via Nathan.Smith@med.ohio.gov.

February 25, 2022

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215

Re: Proposed New Rule, 4731-37-01, Telehealth

Dear Mr. Smith,

Neurocrine Biosciences, Inc. appreciates the opportunity to submit comments to Rule 4731-37-01, proposed as a new rule (proposed new rule) to implement recently enacted telehealth law (Substitute House Bill 122), establishing requirements for the provision of telehealth services by physicians, physician assistants, and other State Medical Board of Ohio licensees.

We strongly support the proposed new rule's recognition of the importance of in-person encounters in health care by requiring that "the standard of care for a telehealth visit must be the same as the standard of care for an in-person visit."¹ We are concerned, however, that the proposed new rule does not contemplate that telehealth visits may never be the same as in-person care for certain diseases and health conditions. In fact, we believe that without additional guidance to health care professionals, the limitations of telehealth visits for certain complex conditions may unintentionally lead to serious health consequences, such as underdiagnosis or a missed diagnosis. We expound on these concerns in our discussion below. Therefore, we recommend the State Medical Board consider providing further guidance to health care professionals that reflect federal policies regarding best practices to balance periodic, in-person visits with telehealth visits, especially in circumstances where equal standards of care via telehealth may be difficult to attain.

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis, uterine fibroids and clinical programs in multiple therapeutic areas. For thirty years, Neurocrine Biosciences has specialized in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems.

¹ See: Proposed Rule 4731-37-01, Sections B(1).

Neurocrine Biosciences appreciates the challenges of developing general policies governing the use of telehealth while, in many cases, germane clinical best practices for delivering health care services via telehealth are being developed in parallel. The proposed new rule establishes that a “health care professional shall follow all standard of care requirements,” and may provide services via telehealth “provided that the standard of care for an in-person visit can be met for the patient and the patient's medical condition through the use of the technology selected”.² We caution that existing standards of care for certain patient populations, such as those at risk of experiencing drug-induced movement disorders (DIMDs), including tardive dyskinesia, may not translate adequately into telehealth service delivery, particularly when services are delivered over the telephone. Our specific recommendations reflect current federal policies and are set out below, and we would welcome the opportunity to discuss those with you at a mutually convenient time.

Tardive dyskinesia can occur because a person is taking prescribed antipsychotic medications to treat a primary mental health diagnosis, such as schizophrenia, bipolar disorder, or major depressive disorder, among other medicines. It is a persistent condition that is often irreversible, and which manifests in involuntary physical movements across multiple regions in the face and body. Tardive dyskinesia is typically, but not always, screened for and diagnosed by psychiatrists treating a primary mental health condition. Periodic screening for and treating disordered movements is expressly the standard of care for patients with schizophrenia who are prescribed antipsychotics.³

According to the medical literature, the prevalence of antipsychotic-related movement disorders such as tardive dyskinesia and drug-induced parkinsonism ranges from approximately 20 to 35 percent.⁴ As the U.S. Food and Drug Administration notes: “Tardive dyskinesia can be disabling and can further stigmatize patients with mental illness...”⁵ Undiagnosed and untreated DIMDs can have profound mental health impacts on the lives of patients,⁶ including reduced quality of life, psychiatric treatment non-adherence, social isolation, and experiencing stigma related to their condition. These disorders straddle the divide between physical and mental health conditions, and they can significantly impact activities of daily living, such as speaking, getting dressed, and eating.

Section (C)(5) of the proposed new rule states:

“The health care professional shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care for an in-person visit...”⁷

² See: [Proposed Rule 4731-37-01](#), Sections B(1-3).

³ American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia, Third Edition. See: Table 2, p. 26. 2021. <https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841>.

⁴ Ward KM and Citrome L. “Antipsychotic-Related Movement Disorders: Drug-Induced Parkinsonism vs. Tardive Dyskinesia—Key Differences in Pathophysiology and Clinical Management.” *Neurol Ther.* July 2018. 7(2):233-248. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6283785/pdf/40120_2018_Article_105.pdf.

⁵ U.S. Food and Drug Administration. “FDA approves first drug to treat tardive dyskinesia.” April 11, 2017. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-tardive-dyskinesia>.

⁶ 7 McEvoy J, et al. “Effect of Tardive Dyskinesia on Quality of Life in Patients with Bipolar Disorder, Major Depressive Disorder, and Schizophrenia.” *Qual Life Res.* August 21, 2019. 28(12):3303-3312. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6863950/>.

⁷ See: [Proposed Rule 4731-37-01](#), Section C(5).

We are concerned that without further guidance, when a visit is conducted via telehealth, health care providers may miss or overlook symptoms of patients living with or at risk of experiencing DIMDs that would otherwise trigger additional evaluation, including screenings. In fact, this is a very real risk, as evidenced by survey data collected by Neurocrine demonstrating that psychiatrists and neurologists, regularly are not screening for tardive dyskinesia when a visit is conducted via telehealth.⁸ Thus, we believe such patients must be periodically seen in-person.

Periodic, in-person visits provide critical opportunities for providers to identify and diagnose certain conditions directly related to mental health that are difficult, if not impossible, to accurately identify via telehealth, particularly when services are delivered over a telephone. As the Centers for Medicare and Medicaid Services described in the final Calendar Year 2022 Physician Fee Schedule Final Rule:

...there may be particular instances where visual cues may help a practitioner's ability to assess and treat patients with mental health disorders, especially where opioids or other mental health medications are involved (for example, visual cues as to patient hygiene, or indicators of self-destructive behavior) ...⁹

This comports with emerging expert opinion, which finds that audio-only treatment may be particularly sub-optimal for new patients, including initial psychiatry visits, patients who may not be sufficiently stabilized, and those for whom a physical assessment is critical to screening or diagnosis.¹⁰ In fact, up to half of providers in a recently conducted survey indicated that patients living with serious mental illness who are new to a practice are at high risk of a missed diagnosis when care is delivered through telehealth.¹¹

Therefore, we respectfully request that the State Medical Board of Ohio consider providing additional guidance to health care professionals to address screenings for disordered movements for patients at risk of developing DIMDs, including patients treated with antipsychotic medications, as they relate to meeting in-person standards of care requirements via telehealth. We also respectfully request the State Medical Board of Ohio provide clear guidance specifically on how to balance periodic in-person visits with telehealth to ensure opportunities for health care professionals to identify and properly screen for DIMDs such as tardive dyskinesia.

Additionally, we recommend the State Medical Board consider aligning with federal policies by articulating in the proposed new rule that, for patients with mental health conditions, and specifically those at risk of developing a DIMD such as TD, the provider and patient must meet in person at least once in the six months prior to delivering the first telehealth service, and at least once annually thereafter. For the subsequent visits, the need for an in-person visit could be waived by a consultation

⁸ Neurocrine Biosciences. Survey of 277 neurologists, psychiatrists, and advanced practice providers (nurse practitioners and physician assistants) affiliated with neurology and psychiatry practices. Data presented at Psych Congress on October 29-November 1, 2021.

⁹ CMS. Calendar Year 2022 Physician Fee Schedule Final Rule (2021-23972), p. 171.
<https://publicinspection.federalregister.gov/2021-23972.pdf>.

¹⁰ Gray J, Tengu D, and Mehrotra A. "3 surprising trends in seniors' telemedicine use during the pandemic." Stat News. August 30, 2021. <https://www.statnews.com/2021/08/30/three-surprising-trends-seniors-telemedicine-use-pandemic/>.

¹¹ Neurocrine Biosciences, data on file. Survey of 277 neurologists, psychiatrists, and advanced practice providers (nurse practitioners and physician assistants) affiliated with neurology and psychiatry practices. Data accepted for publication at Neuroscience Education Institute Congress on November 4-7, 2021.

between the patient and a provider concluding such an in-person visit is not necessary and documenting the results of that consultation in the patient's medical record.¹²

We appreciate the leadership of the State Medical Board of Ohio to address complex, challenging, and timely issues related to Ohio's health care needs. Neurocrine is pleased to serve as a resource to you, and we would welcome a further conversation with members of the Board on these matters at your convenience. Please let us know if we can provide you with any additional information as proposed new rule 4731-37-01 moves through the rulemaking process. Should you have any questions or wish to discuss these comments, please contact me at JTierney@neurocrine.com, or my colleague, Frankie Berger, Director, State Policy, at FBerger@neurocrine.com.

Sincerely,



Jodie Tierney
Director, State Government Affairs – Central and Gulf States

¹² CMS. Calendar Year 2022 Physician Fee Schedule Final Rule (2021-23972), p. 171. <https://public-inspection.federalregister.gov/2021-23972.pdf>; Consolidated Appropriations Act, 2021, Section 123: <https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf>

From: [Nishnick, Amy](#)
To: [Smith, Nathan](#)
Subject: Telehealth administrative rule 4731-37-01 rule for HB 122
Date: Tuesday, March 1, 2022 9:16:08 AM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

As a practicing dietitian we currently provide telehealth care to patients from all over the country for our expertise and world class care. These patients seek us out and are not financially able to visit us in person. We are conducting research at our institution that telehealth does not provide adverse outcomes and provides the same outcomes as in person visits.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Amy Nishnick, RD, LD, CNSC
Advanced Practice Dietitian

Marymount Hospital
123000 McCracken Rd
Garfield Heights, OH 44125

Amy Nishnick, RD, LD, CNSC

Advanced Practice Dietitian | Center for Human Nutrition
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Ohio Association of Acupuncture and Oriental Medicine

Dear Ohio Medical Board,

The Ohio Association of Acupuncture and Oriental Medicine (OAAOM) would ask that Licensed Acupuncturists be included in the list of providers qualified to offer telehealth services in Ohio under the 4731-37-01 Telehealth Proposed New Rule. The current list of providers includes physicians (MD, DO, and DPM), physician assistants, dietitians, respiratory care professionals, and genetic counselors. We understand that this professional group may have been omitted due to the misconception that our medicine is limited to care only by needle insertion. Our goal in pursuing this bill is to provide more information on acupuncturists' roles in the healthcare system.

Acupuncturists have been officially understood as Essential Healthcare Workers dating back to the start of the Covid pandemic.

- Acupuncturists provide care that can help with non-pharmacologic pain management, as well as anxiety management, support for best lifestyle and dietary practices. Telehealth allows providers to perform wellness checks for our patients without needing in-person visits, especially to the elderly, immunocompromised patients, those with limited transportation, in rural areas and other underserved communities.
- Acupuncturists can instruct patients remotely on how to perform self-care techniques such as acupressure and mind-body interventions.

Many of our patients rely on us as an important source of healthcare. We are a frequent point of contact and information for our patients, seeing many of them on a weekly basis. Telehealth visits with an acupuncturist would not replace any form of consultation that should be done with their family or another medical doctor; if a consultation required additional follow-up with a medical doctor it would be immediately referred. We are able to monitor ongoing health conditions, notice medical red flags, and refer for further care if needed.

- In this way we are an important level of care in the healthcare system, with frequent personal contact with patients, providing advice and triage that can help bring patients to the correct providers and keep them out of hospitals unless absolutely necessary -- especially in times when hospitals are already overloaded. Additionally, our medicine's role as an important alternative to opioids for pain relief makes it crucial that we be able to monitor our patients via telehealth.

Licensed acupuncturists have 4-6 years of education and are master or doctorate-level healthcare providers.

25901 Emery Rd. Suite 100 Warrensville Heights, OH 44128

- We are covered by major medical insurance, including Ohio Medicaid -- and have recently been approved for coverage by Medicare for low back pain.
- Our important role in the healthcare system is increasingly recognized and we hope that you'll support our efforts to provide care to our patients via telehealth.
- Ohio would be joining Colorado, New Jersey, Washington, Florida, Texas, California, and Wisconsin, all of whom allow acupuncturists to provide telehealth services

Thank you so much for your consideration. We are happy to answer any questions.

Sincerely,
Jared West
OAAOM Insurance and Medicaid Co-Chair



March 1, 2022

Nathan Smith
State Medical Board of Ohio
30 East Broad Street
Columbus, Ohio 43215

Submitted via: Nathan.Smith@med.ohio.gov

Dear Mr. Smith,

On behalf of the Ohio Association of Community Health Centers (OACHC), thank you for the opportunity to submit comments regarding the State Medical Board draft rules on telemedicine. **We greatly appreciate the Board's consideration to continue to allow telemedicine and increasing access to care.**

The OACHC supports Ohio's 57 Federally Qualified Health Centers and FQHC Look-Alikes (more commonly referred to as Community Health Centers), providing care to nearly one million Ohioans across 452 sites throughout 75 of the 88 counties. Community Health Centers are non-profit health care providers with patient-majority boards that meet the specific needs of the community they serve. For more than 55 years, CHCs have provided integrated whole person care, often times providing medical, dental, behavioral health, pharmacy, vision and other needed supplemental services under one roof.

Community Health Centers are required to offer comprehensive services in areas of high need and have been pioneering telehealth to address geographic, economic, transportation, and linguistic barriers to health care access. Health care leaders across the country, including Community Health Centers, continue to incorporate and grow the use of various telehealth modalities as equity tools to overcome health disparities for underserved populations. Telehealth is providing access and the ability to deliver needed health care to patients who are unable to have an in-person visit with a provider, or plainly prefer the virtual experience and the convenience it brings.

As Ohio Community Health Centers continue to respond to the opioid epidemic and the COVID-19 pandemic, they have greatly expanded their use of telehealth. This vital tool has increased access for high-risk patients and has been used medically and in behavioral health settings extensively. In addition to supporting increased access to timely care for our underserved populations, Health Centers are also using these tools to overcome persistent clinical workforce shortages, decrease of "no-show" rates.

While challenges of broadband connectivity and technology issues remain, overall, the COVID-19 pandemic and ongoing battle against substance abuse issues, has proven how critical it is to utilize tools to connect patients to care at the time it is needed. Ensuring that patients have adequate access to care virtually, as well as in-person, remains essential for improving population health and achieving health equity.

OACHC strongly supports the ability to use telehealth to serve Ohio's communities and most vulnerable populations. We appreciate the opportunity to share our feedback on behalf of Ohio's Community Health Centers and look forward to working with the Board on these rules. If you have any questions or would like to further discuss, please contact Julie DiRossi-King, Chief Operating Officer at (614) 884-3101 or jdirossi@ohiochc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Randy Runyon". The signature is fluid and cursive, with the first name "Randy" and last name "Runyon" clearly distinguishable.

Randy Runyon
President & CEO

OHIO ACADEMY
of Nutrition and Dietetics

an affiliate of the
eat right Academy of Nutrition and Dietetics



Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

3/1/2022

Dear Mr. Smith,

Thank you for permitting the Ohio Academy of Nutrition and Dietetics (OAND) to provide comments on the draft “Telehealth” administrative rule 4731-37-01 that is in circulation, and implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services utilized by Ohioans during the Covid 19 pandemic.

OAND is concerned about the limiting nature of the following language contained in draft rule “4731-37-01 Telehealth”:

4731-37-01 (B) “ A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:”

We believe that restricting Ohio health professionals licensed by the State Medical Board of Ohio (SMBO) including Dietitians from providing telehealth services to patients who live outside of Ohio’s borders is not consistent with the intent of HB 122 – which was to maintain and expand telehealth services provided during the Pandemic.

In looking closely at the enabling statute 4743.09 ORC, we have not been able to identify any language that specifically prohibits Dietitians, Respiratory Therapists, or Genetic Counselors licensed by SMBO from providing telehealth services to patients located outside of this state if permitted by the laws and rules of the state in which the patient is located.

We believe that all health care professionals deserve continuing access to patients under the care of Ohio based providers - whether the patient lives in Ohio or outside the state. Ohio has many regional, national and internationally renowned medical centers that provide highly specialized care to patients and once treatment is complete aftercare at home should be seamless and be provided by the team of professionals who are most familiar with the patient and the patient’s treatment plan. Transitional and home-based care provided to patients after organ transplants, and to those patients with rare diseases and disorders often requires a multi-professional team - including dietitians who are experts in specialized nutrition care and therapy.

On behalf of the OAND, I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) “ A health care professional may provide telehealth services to a patient located outside of this state if permitted by the laws of the state in which the patient is located, and if they comply with all of the following requirements: ”

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside Ohio’s borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering our concerns and comments.

Sincerely,

Kay Mavko, MS, RDN, LD
State Regulatory Specialist
Ohio Academy of Nutrition and Dietetics
614.668.9036

March 1, 2022

Mr. Nathan Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 E. Broad St., 3rd Floor
Columbus, OH 43235

Submitted via email to: Nathan.Smith@med.ohio.gov

Dear Mr. Smith:

On behalf of our 250 member hospitals and 15 health systems, the Ohio Hospital Association (OHA) appreciates the opportunity to provide comments on the Ohio State Medical Board's proposed telehealth rules (proposed 4731-37-01 and 4731-11-09). OHA particularly appreciates being included, along with many of our members, in the Board's early conversations regarding these rules and the collaborative approach the Board has taken with many stakeholders. We look forward to continuing the dialogue with the Board and other stakeholders as these rules continue through the rule-making process. OHA solicited feedback from across our membership and have the following specific comments related to the proposed rules:

Proposed OAC 4731-37-01

"Formal" v. "Informal" Consulting

- The draft rule uses the term "formally consulting," which is not currently defined in the rule. See (A)(1). We agree the distinction between formal and informal consultations needs to be made throughout the rule to ensure certain provisions do not apply to informal consults. Our understanding is that a "formal" consult is one where the patient's records are sent to another provider and that provider bills the patient for their consult. By contrast, an "informal" consult is when Physician A asks Physician B (perhaps a partner in the practice or colleague at the hospital) to review a patient's lab results to see if Physician B agrees with Physician A's diagnosis. In the latter situation the patient often does not know about the consult and would not be billed. OHA believes defining what the Board means by "formal consultation" is important to avoid confusion.
 - Suggested revision: Define "formal consultation" as: "When a health care professional seeks the professional opinion of another health care professional regarding the diagnosis or treatment recommended, transfers the relevant portions of

the medical record to the consulting health care professional, documents the consult in the medical record, and the consulting health care professional bills for such consult.” We also recommend changing references throughout the rule to “formal consultation” where appropriate.

Definition of “Asynchronous communication” in (A)(3):

- As written, the definition of “asynchronous communication” could be interpreted to limit the kinds of “stored clinical data” that may be transmitted via asynchronous technologies to video clips, sound/audio files, and photo images. This could unnecessarily exclude other types of clinical data – such as vital signs, lab test results, patient medical histories, and/or patient descriptions of symptoms – that are often part of asynchronous telehealth visits.
 - Suggested revision: Edit the definition as follows: “Asynchronous communication technology, also called store and forward technology, means the transmission of a patient’s stored clinical data from an originating site to the site where the healthcare professional is located. The health care professional at this distant site can review the stored clinical data at a later time from when the data is sent and without the patient being present. Stored clinical data that may be transmitted via asynchronous communication technology means includes, but is not limited to, video clips, sound/audio files, or photo images that may be sent along with electronic records and written records about the patient’s medical condition. Asynchronous communication technology in a single media format does not include telephone calls, images transmitted via facsimile machines, and text messages, such as electronic mail, without visualization of the patient. Photographs or video images that are visualized by a telecommunications system must be both specific to the patient’s medical condition and sufficient for furnishing or confirming a diagnosis and/or a treatment plan.

Definition of “Consent for Treatment” in (A)(7).

- Note that a prior draft of this rule used the term “Informed Consent” in multiple places where we believe it is not the appropriate term, given its general usage in situations involving surgeries or procedures. We appreciate the Board’s responsiveness to our prior feedback on this issue. We do not necessarily have concerns with the definition of “Consent for Treatment” in this draft (in section (A)(7)). However, we have received feedback from members who believe this term will still be confused with the concept of “informed consent.” Accordingly, in the interest of avoiding as much confusion as possible, we recommend changing the term “Consent for Treatment” to “Consent for Telehealth

Treatment” to make clear the Board is referring to consent to receive treatment via a telehealth modality.

- We also believe there are sections of the proposed rule where “Consent for Telehealth Treatment” may be the appropriate term and other sections where it is not the appropriate term. For example:
 - (C)(2) and (F)(2) seem to be an appropriate use of “consent for telehealth treatment.”
 - (D)(1) – Instead of “consent for treatment” we believe “acknowledgment” may be a better term. This sentence would read: “. . . health care professional shall document the acknowledgement of the patient.” In consult situations “consent for treatment” or “consent for telehealth treatment” are not terms that are generally used for in-person visits where consults are conducted, though it is common for the patient to acknowledge that a consult may occur during their discussion with the health care professional.

Use of “Patient or the parent or guardian of a patient” Throughout

- Throughout the draft rule the term “patient or the parent or guardian of a patient” is used to describe who can consent and make decisions on behalf of the patient. Under federal and state law, a patient may have a legal representative or health care power of attorney with authority to make decisions that is not the patient or the parent or guardian of the patient.
 - Suggested revision: We suggest broadening the decision-making authority to ensure all legal representatives of the patient are included by changing the language throughout the document from “patient or the parent or guardian of a patient” to “patient or a legal representative of a patient.”

When Health Care Professional Determines In-Person Visit is Necessary

- Several member hospitals have expressed concerns regarding proposed subsection (B)(4)(a) regarding use of the term “immediately” and the limitations regarding to whom the provider can refer a patient. This provision establishes a standard different than what would be required for an in-person visit, as it may not be necessary for the in-person visit to be “immediate” in order to meet the standard of care, and the limits on who the provider can refer the patient to may cause significant access to care problems for many Ohioans, particularly those in rural communities. Further, the language suggests the health care professional is in a position to immediately schedule a patient for an in-person visit, when in reality the provider rarely has access to scheduling systems and other resources necessary to meet that requirement.

- Suggested revision: Delete the current language of (B)(4)(a) in its entirety and replace with the following: "If at any time during the telehealth visit the provider determines that the patient must be seen in person, but not in an emergency room, the health care professional providing telehealth services should direct the patient to the appropriate in-person health care services. The health care professional providing telehealth services shall document and provide this direction to the patient at the time of the telehealth visit." This suggested language makes it clear that the provider has an obligation to direct a patient to non-emergent, in-person services in the same way they would if the visit was in-person and required referral to a different provider.
- We believe further clarity is needed to distinguish the scenarios covered under (B)(4)(b) and those addressed in (B)(4)(c). Additionally, use of the term "scheduling" suggests that the telehealth provider has access to schedules and systems to schedule within the originating site. Most providers do not have that capability during a telehealth visit. We suggest a revision to reflect that the provider must direct the patient to appropriate clinical resources at the time of the telehealth visit.
 - Suggested revision: Revise (B)(4)(b) to read as follows: "If the patient does not need to be seen immediately, and does not need to be seen by a specialist under subsection B(4)(c), the health care professional shall direct the patient to schedule ~~the patient for~~ an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented."
- Regarding subsection (B)(4)(d), we believe that requiring the provider to notify an emergency room that a particular patient *may arrive* at the emergency room will lead to confusion in the emergency room. There is no way for the referring provider or receiving emergency room to know whether such patient will arrive at the emergency department, or if that patient will elect to go somewhere else or choose to not receive services at all.
 - Revise subsection (B)(4)(d) as follows: If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency room and provide notification to the emergency room of the patient's potential arrival.

Standard of Care Requirements in Subsection (C)

- Subsection (C)(1) requires the professional to verify the patient's identity and physical location in Ohio, but is not clear on the method to be used for such verification. We recommend a clarification to reflect that a patient's verbal verification of their identity and physical location is sufficient.
 - Suggested revision: Add the word "verbally" after "verify."

- Subsection (C)(4) requires the patient's authorization before transferring records to another provider. However, under HIPAA, providers are not required to obtain patient authorization to share medical records with other providers of the patient for treatment purposes. Thus, if the patient has designated a primary care provider or other health care provider as someone they want to be informed about their care, then the health care professional can disclose medical information without obtaining authorization for each disclosure. This allows for greater efficiency and better continuity of care.
 - Suggested revision: Edit (C)(4) as follows: If applicable, the health care professional shall ~~request the patient's authorization and, if granted,~~ forward the medical record to the patient's primary care provider, ~~or~~ other health care provider designated by the patient, or ~~refer the patient~~ to an appropriate health care provider ~~or health care facility to whom the patient is referred.~~
- Subsection (C)(7) requires the provider to document the patient's consent for treatment through telehealth, which we believe is already adequately covered in (C)(2) of this section.
 - Suggested revision: Delete "or patient's parent or guardian's consent for treatment through telehealth," from subsection (C)(7).
- It is our assumption that normal physician delegation rules apply to the provisions of subsection (C), such that a physician may delegate many of the requirements in subsection (C) to a medical assistant or nurse or others.

Consultations

- We believe the requirements of subsection (D) should only apply to "formal" consultations, as we have suggested that term be defined above.
 - Suggested revision: Add the word "formal" before "consultation."
 - Suggested revision: In subsection (D)(1), change "referring health care professional" to "health care professional who seeks a formal consultation." We recommend this change because there are other provisions of the rule that deal with "referrals," while this section of the rule deals with "consultations" sought by the provider. We believe this change will avoid confusion.
- In subsection (D)(1), we believe "consent for treatment" is not the appropriate term here, as we noted above.
 - Suggested revision: Change "consent for treatment" to "acknowledgment."

- We have heard significant concern regarding use of the word “all” in subsection (D)(3) when requiring the consulting physician to have received and reviewed “all” medical records. We believe inclusion of the word “all” will cause confusion and lead to disputes over whether the consulting physician did, in fact, receive and review “all” medical records. We believe use of “all” in this context is overbroad and unnecessary. For example, it would be very difficult to comply with this requirement if a patient has a chronic illness and has received treatment from multiple previous specialists at multiple facilities.
 - Suggested revision: Delete the word “all.”

Proposed OAC 4731-11-09

- Section (E) of this proposed rule allows a physician or physician assistant to prescribe a controlled substance to a new patient as part of the provision of telehealth services in certain situations. OHA supports the exceptions that are permitted by proposed section (E). However, the existing version of this rule that is in effect includes scenarios for prescribing controlled substances to patients via telehealth that are not covered under the proposed rule. We believe these scenarios should continue to be allowed so long as the requirements of the new telehealth rule (proposed 4731-37-01) are met.
- Suggested revision: Add the following subsections from existing 4731-11-09(D) to proposed new 4731-11-09(E):
 - Add existing -09(D)(1) as proposed -09(E)(5): The person is an active patient of an Ohio licensed physician or other health care provider who is a colleague of the physician and the drugs are provided pursuant to an on call or cross coverage arrangement between them.
 - Add existing -09(D)(2) as proposed -09(E)(6): The patient is physically located in a hospital or clinic registered with the United States drug enforcement administration to personally furnish or provide controlled substances, when the patient is being treated by an Ohio licensed physician or other healthcare provider acting in the usual course of their practice and within the scope of their professional license and who is registered with the United States drug enforcement administration to prescribe or otherwise provide controlled substances in Ohio.
 - Add existing -09(D)(3) as proposed -09(E)(7): The patient is being treated by, and in the physical presence of, an Ohio licensed physician or healthcare provider acting in the usual course of their practice and within the scope of their professional license, and who is registered with the United States drug enforcement administration to prescribe or otherwise provide controlled substances in Ohio.

Mr. Nathan Smith/Medical Board

March 1, 2022

Page 7

- Add existing -09(D)(4) as proposed -09(E)(8): The physician has obtained from the administrator of the United States drug enforcement administration a special registration to prescribe or otherwise provide controlled substances in Ohio.

Thank you again for the opportunity to provide comments on behalf of Ohio's hospitals. Please let us know if you have any questions regarding our comments. We look forward to continuing to work with you and the Board on these rules as we move telehealth forward in Ohio.

Sincerely,

A handwritten signature in black ink, appearing to read "Sean McGlone", written in a cursive style.

Sean McGlone

Sr. V.P. & General Counsel



17 S High Street, Suite 799, Columbus, OH 43215
614-228-0747 | www.TheOhioCouncil.org
f t i @theohiocouncil

Ohio Council on the State Medical Board of Ohio's Telehealth Rules

Soley Hernandez, LISW-S, Associate Director

February 24, 2022

The Ohio Council of Behavioral Health and Family Services Providers appreciates the opportunity to provide comments on the State Medical Board of Ohio's telehealth rules and to provide recommendations on these important changes. We would like to offer the following comments and recommendations for consideration:

In 4731-37-01, paragraphs (A)(2) and (A)(3) define synchronous and asynchronous communication. Synchronous communication includes two-way "audio and/or video" technology which presumably includes telephone calls but is not specifically indicated. However, asynchronous communication specifically indicates telephone calls are not included. The Ohio Department of Medicaid's definition of asynchronous communications in 5160-1-18 includes telephone calls, which could cause confusion for providers who are familiar with this rule. For clarity, we would recommend including telephone calls in the definition of synchronous communication.

- **Recommendation:** Specifically indicate telephone calls are included in the definition of synchronous communications in paragraph A(2).

Thank you for considering this recommendation. Please do not hesitate to contact me if further detail or clarification is needed.



March 1, 2022

Ms. Stephanie Loucka
Executive Director
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

RE: PROPOSED TELEHEALTH RULES

Dear Ms. Loucka,

On behalf of OneFifteen, I am writing to express our thanks and support of the Medical Board's proposed new rules 4731-37-01 (Telehealth) and 4731-11-09 (Controlled substance and telehealth prescribing).

OneFifteen's mission is to heal people experiencing substance use disorders through learning, science, and partnership. OneFifteen supports new and amended federal and state rules to improve access to care via telehealth, especially in underserved communities in Ohio.

We greatly appreciate the Medical Board's rigorous efforts over the past several months in working through telehealth matters and drafting these proposed telehealth rules. We believe the proposed rules go a long way in recognizing those appropriate situations where prescribing via telehealth makes sense. That being said, we have a few additional suggestions and/or clarifications to help align the Medical Board's various regulations that touch on telehealth with the goal of increased access to quality care, as follows:

(1) Office-Based Opioid Treatment (OBOT) Rule OAC 4731-33-03(B)(1)(e) – Buprenorphine is a Schedule III controlled substance often prescribed for substance use disorder treatment, including by practitioners providing OBOT under OAC 4731-33-03. The proposed rules at 4731-37-01 and 4731-11-09 would permit a health care professional to prescribe buprenorphine via telehealth. However, OAC 4731-33-03(B)(1)(e), pertaining to OBOT specifically, requires a physician who provides OBOT to conduct an "appropriate physical examination" prior to providing OBOT, including prescribing buprenorphine. There are exceptions allowing examinations conducted within a reasonable time *prior to* the visit to satisfy the physical exam requirement and there is a provision allowing a physician to document any part of the assessment that cannot be completed prior to initiation of OBOT. These provisions appear to provide some flexibility, but do not clearly permit first visit telehealth prescribing of buprenorphine. To align this rule with the proposed rules and goal of increased access to telehealth, specifically for those with substance use disorders, **we suggest revising Ohio's OBOT rules prior to the scheduled revision date of 2024 by clarifying that an appropriate physical**

examination may be conducted via telehealth with a synchronous audiovisual connection. We are happy to support the Medical Board in this process by sharing the expertise of our clinical leadership team in the rule revision process or as a member of an advisory council on OBOT rule changes.

(2) Interaction with Nursing Rules – We respect that the Medical Board has revised these rules within its sphere of administrative authority, and we believe that congruence with nursing practice rules will help achieve further clarity. More consistent definitions across the span of the rule sets will allow for the degree of flexibility for advanced practice providers (physician assistants and advanced practice nurse practitioners) intended by federal rules. For example, the new version of OAC 4731-37-01(A)(1) defines telehealth services as the practice of telemedicine by a “health care professional” within the state of Ohio. Though the Medical Board’s new rules provide a definition of “certified nurse practitioner”, they do not include this category of practitioner within the list of professionals authorized to practice telehealth. Meanwhile, the Board of Nursing (BON) statutes presently include “advanced practice nurse” within their own definition of “health care professional.” **We believe that the new Medical Board rules should cross-reference the categories of APRNs that the BON approves for the practice of telehealth, and include them in the definition of “health care professional.”**

To reiterate, we are grateful for the ongoing dialogue we have had with you and others there, and appreciate the staff and Medical Board’s work in addressing telehealth in light of the pandemic and evolving innovations in the health care world.

If you have any questions or would like to discuss further our perspective, please contact me at martit@verily.com.

Very truly yours,



Marti Taylor
President & CEO
OneFifteen

From: [Abigail Opher](#)
To: [Smith, Nathan](#)
Subject: Letter of Concern for 4731-37-01 Telehealth
Date: Saturday, February 26, 2022 3:53:11 PM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth": 4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:" Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Specifically, as a pediatric dietitian, I see patients with a variety of health needs, including failure to thrive, diabetes, obesity, tube feeders, malnutrition, and eating disorders. I would like to demonstrate how expanding telehealth services outside of Ohio would be beneficial (and oftentimes CRITICAL) to my patients by discussing my experience with patients with eating disorders.

Typically I see these patients on a weekly basis, sometimes twice weekly in order to provide the incredible support required to live with an eating disorder. These visits can last anywhere from a quick 10 minute check in to up to 60 minutes. As you may imagine, we discuss issues that are very personal and emotionally charged. Many of my patients rely on these visits to prevent them from giving in to their disordered eating patterns.

Additionally, many of these patients are the age at which they are about to go to college, a tremendously difficult transition in their lives. Typically, for my patients going out of state for school, this means finding an entirely new care team in an unfamiliar environment. These patients have shared with me that this burden of finding a new dietitian, therapist, doctor, etc. to manage their care is incredibly taxing and often results in a backslide of their eating disorder due to delays I care or re-establishing rapport with these providers. One patient was unable to establish care at her university for 2 months and fell into a deep depression, restricting herself

to eating only 200 calories per day and losing over 10 pounds. If I had been able to continue our telehealth visits, I am almost certain I could have provided her with the support she needed while away at school. This rule could potentially be the difference between life and death for these patients.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows: 4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Abby Opher MS, RD, LD
Pediatric Dietitian
Cleveland Clinic Children's Hospital

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From: [Janet Shaw](#)
To: [Smith, Nathan](#)
Subject: OPPA Comments on Draft Telehealth Rules
Date: Tuesday, March 1, 2022 3:54:20 PM
Importance: High

Good afternoon, Nathan,

The Ohio Psychiatric Physicians Association (OPPA) appreciates the opportunity to comment on the board's draft telehealth rules. The OPPA was pleased that three of its psychiatric physician members, who are experienced with providing psychiatric treatment via telehealth, could participate in the stakeholder meeting with members of the board. We appreciate that many of the issues raised by our members were included in the draft rules currently before the medical board.

The OPPA would like to offer the following comments and recommendations for consideration:

OAC 4731-37-01 (B) (4)(b)

We appreciate that the language in this section was amended from the original version, however, as discussed during the stakeholder meeting, we would like the board to incorporate a scenario in which the patient does not need emergency care nor to be seen by a specialist but needs an in person visit with a physician of the same specialty. For instance, a patient in southern Ohio has a telehealth visit with a physician in the Cleveland area who suggests the patient be seen in person. Rather than having a patient from Columbus drive to Cleveland for the in-person visit, it may be more appropriate for the patient to see a physician of the same specialty locally. This is not addressed in the current draft.

The OPPA suggests the following changes:

(b) If the patient does not need to be seen immediately, the health care professional shall do one of the following:

(i) schedule the patient for an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their current condition presented.

(ii) refer the patient to a health care provider of the same specialty to conduct an in-person visit within an amount of time that is appropriate for the patient and their condition.

OAC 4731-37-01 (C)(2)

“The health care professional shall document the consent for treatment through telehealth of the patient or, if applicable, the patient's parent, guardian, or person designated under the patient's health care power of attorney.” While the language doesn't state explicitly that documentation consent needs to occur at EACH telehealth visit, it could certainly imply it.

The OPPA suggests the following change:

At the end of the sentence, following “attorney” insert “at the initial telehealth visit.”

OAC 4731-37-01 (F)(1)

During the stakeholder meeting, regarding the initial draft rules, one of the physicians representing OPPA expressed that he felt this section was an unnecessary addition to the rule. At the time, other stakeholders agreed. While OPPA appreciates the intent of this section, we do not believe that the State Medical Board of Ohio's telehealth rules should consider whether telehealth rules from other states support a physician in Ohio practicing telehealth in another state.

OPPA suggests the following:

We recommend deleting this section from the proposed rules. We support including information about this topic in educational information that will be developed to support the new telehealth rules.

The OPPA sincerely appreciates the opportunity to comment, and we look forward to working with the medical board as the process moves forward.

If you have any questions, please contact me. If it would be helpful, I can connect you with one of the physicians from OPPA who attended the stakeholder meeting.

Best regards,

Janet

Janet Shaw, MBA
Executive Director
Ohio Psychiatric Physicians Association
3510 Snouffer Road, Suite 101
Columbus, OH 43235
614-763-0040
www.oppa@oppa.org

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From: [Jennifer Hayhurst](#)
To: [Smith, Nathan](#)
Cc: ["Janet Shaw"](#); ["Jill Hostetler"](#); [Todd Baker](#); ["Jill Hostetler"](#); [Loucka, Stephanie](#)
Subject: OSMA Comments on Draft Telehealth Rules
Date: Monday, February 28, 2022 3:04:25 PM

Nathan,

Good afternoon.

The Ohio State Medical Association (OSMA) appreciates the opportunity to comment on the board's draft telehealth rules. Before the rules were drafted, the OSMA reached out to our members and our contacts at various specialty associations in an effort to locate, and consult with, physicians who have experience utilizing telehealth in their medical practices. As you are aware from our recent stakeholder meeting with the board, we were able to locate some outstanding physicians who were able to provide valuable feedback at that meeting and on the draft rules currently before the medical board.

The OSMA, in consultation with the Ohio Dermatological Association and the Ohio Psychiatric Physicians Association, would like to offer the following comments and recommendations for consideration:

OAC 4731-37-01 (A)(2)

While section (A)(3) of 4731-37-01 clearly states that telephone calls are not an appropriate means of asynchronous communication, the rule is not clear whether telephone calls are permitted in the rule's definition of synchronous communication. The fact that the rule allows audio and/or video "synchronous communication technology" suggests that conducting a telephone visit via telephone communication only, would be an appropriate use of synchronous communication technology.

The OSMA suggests the following changes:

(2) Synchronous telehealth is the delivery of health information in real-time. Synchronous communication technology means audio and/or video technology that permits two-way, interactive, real-time electronic or telephonic communication between the health care professional and the patient or between the health care professional and the consulting health care professional regarding the patient.

OAC 4731-37-01 (B)(4)(b)

While we appreciate that the language in this section was amended from the original version, the Board failed to incorporate a scenario in which the patient does not require emergency care or care by a different specialist but needs an in-person visit with a provider of the same specialty. For instance, a patient may have a telehealth visit with an Ohio specialist who is not located in the same city where the patient resides. If the provider does not feel it is necessary to personally treat that patient, but does feel follow-up care with another specialist of the same specialty is needed, the provider should have the ability to refer the patient to a local provider within the same specialty.

The OSMA suggests the following change to section 4731-37-01(B)(4)(b):

(b) If the patient does not need to be seen immediately, the health care professional shall do one of the following:

(i) schedule the patient for an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented.

(ii) refer the patient to a health care provider of the same specialty to conduct an in-person visit within an amount of time that is appropriate for the patient and their condition.

OAC 4731-37-01(F)(1)

As was discussed at our meeting regarding the initial draft rules, many stakeholders, including the OSMA, felt that this section was an unnecessary addition to the rule. While we appreciate the intent of this section, we do not feel that the State Medical Board of *Ohio's* telehealth rules should consider whether other state's telehealth rules support an Ohio physician practicing telehealth in that state. We recommend deletion of this section and support including information regarding this topic in educational information that is developed to support the new telehealth rules.

We appreciate the opportunity to comment and look forward to working with the medical board on this important topic.

If you have any questions, please feel free to contact me.

Sincerely,

Jennifer Hayhurst
Director, Regulatory Affairs, OSMA

Jennifer Hayhurst

Director, Regulatory Affairs

Ohio State Medical Association

5115 Parkcenter Ave. Ste.200

Dublin, OH 43017

OSMA Office (800) 766-6762, (614) 527-6762

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February 25, 2022

Nathan Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215

Dear Nate,

The Ohio Society for Respiratory Care has reviewed the current proposed Telehealth rules and would like to address proposed rule OAC 4731-37-01 sections B (1) and F (1) and (2).

We understand that the licensing boards of all health care professionals can only write rules that are consistent with the law created by Sub. HB 122. The OSRC is not certain that the medical board is accurate with its legal interpretation of section 4743.09 (5) (a) and (b) in imposing these out of state and remote monitoring restrictions on their licensees who are not physicians or physician assistants in rules. We have been in dialogue with the bill's sponsors about specific limitations imposed by rule OAC 4731-37-01.

During the COVID crisis, telehealth was a lifeline to patients who were not able to be seen in person by physicians and their clinical teams, especially those with chronic disease in need of routine monitoring. Best practices evolved to include respiratory care professionals to assess, instruct, troubleshoot equipment with cardiopulmonary patients using synchronous and asynchronous methods with remote monitoring devices. Respiratory Therapists (RCPs) provide telehealth incident to their physician or advanced practice provider and do not bill for telehealth services.

OAC 4731-37-01: Definitions:

(B)(1) A healthcare professional may provide telehealth services to a patient located in this state.

Comment: The OSRC believes that all health care professionals need access to patients under the care of Ohio based providers whether the patient lives in Ohio or outside the state. Ohio has many regional, national, and internationally renowned centers that provide organ transplants, manage high-tech implants, provide care for rare diseases and disorders that require regular well assessments, and troubleshooting or monitoring of equipment by health care personnel under physician approved protocols or orders. Ohio also has many hospitals along state borders who treat patients from

bordering states. Seniors who travel during winter months could benefit from well assessments performed their Ohio provider's healthcare team for consistent disease management.

(F) A healthcare professional that is a physician or physician assistant may provide the following additional telehealth services:

(1) A physician or physician assistant may provide telehealth services to a patient located out of this state if permitted by laws of the state in which the patient is located.

(2) A physician or physician assistant may provide telehealth services through the use of remote monitoring devices provided that: (a) the patient or patient's guardian gives consent for treatment to the use of remote monitoring devices; (b) the remote devices that enable remote monitoring have been cleared, approved, or authorized by the United States food and drug administration for the specific purpose for which the physician or physician assistant are using it for the patient, and the remote monitoring devices otherwise comply with all federal regulation.

Comment: Remote monitoring using durable medical equipment is routinely performed by non-provider level health care personnel as a part of assessing a patient's health status and compliance with prescribed therapy. Physicians and advanced practice providers (PAs and APNs) delegate this type of monitoring to their professional team members, who regularly monitor these parameters as a part of their scope of practice. In respiratory care, this includes remotely performed spirometry in post-transplant patients and CF/COPD patients, the downloading of non-invasive ventilation parameters to assess patient compliance with CPAP and BiPAP use and effectiveness in sleep medicine, troubleshooting home settings using a data hub which contains ventilator parameters plus physiologic responses. These assessments and monitoring results are shared with the provider who determines the plan of care. Remote access is used to adjust ventilator settings with provider orders.

If this rule passes as it is, 1) this will prevent RCPs involved in regional programs or those working in border cities from reaching their out-of-state patients and 2) restrict the RCP's ability to use "standard of care" remote equipment and physiologic monitoring in all patients.

Thank you for your consideration of our concerns. If you have any questions or would like to contact the OSRC, our contact information is below.

Sincerely,

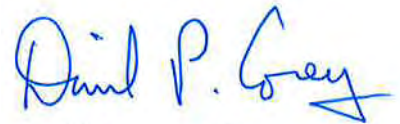


Sue Ciarlariello MBA, RRT-NPS RCP

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David P. Corey MBA

OSRC Executive Director

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614-784-9772

March 1, 2022

Stephanie Loucka
Executive Director
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio, 43215

Re: Telehealth Rule 4731-37-01 and Controlled substance and telehealth prescribing Rule 4731-11-09

Dear Director Loucka:

On behalf of over 1,500 faculty physicians and over 900 residents and fellows at The Ohio State University Wexner Medical Center (OSUWMC) and OSU Physicians, Inc. (OSUP), we appreciate the State Medical Board of Ohio's attention to updating its rules and requirements related to telehealth. The COVID-19 pandemic has caused us to significantly expand our telehealth capabilities and our patients and providers would like to see this option remain as flexible as it has been under the federal and state public health emergency periods.

Overall, we believe that these proposed rules are well crafted and make clear that the primary regulatory purpose is to make sure that telehealth is delivering standard of care. In addition, we greatly appreciate the current version of the substance use prescribing rule. In addition, we support the Board, in this updated version, expanding those who are allowed to provide consent for a patient beyond the patient.

However, we continue to have some requests for clarification and recommended modifications which we will elaborate on below.

OSUWMC and OSUP experience with telehealth

We bring to our answers an extensive experience with telehealth even before the pandemic, an experience that has massively expanded as a result of the pandemic. Our telehealth journey began back in 1995 as we began using telemedicine to increase Ohio Department of Rehabilitation and Corrections (ODRC) inmate access to care. The State of Ohio found significant savings from a reduction in inmate trips to the emergency room and doctors' offices as well as unnecessary medical tests. We have provided more than 10,000 telemedicine visits with inmates and currently offer 28 specialty clinics to 29 prison sites across the state.

In 2011, the OSUWMC Comprehensive Stroke Center began tele-stroke services across the state – offering the highest level of timely, evidence-based stroke care regardless of where someone lives.

In 2013, Ohio State psychiatrists began providing tele-behavioral health services for emergency department patients. Timely patient evaluation decreases length of stay, prevents escalation of psychiatric issues, and increases the number of patients that can be discharged home instead of being admitted to a psychiatric facility.

Before the current pandemic, our primary care physicians (PCPs) and specialty areas, including dermatology, pulmonology, gastroenterology, hepatology, congestive heart failure, and otolaryngology, were all using telehealth.

We provide telehealth care through the following means:

- Two-way interactive, audio and video visits between the clinician and the patient.
- Audio-only telephone visits between the clinician and the patient.

In addition, we use eConsults between providers to help our patients, reducing the need for our patients to have to visit with another provider. These eConsults help address health inequities by giving access to specialists to individuals who face geographic distance, transportation, or other barriers to attending in-person medical appointments.

The COVID-19 pandemic forced us, like other health systems, to significantly expand our telehealth investments. As a result, our volume of telehealth visits has expanded exponentially. We have conducted more than 855,000 telehealth visits since mid-March 2020. After a peak of 2,898 visit per day in May 2020, we average approximately 1,020 per day currently.

Unlike most Ohio hospitals systems, we have patients who live in all 88 Ohio counties, including a large number from Ohio's Appalachian counties. In addition, OSUWMC has an extensive Medicare and Medicaid patient population. Telehealth has improved access for those patients who live outside of Central Ohio, along with our seniors and low-income families here in Central Ohio.

Telehealth has quickly become a normal way of providing care to our patients across all types of providers and conditions – from primary care to specialty care and disease management. Telehealth services are offered in primary care and more than 60 specialties and subspecialties at 65 locations.

One clear benefit we have witnessed from our use of telehealth has been a reduction in missed appointments. Since fiscal year 2020 to date our overall no show rate has been 9.1%: 7.0% for

telehealth visits and 9.4% for in-person visits. This rate has varied among specialty grouping with the no show rate for telehealth visits compared to in-person visits being:

- 7.8% compared to 9.4% for medical specialists (overall rate of 9.1%)
- 5.9% compared to 10.2% for primary care (overall rate of 9.4%)
- 6.1% compared to 8.9% for surgical specialists (overall rate of 8.7%)

During a review of our telehealth experience between March and June 2020 we found our overall no-show rate dropped from 8.5% for in-person visits to 5.4% for telehealth visits for all patients, a 36.3% reduction. For our Medicaid patients this rate declined from 11.9% for in-person visits to 8.3% for telehealth, a 30.1% reduction for patients with Medicaid, while it dropped from 4.3% in-person to 3.4% for telehealth visits for our Medicare patients, a 20.6% reduction. This decline in missed appointments translated into an estimated 1,567 more Medicaid visits and 686 more Medicare visits during this period.

In addition, our patients experience benefits outside of their access to health care, including missing less work time and saving money from driving fewer miles. We've saved Ohioans almost 31.5 million miles of travel and 1.42 million gallons of gas, which is equivalent to 70 rail cars of coal burned, or 515,094 propane cylinders for home barbeques. Overall, our telehealth visits have led to avoiding around 23 metric tons of physical waste.

Clarifications and recommended edits

We have shared your draft rule broadly across our system and have the following clarifications and recommended edit for both the telehealth and the controlled substance prescribing rules.

Telehealth

- 4731-37-(A)(3) – recommended edit
 - We believe that definition of asynchronous communication technology is unnecessarily restrictive and confusing. Our concerns include:
 - The definition could be interpreted to limit the kinds of “stored clinical data” as it limits it to video clips, sound/audio files, and photo images. This limitation excludes other types of clinical data that can be submitted electronically such as vital signs, test results, patient medical histories, and/or patient description. The rule’s language should allow for these and other future ways of storing data by not limiting it to those listed.
 - The definition singles out particular modalities as qualifying as asynchronous care. Given that technologies change and new formats and modalities may arise we recommend not limiting what can be used to these specific items.

- 4731-37-01 (B) (4) -recommended edit
 - While this section is more nuanced in this version, allowing for multiple scenarios, it overly complicates and prescribes what are already the standard of care should patients need additional care. We don't see why this level of detail is needed and recommend replacing this entire section with a simple statement, such as, "If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional will either see the patient in-person in a reasonable timeframe or make the appropriate referral as is standard of care, which could include scheduling the patient for a telehealth or in-person with another health care professional"
 - This proposed language:
 - Allows for making a telehealth referral to another provider if telehealth could be appropriate for the visit
 - Avoids the need to revise the rule should additional scenarios arise
 - Recognizes that there are already established referral processes that health care professionals follow when necessary
- 4731-37-01 (C) – clarification and recommended edit
 - This section specifies some of the tasks that the health professional must do during a visit, such as obtain consent or verify the patient's identity and physical location. In our in-person visits these tasks are done by non-physician staff.
 - Does the rule as written allow for the delegation of these tasks?
 - If not, we recommend allowing such delegation so as to maximize the health care professional time interacting with the patient
- 4731-37-01 (F) Recommended edit
 - Incorporate more than medical devices that allow for remote patient monitoring and are approved by the FDA. To this end, we recommend including digital therapeutics, digital software, and digital algorithms

Controlled Substance Prescribing

- Section 4731-11-09 (E) clarification
 - We support the detailed exceptions for in-person requirements for new patients, but we want to be clear on the expectation on how soon an in-person visit needs to take place
- Section 4731-11-09 clarification
 - Is there a reason that this section does not mention nurse practitioners when 4731-37-01 mentions them?
 - We are hoping we can get a similar rule update for nurse practitioners from the Board of Nursing

- Section 4731-11-09 (D) clarification
 - Are we correct that this rule allows providers to prescribe controlled substances for patients who have an ongoing relationship with the provider or another provider in the practice?
- Section 4731-11-09 (D) clarification
 - We want to make sure that patients facing a sickle cell crisis would be captured under the emergency medical condition exception

We greatly appreciate the Medical Board's focus on telehealth and the ability to review and comment on these rules.

Sincerely,



Andrew Thomas, MD
 Interim Co-Leader & Chief Clinical Officer
 OSU Wexner Medical Center
 Senior Associate Vice President for Health Sciences



L. Arick Forrest, MD, MBA
 Vice Dean for Clinical Affairs, OSU College
 of Medicine
 President, The OSU Physicians, Inc
 Medical Director, Ambulatory Services

From: [Pehling, Victoria](#)
To: [Smith, Nathan](#)
Subject: Concern for Telehealth Visits
Date: Tuesday, March 1, 2022 9:23:35 AM

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Dr. Mr. Smith

I am writing to you regarding the recent draft of "Telehealth" administrative rule 4731-37-01 that implements portion of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

This type of limiting language will significantly impact my practice and limit the care I can provide to our patients. As a dietitian at Cleveland Clinic at the Center for Gut Rehab and Transplantation, we provide specialized world class care, often receiving referrals from out of state providers due to the complex nature of the patients. Patients that travel from all over the country to see us to seek treatment for rare diseases. In order to continue the care. it is very important to continue to care for them after they return home. Especially in the winter time when road conditions are bad making it difficult to drive long distances, it is important for patients to have access to healthcare professionals who understand their disease. Telehealth visits makes it possible to continue to provide high level of care for patients with rare diseases.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply

with all of the following requirements:" It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Victoria Pehling, LD, RD, CNSC
Registered Dietitian Nutritionist
Center for Gut Rehab and Transplantation
Cleveland Clinic
9500 Euclid Ave
Cleveland OH, 44195

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From: [Laura Poland](#)
To: [Smith, Nathan](#)
Subject: Telehealth Administrative Rule 4731-37-01 Comments
Date: Thursday, February 24, 2022 11:12:48 AM
Attachments: [TelehealthLetterDietitianInYourKitchen.pdf](#)

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

February 24, 2022

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the Covid 19 pandemic.

As a dietitian in private practice, Ohio Academy of Nutrition & Dietetics board member (State Media Representative) and interested party I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) " A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

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I work with clients who occasionally leave the state for extended periods of time, I have found that when we are not able to continue our visits, compliance with the treatment plan declines. In addition, there are alternative concerns that come up when they are not in their home environment.

In addition, with the new telehealth law, I may consider extending my license to bordering states to Ohio. I accept Medicaid, and I've had patients reach out to me during this pandemic, because they couldn't find a dietitian in their state who accepts their insurance plan. The Medicaid population is severely underserved, and telehealth has allowed me to work with patients in remote areas of Ohio. Why would we limit this to other states if we can help?

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) " A health care professional may provide telehealth services and shall comply with all of the following requirements: "

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Laura Poland, RDN, LD

Registered Dietitian Nutritionist, Licensed Dietitian
Dietitian In Your Kitchen
212 Tallowood Drive
Westerville, OH 43081

Letter attached as well

Dietitian In Your Kitchen, LLC

Call or Text: 614-706-3495

Email: laura@dietitianinyourkitchen.com

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Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

February 24, 2022

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the Covid 19 pandemic.

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Thank you for considering my concerns and comments.

Sincerely,



Laura Poland, RDN, LD

Registered Dietitian Nutritionist, Licensed Dietitian
Dietitian In Your Kitchen
212 Tallowood Drive
Westerville, OH 43081



WWW.dietitianinyourkitchen.com | 614-706-3495 | laura@dietitianinyourkitchen.com

From: [Reed, Kelly](#)
To: [Smith, Nathan](#)
Subject: Telehealth
Date: Tuesday, March 1, 2022 11:04:41 AM

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

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I see patients at Cleveland Clinic Akron General for the Diabetes Center, Maternal Fetal Medicine and General Nutrition. Most if not all my patients that I have seen virtually have been in Ohio but I have had a few that have been outside Ohio for a couple months for vacation, caring for family. If this is passed it would hinder the relationship that we have built and their care. We are expanding our Maternal Fetal Medicine program and many of these women are coming from rural areas that boarder our State.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this

state.

Thank you for considering my concerns and comments.

Sincerely,

*Kelly M Reed MS RD LD CDCES
Clinical Dietitian and Diabetes Educator
Cleveland Clinic Akron General*



Kelly Reed MS RD LD CDCES | Clinical Dietitian/Diabetes Educator | Human Nutrition
Cleveland Clinic Akron General | 1 Akron General Avenue | Akron, OH 44307
P: 330-344-7762 | F: 330-344-0075 | kreedk2@ccf.org

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4KidHelp, 4368 Dressler Rd NW, Suite 103, Canton, OH 44718 330-433-1300 www.4KidHelp.com

February 22, 2022

State Medical Board of Ohio

Re: Comments on Controlled Substance rule in Telehealth

To the Board,

Suggested change to rules: Exempt children with Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) from requiring in person session(s) to receive stimulants.

Rationale: I am a board-certified child and adolescent psychiatrist (as well as an addiction psychiatrist) in an underserved part of Ohio. About 60% of my patients have complicated ADD/ADHD, where primary care physicians have not been able to manage the illness and they are sent to me as a specialist. Given that 7% of children have ADD/ADHD, we are talking about a sizeable number of children in Ohio. As you are aware, ADHD has significant morbidity and mortality – higher rates of dropout, death through accidents, substance abuse and teenage pregnancy. Stimulants remain the primary treatment for ADD/ADHD, which are a class 2 controlled substance. They work in 75% of patients and after decades of experience have few serious side effects. Moreover persons with ADD/ADHD who receive stimulants cut their risk of addiction by 50%!

My patients travel from about a 2-hour radius to see me. Telehealth has been so helpful for parents who are already overwhelmed with the extra responsibilities of raising these children (e.g., attending multiple school meetings, taking the child to counseling or other health services such as Occupational Therapy). Going back to requiring in person sessions would add another burden to these families. As a practitioner, I don't see how face to face meetings decreases the likelihood of misuse or diversion of these substances. I think the effect of requiring face to face meetings would be to limit care and deny children services. As you are aware there is no physical examination which establishes the diagnosis or guides treatment. Such decisions are made through questionnaires and history. The one group of physical health data that is required, vital signs, can be collected through local resources and reported at the visit. I believe that telehealth has been very helpful in serving more children, particularly rural children, with ADD/ADHD. Many of these families are the rural poor and the cost of gasoline and availability of a car limits access to care. For these reasons I suggest that children with ADD/ADHD who receive stimulants not require face to face examination.

Thank you.

Sincerely,

A handwritten signature in black ink that reads "Lee Reynolds, MD".

Thomas (Lee) Reynolds, MD, Nationally Board-Certified in Child & Adolescent, Adult, and Addiction Psychiatry

From: [Rodich, Melanie](#)
To: [Smith, Nathan](#)
Date: Thursday, February 24, 2022 2:30:43 PM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

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Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Explain here how the language negatively could negatively affect the health of your patients/clients. Give an example here of how only being able to provide telehealth in-state caused a business or patient problem (especially during the pandemic), or how your business or patient could benefit from being able to provide telehealth across state lines.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,
Melanie Rodich

Melanie Rodich, MS,RDN,LD,CNSC | Clinical Dietitian

The Congenital Heart Collaborative
UH Rainbow Babies & Children's Hospital
11100 Euclid Avenue
Cleveland, OH 44106-6007

Phone: (216) 844-0193

Pager: 35932

Fax: (216) 201-8293

e-mail: Melanie.Rodich@UHhospitals.org

Facebook: [UHRainbowBabies.com](https://www.facebook.com/UHRainbowBabies.com) | Twitter: [UHRainbowBabies.com](https://twitter.com/UHRainbowBabies.com)

Visit us at www.UHhospitals.org.

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Nathan Smith

State Medical Board of Ohio

Nathan.Smith@med.ohio.gov

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I currently see patients from out of state as a Registered Dietitian in Ohio for *Teledoc*, considered one of the pioneers in telemedicine. Telehealth is here to stay as a venue for people to get the best medical care, particularly if time, availability of medical care in their community is poor, or inability to get out of the home. These are just a few of the many reasons people are choosing this brand of medicine. It will not replace in person medical care, but instead, offer relief to the overworked medical community as we have witnessed these past two years with the pandemic.

As my practice has grown, I see many people from within Ohio but also from Maryland, Virginia, California and Michigan to name a few. An example I can share is a 70-year-old female with Chronic Kidney Disease who was interested in gaining weight and learning more about the diet involved in keeping her healthy. I was able to research her dietary issues and offer recommendations. Her personal health did not allow her to leave her home yet she was able to contact me through Teladoc and get important and necessary dietary information that hopefully will help her. She lives in Virginia.

I also spoke to a family in California about their teenage son and the multiple allergy issues he was going through. I was able to discuss with the parents the issues their child was experiencing and come to some recommendations for them. I have been a Registered Dietitian for a very long time. I ask my patients why they chose me and often they respond because of my length of time in this field.

I have been a Registered Dietitian for 39 years. I have a Bachelor degree from The Ohio State University received in 1980 and a Master's degree in Nutrition Education from the University of Cincinnati. I wrote my Master's thesis on the topic of "Dietitians in Private Practice" which was not even conceived of in

1983. I gave talks around the country to convince dietitians who worked in hospital kitchens that this could be possible. Today, there are no dietitians running hospital kitchens. Hospital food service is managed by outside corporations like Aramark and Sysco and even this trend is changing to meet the needs of the local communities.

It would be a shame for the legislature of Ohio to deny medical access, specifically nutrition access to people across the United States who would truly benefit from experienced Registered Dietitians like me and others. After all, the Academy of Nutrition and Dietetics, originally known as the American Dietetic Association was founded in 1917 in Cleveland, Ohio “during WWI by a visionary group of women, led by Lenna F. Cooper.” We recently celebrated our 100 years in 2017.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) “A health care professional may provide telehealth services and shall comply with all of the following requirements:”

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio’s borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Robin S. Rood RD, LD, MEd, MA

Registered Dietitian Nutritionist

5192 Chillicothe Road

South Russell, Ohio 44022

From: [Shawhan, Stacy](#)
To: [Smith, Nathan](#)
Subject: Telehealth Rules: 4731-37-01(B)
Date: Monday, February 21, 2022 4:52:32 PM
Attachments: [image011.png](#)
[image012.png](#)

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Hello Nathan,

I am writing to comment on the proposed new rule regarding telehealth, 4731-37-01, specifically part B which specifies that the patient must be physically in the state of Ohio at the time that telehealth services are rendered. It appears, from the language, that this rule would be applied to registered dietitians like myself.

In contrast, it appears that physicians and midlevel providers like PAs would be allowed to provide telehealth across state lines.

I am an oncology dietitian working in Cincinnati's largest academic medical center. Being so close to the state border, I see an almost equal number of patients from Kentucky as I do from Ohio. I am concerned that this rule would limit my ability (as well as the ability of other dietitians in similar situations) to provide safe, timely, and adequate care to my patients just across the river.

Many of my patients are immunocompromised and continue to prefer telehealth consults during the ongoing pandemic. Our clinical trials department draws patients from long distances for lifesaving treatment and I do have some patients who live out of state, 1-1.5 hours away. I am not sure how I would explain to them that they can proceed with telehealth for their MD visits, but not their nutrition consults.

Thank you for considering my concerns; I am happy to clarify as needed.

Best regards,



Stacy Shawhan, RD, CSO, LD (she/her/hers)
Registered Dietitian | Certified Specialist in Oncology Nutrition
University of Cincinnati Cancer Center | UC Health
2022 PanCAN Patient Champion
☎ (513) 584-4545
✉ stacy.shawhan@UCHealth.com
🌐 www.uchealth.com/cancer

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From: [Sowa, Agnieszka](#)
To: [Smith, Nathan](#)
Subject: Letter of concern re: "Telehealth" administrative rule 4731-37-01
Date: Tuesday, March 1, 2022 8:35:24 AM
Attachments: [Outlook-Descriptio.png](#)

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

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At Cleveland Clinic, my team of outpatient dietitians see patients from all over the United States. Our registered dietitians are experts in the treatment of numerous diseases and conditions, including those for which the patients may not be able to get care elsewhere. The ability to see our patients virtually who live outside of Ohio borders is imperative in order to be able to provide continuity of care and ensure the best outcomes.

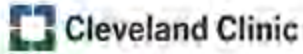
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Thank you for considering my concerns and comments.
Sincerely,

Agnes



Agnieszka Sowa MS, RD, LD, CNSC

Clinical Nutrition Manager: Outpatient Nutrition Therapy & South Pointe Hospital
Center for Human Nutrition

Digestive Disease and Surgery Institute | Cleveland Clinic

9500 Euclid Ave. | M1-146A | Cleveland, OH 44195

Tel: (216) 445-2230 | Cell: (216) 538-4629 | Fax: (216) 445-4357

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From: [Sullivan, Lauren](#)
To: [Smith, Nathan](#)
Subject: 4731-37-01 Telehealth Draft
Date: Tuesday, March 1, 2022 9:12:48 AM
Attachments: [Outlook-yqm33l4d.png](#)

Dear Mr. Smith,

The State Medical Board of Ohio (SMBO) requested comments regarding a recent draft of “Telehealth” administrative rule 4731-37-01 than implements portions of HB 122 recently becoming law in Ohio. Patients and healthcare professionals are anticipating the enactment of this legislation that permanently authorizes and expands access to include the telehealth services used successfully by Ohioans during the last two years of the COVID-19 pandemic.

I am an interested in this legislation because I am a health care professional, a registered dietitian licensed by the SMBO, and a patient. The language of the draft rule “4731-37-01 Telehealth” seems to limit the reach of Ohio dietitians.

4731-37-01 (B) “A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of following requirements.”

Restricting Ohio dietitians from providing telehealth services to patients that live outside of Ohio’s borders does not seem to be consistent with the intent of the HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professional (including dietitians licensed by the SMBO) from providing telehealth services to people living outside of Ohio.

For 12 years, I served as a dietitian to the Bariatric and Metabolic Institute of the Cleveland Clinic Foundation (CCF), traditionally practicing in-person patient care. In the past 2 years, telehealth has expanded my ability to provide my patients with exceptional care without the patient taking time off of work, pay for travel, and pay for accommodations when traveling to an appointment. The bulk of my patient schedule (> 75%) has been virtual over the past 1.5 – 2 years, and preferred by my patients. The telehealth option allows my patients to prepare for and follow routine care post-bariatric surgery. Many of our patients, including those out-of-state, have serious medical co-morbidities and cannot be treated at their local hospitals. They seek out the care at CCF as a result. This rule would limit health care to our patients. Many patients are from as little as 90 minutes away (New York, Pennsylvania, Michigan, West Virginia) and may be excluded from the Telehealth option under the current language of the rule.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule in this way: 4731-37-01 (B) “A health care professional may provide telehealth services and shall comply with all of the following requirements:” It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio’s border but are served by health care facilities and health care professionals working in this state.

Thank you for considering my comments and my concerns regarding the draft of “Telehealth” administrative rule 4731-37-01 than implements portions of HB 122.

Lauren Sullivan, MSAN, RDN, LD

Clinical Nutrition Manager, Inpatient Nutrition Therapy, Main Campus

Center for Human Nutrition

Digestive Disease and Surgery Institute | Cleveland Clinic

9500 Euclid Avenue | M1-141 | Cleveland, OH 44195

Tel: (216) 444-6103 | Cell: (216) 644-2743 | Fax: (216) 444-9415



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From: [Carter, Tracy L.](#)
To: [Smith, Nathan](#)
Cc: [Stephanie Gilligan](#)
Subject: Summa Health public comments regarding OSMB proposed telemedicine rules
Date: Tuesday, March 1, 2022 6:55:40 PM

Dear Mr. Smith,

Please accept Summa Health's public comments in response to the state medical board's draft telemedicine rules.

Summa's mission is to provide the highest quality, compassionate care to our patients, members, and to contribute to a healthier community. We serve as the largest employer and healthcare provider across the Greater Akron region which includes Summit, Stark, Portage, Medina, and Wayne counties. When you consider SummaCare, our provider owned health plan, our service area extends across thirty northern Ohio counties.

We applaud our state legislators and medical board for supporting telemedicine to be practiced more broadly to help a greater percentage of patients access healthcare services in a timely manner. We reviewed the Ohio State Medical Board's proposed telemedicine rules and offer the following public comments:

Clarity about in person visits

- Please clarify when one "in person" visit should be conducted. Does the board expect the in-person visit to occur at any time during a twelve month timeframe or is the board expecting the first visit between a patient and provider to be held in person?

Flexibility with prescription refills

- We welcome clarity on how to handle drug (not a controlled substance) refills for patients. We prefer providers have the authority to prescribe the full supply of a medication to patients given that we can review their electronic medical record and could note any health status concerns and updates and medication orders in the record.

Flexibility for clinicians providing cross coverage of patients

- We recommend for those who provide cross coverage for another healthcare professional's practice that they not be required to see the patient in-person first before prescribing drugs (not a controlled substance). If the clinician who is providing coverage has access to the electronic health record and notes he or she spoke to the patient to assess their health status and discussed medications needed to treat the health concern, he or she will have assured continuity of care and communication with the patient and the medical record process. These steps should be accepted as medical board rule.

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From: [Teague, Erin](#)
To: [Smith, Nathan](#)
Subject: telehealth needs
Date: Thursday, February 24, 2022 2:43:49 PM

Nathan Smith
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

Explain here how the language negatively could negatively affect the health of your patients/clients. Give an example here of how only being able to provide telehealth in-state caused a business or patient problem (especially during the pandemic), or how your business or patient could benefit from being able to provide telehealth across state lines.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Erin E. Teague, MS, RD, LD, CNSC

Clinical Dietitian, Metabolism
Center for Human Genetics
University Hospitals Cleveland Medical Center
11100 Euclid Avenue, LKSD 1500
Cleveland, OH 44106
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***Please note I am not in the office on Fridays**

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February 28, 2022

Nathan Smith, Senior Legal and Policy Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Re: Proposed Rule 4731-37-01; Telehealth

Dear Mr. Smith:

Teladoc Health appreciates the opportunity to comment on the Ohio State Medical Board's proposed rule relating to telehealth. Telehealth is dynamic and evolving. Teladoc Health respects the role of the Board in considering the appropriate rules and clinical practice guidelines that are designed to be protective of public health and maintain high-quality care for patients while permissive of new technological innovations. Teladoc Health has been an active participant over the last eight years to work in a collaborative manner with the Board to ensure that perspectives other than traditional bricks-and-mortar practices are heard. Our mission is built on a simple but revolutionary idea: that everyone should have access to the best healthcare, anywhere in the world on their terms.

Teladoc Health is the world's largest telehealth company and has more than 2,400 employees, delivers health care in 175 countries and in more than 40 languages, and partners with employers, hospitals, health systems, and more than 50 health insurance plans in all 50 states, including in Ohio, to transform health care delivery. Teladoc Health provides health care services to more than 40 percent of Fortune 500 employers, as well as thousands of small businesses, labor unions and public-sector employers, which offer our virtual care services to their employees.

For context, Teladoc Health is offered as a benefit by over 9,500 Ohio employers covering over 1.8 million patients in the state. Some of these employers include: Ohio State University, Marathon Petroleum, Honda Motor Company, Kraft Heinz Company, Macy's, Procter & Gamble, and Owens Corning. Teladoc also contracts with Aetna, Molina Healthcare, and Northern Buckeye Health Plan to provide virtual care services for their commercial health plans.

While Teladoc Health appreciates the Board's efforts to protect patient safety and ensure high-quality care, we are concerned that the proposed telehealth rule would threaten access to health care via telehealth by limiting the viable options available for patients to seek care. Below please find our comments and recommendations for the Board's consideration.

Comments on Proposed Ohio Telehealth Rule

A.

4731-37-01.A(1)

Telehealth services means health care services provided through the use of information and communication technology by a health care professional licensed in Ohio, within the professional's scope of practice, who is located at a site other than the site where the patient is

receiving the services or the site where another health care professional with whom the provider of the services is formally consulting regarding the patient is located.

NOTE: This definition does not track with the statutory definition in ORC 4743.09(3)(1)(6) (effective March 23, 2022)

“Telehealth services” means health care services provided through the use of information and communication technology by a health care professional, within the professional's scope of practice, who is located at a site other than the site where either of the following is located:

- (a) The patient receiving the services;
- (b) Another health care professional with whom the provider of the services is consulting regarding the patient.

B.

4731-37-01.A(3)

Asynchronous communication technology, also called store and forward technology, means the transmission of a patient’s stored clinical data from an originating site to the site where the health care professional is located. The health care professional at this distant site can review the stored clinical data at a later time from when the data is sent and without the patient being present.

Stored clinical data that may be transmitted via asynchronous communication technology means video clips, sound/audio files, or photo images that may be sent along with electronic records and written records about the patient’s medical condition. Asynchronous communication technology does not include telephone calls, images transmitted via facsimile machines, and text messages, such as in electronic mail, without either visual or audio files of the patient included with the text message. Photographs or video images that are visualized by a telecommunications system must be both specific to the patient’s medical condition and sufficient for furnishing or confirming a diagnosis and/or a treatment plan.

NOTE: This definition arbitrarily limits the types of clinical data that may be transmitted through asynchronous communications technology.

C.

4731-37-01.B(4)

A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:

- (a) If the patient must be seen immediately but not in an emergency room, the health care professional shall immediately schedule the patient for an in-person visit with the health care professional and promptly conduct that visit or refer the patient for an in-person visit with one of the following licensed health care professionals who can provide the services in-person that are appropriate for the patient and the condition for which the patient presents:
 - (i) another health care professional with whom the health care professional has a cross-coverage agreement,
 - (ii) in the case of a physician, a physician assistant with whom the physician has a supervision agreement or a certified nurse practitioner with whom the physician has a standard care arrangement; or
 - (iii) in the case of a physician assistant, a physician with whom the physician assistant has a supervision agreement.

(b) If the patient does not need to be seen immediately, the health care professional shall schedule the patient for an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented.

(c) If the patient must be seen by a specialist other than the health care professional, the health care professional shall make a referral to a specialist, licensed in this state, whom the healthcare professional knows has an appropriate scope of practice and is capable of conducting an in-person visit appropriate for the diagnosis and treatment of the patient's condition and ensure that all necessary medical files are shared upon request.

NOTE: This provision goes well beyond typical medical service referral scenarios with in-office health care and requires a "hot hand off" to another health care provider. In effect, it requires the health care professional to have access to another health care provider's schedule and the ability to schedule a patient with an appointment within an appropriate "amount of time." This not only places a significant burden on health care providers but also interdicts patient choice of health care provider. Moreover, it does not take into consideration a patient's health insurance plan and which health care providers are "in network." Further, it does not contemplate the current physician shortage and wait times for in person visits. ORC 4731.741 (effective March 23, 2022) provides that "a physician may provide telehealth services in accordance with sections 4743.09 of the Revised Code." ORC 4743.09(B)(1) (effective March 23, 2022) allows the Board to promulgate rules to implement the telehealth provisions under the section except that the Board "shall establish a standard of care for telehealth services that is equal to the standard of care for in-person services." Current Ohio Administrative Rules have no similar "hot hand off" and scheduling referral provisions for in-office care. Accordingly, proposed 4731-37-01.B(4) is arbitrary and capricious and unsupported by current statute.

D.

4731-37-01.B(4)(d)

"If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency room and provide notification to the emergency room of the patient's potential arrival."

NOTE: This provision is not a best practice in telehealth. The provision should be amended to require the health care professional to have in place appropriate protocols to deal with emergency situations if and when they occur. For example, it is not going to be helpful to a patient experiencing a stroke to be told where the nearest emergency room is located and calling the emergency room to let them know about a patient who is probably not going to arrive there in time. Consider also serious behavior health episodes where the patient is contemplating suicide. In these cases, and in many others, it is more appropriate for the health care provider to call for emergency services and remain in contact with the patient until help arrives. The proposed rule is overly prescriptive and does not reflect current best practice.

E.

4731-37-01.C(7)

The health care professional shall promptly document in the patient's medical record the patient's or, if applicable, the patient's parent, guardian, or person designated under the patient's health care power of attorney, consent for treatment through telehealth, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;

NOTE: There is no definition provided for what constitutes a “prompt” documentation of the patient record. Rather, other sections of the Ohio Administrative Code provide for the documentation of patient records “in a timely manner and in accordance with acceptable standards of practice.”

F.

4731-37-01.D(3)

The health care professionals involved in the consultation must have received and reviewed all medical records of the patient relevant to the medical condition which is the subject of the consultation before the consultation occurs, unless this is not possible due to an emergency situation.

NOTE: It is unreasonable to expect any health care professional to know at the time of diagnosis and treatment that he or she has received all medical records of the patient relevant to the medical condition which it the subject of the consultation before the consultation occurs. A prudent health care provider makes a good faith effort to gather all relevant clinical information related to the medical condition as presented by the patient, including medical records, prior to diagnosis and treatment. However, it is unreasonable to expect a prudent health care professional to know about a medical record that has been lost or purposefully withheld and therefore neither obtainable nor reviewable. This subsection should be amended as follows: The health care professionals involved in the consultation must have received and reviewed all medical records of the patient provided by the patient and the health care professional relevant to the medical condition which is the subject of the consultation before the consultation occurs, unless this is not possible due to an emergency situation.

As the Board contemplates good public policy that ensures patient safety as well as expanded access to health care, it is important to implement language that accommodates all forms and modalities of care and not serve to protect the business interests of Ohio bricks-and-mortar practices. Telehealth is dynamic and evolving, and – if permitted – has the ability to improve patient lives and health outcomes.

Thank you again for the opportunity to provide comments on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to be 'CD' followed by a long horizontal stroke.

Claudia Duck Tucker
Teladoc Health
Senior Vice President, Government Affairs and Public Policy

February 22, 2022

Nathan Smith
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215
Submitted via: Nathan.Smith@med.ohio.gov

Mr. Smith:

On behalf of the Ohio Chapter of the American College of Emergency Physicians (Ohio ACEP) which represents over 1,600 emergency physicians across the State, we are writing to express our thoughts on the proposed rules regarding telehealth. We believe the rules are generally well-crafted but we do have some requested technical changes and also seek clarity on some provisions.

4731-37-01 (A)(1) Telehealth services means health care services provided through the use of information and communication technology by a health care professional licensed in Ohio, within the professional's scope of practice, who is located at a site other than the site where the patient is receiving the services or the site where another health care professional with whom the provider of the services is formally consulting regarding the patient is located.

Ohio's emergency physicians often seek advice from specialists regarding the care of ED patients. With ED crowding and length of stay a significant public health concern we may use utilize telehealth to expedite these consultations and improve ED throughput. It is often significantly more expedient for a specialist to provide a telehealth consultation (when appropriate) then to come in person which could delay care, even when they are on the same campus. Would this definition cover those situations as well? We would encourage the board to allow for these scenarios and clarify the verbiage.

4731-37-01 (A)(4)(d) If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency room and provide notification to the emergency room of the patient's potential arrival.

We support this provision and believe it increases patient care by creating a more formalized handoff for when the patient arrives at the emergency department.

Throughout the rule package, we would request references to "emergency room" be amended to "emergency department". This is a more accurate and modern term for our practice setting. It is also used already throughout the Ohio Revised Code, so there is precedence for this term. For example, emergency department is used in [1753.28](#).

We appreciate your consideration of these comments. Should you have questions or need additional information, please contact Ohio ACEP representative Amanda Sines at amanda@gov-advantage.com.

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From: [Kinsey Jolliff](#)
To: [Smith, Nathan](#); [Reardon, Jill](#)
Cc: [Allison Poulos](#); [Michael Dalton](#)
Subject: The MetroHealth System Comments - SMBO Telehealth Rules
Date: Monday, February 28, 2022 12:16:52 PM

Good Afternoon,

Thank you for allowing us to provide comments on the Medical Board's proposed telehealth rules (OAC 4731-37-01, 4731-11-09). On behalf of our patients and physicians, thank you for efforts to permanently expand telehealth in the State of Ohio.

Below are our comments and suggested changes to OAC 4731-31-01. If you'd like to further discuss the comments, please don't hesitate to reach out. Our physicians are supportive of OAC 4731-11-09 as proposed.

1. **Definition of Asynchronous Communication Technology**

-
We believe that 4731-37-01 (A)(3), as drafted is too restrictive. The definition of asynchronous communication technology could be interpreted to limit the kinds of "stored clinical data" to video clips, sound/audio files, and photo images. However, if limited to these modalities, this could unnecessarily limit other types of clinical data such as the results of symptom surveys, vital signs, results of lab tests, and patient medical histories that are often crucial elements of asynchronous telehealth visits.

In addition, the definition, as written, singles out specific modalities from qualifying as asynchronous care. We believe that licensed providers should be governed by meeting the standard of care in determining which technologies are best to provide telehealth to ensure that a wide breadth of technologies can be utilized in the delivery of virtual health care without sacrificing the quality of that care.

Therefore, we recommend the Board amend the definition of asynchronous communication technology to read as follows:

*Asynchronous communication technology means the transmission of a patient's stored clinical data from an originating site to the site where the healthcare professional is located. The health care professional at this distant site can review the stored clinical data at a later time from when the data is sent and without the patient being present. Stored clinical data that may be transmitted via asynchronous communication technology **includes but is not limited to** video clips, sound/audio files, vital signs, symptom surveys, and photo images that may be sent along with electronic records and written records about the patient's medical condition.*

-
2. **Definition of A Remote Monitoring Device**

We thank the Medical Board for including devices that have been authorized by the FDA in their definition of a remote monitoring device. **We ask that the Board go further and include FDA-**

approved algorithms in their definition. In several of the devices that we and many other providers utilize to provide chronic disease management supported through remote patient monitoring, it is the algorithm that is authorized, not the device itself. Increasingly, algorithms that utilize artificial Intelligence and machine learning are helping with the provision of telehealth, virtual care and remote monitoring.

3. **Care Continuity**

-
We applaud the steps the Medical Board has taken in 4731-37-01(B)(4) to ensure that patients who receive telehealth services are best served when their care must be transitioned to being seen in person. The rule, as written, prioritizes the care of patients, the citizens of Ohio, rather than providers who may have no connection to Ohio who only provide care at a singular point of time.

The only modification that we would make is to amend 4731-37-01(B)(4)(d) to read **“If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency room.”** To ask that the provider notify the emergency room of the patient’s *potential* arrival could lead to confusion in the emergency room. There is no readily available way for the receiving ER to understand who that patient may be and if that patient will actually travel to that specific ED. To ask that the provider help them identify the closest ER is not a small task but we do believe it will help ensure the best possible care transition.

-
Kinsey Jolliff
The MetroHealth System
Principal, Government Relations
P: 614-348-7608
kjolliff@metrohealth.org

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From: [DiBlasio, Carla F](#)
To: [Smith, Nathan](#)
Cc: [Reardon, Jill](#); [Chiarelli, Laura](#); [Smith, Jonathan R](#)
Subject: University Hospitals Comments on Telehealth Proposed Rules
Date: Monday, February 28, 2022 3:04:43 PM

Nathan,

Please find below brief comments from University Hospitals Health System regarding 4731-37-01 Telehealth Proposed New Rule. We also greatly appreciate the changes to the 4731-11-09 Controlled substance and telehealth prescribing proposed rule.

We greatly appreciate the change from “informed consent” to “consent for treatment” – this is very helpful.

The one addition the Board made that we think adds some ambiguity is the inclusion of the word “formal” before consulting in the definition of telehealth services. That is not really a term of art and is not otherwise defined anywhere. Can the Board please clarify their intent in this regard?

Additionally, in 4731-37-01(D)(1), the Board adjusted the language so that the referring health care professional’s documentation of consent is sufficient prior to seeking the “formal” consultation with another health care professional. The consulting health care professional does not need to separately obtain or document consent. That said, the new language may still mean that there needs to be a separate documentation of consent prior to the formal consultation (meaning two consents may be required). We’d appreciate some clarity on this, particularly since we don’t think this should be necessary. If the patient has already consented to treatment, what is the rationale for an additional consent on a “formal” consult?

Lastly, we feel it’s worth mentioning that we generally agree with the ATA’s comment letter (see [here](#)). Specifically, we believe the first and second issue raised in the letter are well worth the Board’s consideration.

If you have any questions or require additional information, please contact John Smith (copied).

Many thanks!

Carla DiBlasio, JD
Director of Government Relations and Health Finance Policy
University Hospitals and
Rainbow Babies & Children's Hospital
11100 Euclid Avenue
Cleveland, OH 44106
440-346-7298

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From: [Wise, Julie R](#)
To: [Smith, Nathan](#)
Subject: Telehealth for Medical Nutrition Therapy
Date: Thursday, February 24, 2022 2:52:28 PM

Dear Mr. Smith,

I understand that the State Medical Board of Ohio (SMBO) is seeking comments on a recent draft of "Telehealth" administrative rule 4731-37-01 that implements portions of HB 122 which recently became law in Ohio. Health care professionals and patients have been looking forward to the enactment of this legislation that permanently authorizes and expands access to the telehealth services used successfully by Ohioans during the COVID-19 pandemic.

As a dietitian, health professional, and interested party, I am concerned about the limiting nature of the following language contained in draft rule "4731-37-01 Telehealth":

4731-37-01 (B) "A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:"

Restricting Ohio dietitians from providing telehealth services to patients who live outside of Ohio's borders does not seem to be consistent with the intent of HB 122. Also, there is no language in the enabling statute 4743.09 ORC that specifically prohibits health care professionals (including dietitians licensed by SMBO) from providing telehealth services to people living outside of Ohio.

I specialize in the treatment of patients with eating disorders. In this population, being able to see patients every week is vital to their support and healing. Having telehealth sessions while they're on a trip, at school, visiting a friend is an essential part of treatment. These environments can be extremely triggering for the eating disorder – challenging foods, unknown meals provided to them, comments made about their body and health, etc.

Receiving the appropriate care for an eating disorder already has numerous barriers, including financial, accessibility, insurance coverage and more. Adding the barrier of not being able to see a patient via telehealth would be causing unnecessary harm.

I respectfully request that the State Medical Board of Ohio revise the Telehealth rule as follows:

4731-37-01 (B) "A health care professional may provide telehealth services and shall comply with all of the following requirements:"

It is important that telehealth services continue to be broadly available to all persons living in Ohio and to our patients who live outside of Ohio's borders but are served by health care facilities and health care professionals working in this state.

Thank you for considering my concerns and comments.

Sincerely,

Julie Wise
University Hospitals, Westshore Primary Care

Julie Wise, MS, RDN, LD, CDCES
(she/her/hers)
Registered Dietitian Nutritionist
Certified Diabetes Care & Education Specialist
Certified Intuitive Eating Counselor

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4731-37-01

Telehealth.

(A) As used in Chapters 4730, 4731, 4759, 4761, and 4778 of the Administrative Code:

- (1) Telehealth services means health care services provided through the use of information and communication technology by a health care professional licensed in Ohio, within the professional's scope of practice, who is located at a site other than the site where the patient is receiving the services or the site where another health care professional with whom the provider of the services is consulting regarding the patient is located.
- (2) Synchronous communication technology means audio and/or video technology that permits two-way, interactive, real-time electronic communication between the health care professional and the patient or between the health care professional and the consulting health care professional regarding the patient.
- (3) Asynchronous communication technology, also called store and forward technology, means the transmission of a patient's stored clinical data from an originating site to the site where the health care professional is located. The health care professional at this distant site can review the stored clinical data at a later time from when the data is sent and without the patient being present. Stored clinical data that may be transmitted via asynchronous communication technology means video clips, sound/audio files, and photo images that may be sent along with electronic records and written records about the patient's medical condition. Asynchronous communication technology in a single media format does not include telephone calls, images transmitted via facsimile machines, and text messages, such as in electronic mail, without visualization of the patient. Photographs or video images that are visualized by a telecommunications system must be both specific to the patient's medical condition and sufficient for furnishing or confirming a diagnosis and/or a treatment plan.
- (4) Remote monitoring device means a medical device cleared or approved by the United States food and drug administration for the specific purpose which the health care professional is using it and which reliably transmits data electronically and automatically.
- (5) Health care professional means:
 - (a) a physician assistant licensed under Chapter 4730. of the Revised Code;
 - (b) a physician licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;
 - (c) a dietitian licensed under Chapter 4759. of the Revised Code;

- (d) a respiratory care professional licensed under Chapter 4761. of the Revised Code; or
 - (e) a genetic counselor licensed under Chapter 4778. of the Revised Code.
- (6) "Certified nurse practitioner" means an advanced practice registered nurse who holds a current, valid license issued under Chapter 4723. of the Revised Code and is designated as a certified nurse practitioner in accordance with section 4723.42 of the Revised Code.
- (7) "Informed consent" means a process of communication between a patient or the parent or guardian of a patient and the health care professional discussing the risks and benefits of, and alternatives to, treatment through a remote evaluation that results in the patient's or parent or guardian's agreement or signed authorization for the patient to be treated through an evaluation conducted through appropriate technology, as specified in this rule, when the health care professional is in a location remote from the patient.
- (B) A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:
 - (1) The standard of care for a telehealth visit is the same as the standard of care for an in-person visit.
 - (2) The health care professional shall follow all standard of care requirements which include but are not limited to the standard of care requirements in paragraph (C) of this rule.
 - (3) The health care professional may provide the telehealth services through the use of synchronous or asynchronous communication technology provided that the standard of care for an in-person visit can be met for the patient and the patient's medical condition through the use of the technology selected. Telephone calls, as a synchronous communication technology, may only be used for telehealth services when all of the elements of a bona fide health care visit meeting the standard of care are performed. Telephone calls that are routine or simply involve communication of information without patient interaction do not constitute a telehealth service.
 - (4) If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall do all of the following:
 - (a) The health care professional shall immediately schedule the patient for an in-person visit with the health care professional and promptly conduct

that visit or refer the patient for an in-person visit with one of the following licensed health care professionals who can provide the services in-person that are appropriate for the patient and the condition for which the patient presents:

(i) another health care professional with whom the health care professional has a cross-coverage agreement,

(ii) in the case of a physician, a physician assistant with whom the physician has a supervision agreement or a certified nurse practitioner with whom the physician has a standard care arrangement; or

(iii) in the case of a physician assistant, a physician with whom the physician assistant has a supervision agreement.

(b) The health care professional shall document the in-person visit or the referral in the patient's medical record.

(C) A health care professional must comply with all standard of care requirements to provide telehealth services to a patient including but not limited to:

(1) The health care professional shall verify the patient's identity and physical location in Ohio and communicate the health care professional's name and licensure information to the patient;

(2) The health care professional shall obtain the patient or the patient's parent or guardian's informed consent for treatment through telehealth;

(3) The health care professional shall provide the telehealth services in a manner that complies with the privacy and security requirements for the patient and their protected health information required by the law of this state and federal law. Also, the health care professional shall ensure that any username or password information and any electronic communications between the health care professional and the patient are securely transmitted and stored.

(4) The health care professional shall request the patient's consent and, if granted, forward the medical record to the patient's primary care provider or other health care provider, if applicable, or refer the patient to an appropriate health care provider or health care facility;

(5) The health care professional shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care for an in-person visit, which may include portions of the evaluation having been conducted by other Ohio licensed healthcare providers acting within the scope of their professional license;

- (6) The health care professional shall establish or confirm, as applicable, a diagnosis and treatment plan, which for those health care professionals designated as prescribers in section 4729.01 of the Revised Code, includes documentation of the necessity for the utilization of a prescription drug. The diagnosis and treatment plan shall include the identification of any underlying conditions or contraindications to the recommended treatment;
- (7) The health care professional shall promptly document in the patient's medical record the patient's informed consent to treatment through telehealth, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;
- (8) The health care professional shall provide appropriate follow-up care or recommend follow-up care with the patient's primary care provider, other appropriate health care provider, or health care facility in accordance with the minimal standards of care;
- (9) The health care professional shall make the medical record of the visit available to the patient upon request.
- (D) A health care professional must comply with the following requirements to provide telehealth services that involve consultation with another health care professional:
 - (1) The referring health care professional shall obtain the informed consent of the patient before seeking the telehealth services consultation with the consulting health care professional;
 - (2) The consulting health care professional must meet the licensure or certification requirements in division (C) of section 4743.09 of the Revised Code; and
 - (3) The health care professionals involved in the consultation must have received and reviewed all medical records of the patient relevant to the medical condition which is the subject of the consultation before the consultation occurs.
- (E) While providing telehealth services, a health care professional that is a physician or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority shall comply with the following requirements regarding prescription drugs:
 - (1) the physician or physician assistant may only prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is not a controlled substance to a patient through the provision of telehealth services by complying with all requirements of this rule;

(2) the physician or physician assistant may only prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug to a patient that is a controlled substance through the provision of telehealth services by complying with the following requirements:

(a) federal law governing prescription drugs that are controlled substances;

(b) the requirements of this rule; and

(c) the requirements in rule 4731-11-09 of the Administrative Code.

(F) A health care professional that is a physician or physician assistant may provide the following additional telehealth services:

(1) A physician or physician assistant may provide telehealth services to a patient outside of this state if the physician or physician assistant confirms and documents in the medical record both of the following:

(a) the location of the patient; and

(b) that the laws of the state in which the patient is located permit the physician or physician assistant to provide telehealth services in that state.

(2) A physician or physician assistant may provide telehealth services through the use of remote monitoring devices provided that:

(a) the patient gives informed consent to the use of remote monitoring devices;

(b) the medical devices that enable remote monitoring have been cleared or approved by the United States food and drug administration for the specific purpose for which the physician or physician assistant are using it for the patient, and the remote monitoring devices otherwise comply with all federal requirements.

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

(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; or

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

(2) For a physician assistant:

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

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

(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.

(3) For a dietitian:

(a) "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 or the rules adopted by the board," as that clause is used in division (A)(1) of section 4759.07 of the Revised Code; or

(b) "A departure from, or 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 (A)(11) of section 4759.07 of the Revised Code.

(4) For a respiratory care professional:

(a) "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 or the rules adopted by the board," as that clause is used in division (A)(7) of section 4761.09 of the Revised Code; or

(b) "A departure from, or 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 (A)(10) of section 4761.09 of the Revised Code.

(5) For a genetic counselor:

(a) "Failure to comply with the requirements of this chapter, Chapter 4731. of the Revised Code, or any rules adopted by the board." as that clause is used in division (B)(2) of section 4778.14 of the Revised Code;

(b) "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 4778.14 of the Revised Code; or

(c) "A departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances whether or not actual injury to the patient is established," as that clause is used in division (B)(4) of section 4778.14 of the Revised Code.

4731-11-09

Controlled substance and telehealth prescribing.

(A) As used in this rule:

- (1) Hospice care means the care of a hospice patient as that term is defined in section 3712.01 of the Revised Code.
- (2) Palliative care has the same meaning as in section 3712.01 of the Revised Code.
- (3) Medication assisted treatment and substance use disorder have the same meanings as in rule 4731-33-01 of the Administrative Code.
- (4) Mental health condition means any mental health condition, illness, or disorder as determined by the diagnostic criteria in the “Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition” or DSM-5.
- (5) Emergency situation means a situation involving an “emergency medical condition” as that term is defined in section 1753.28 of the Revised Code.

(B) A physician or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority must comply with federal law governing prescription drugs that are controlled substances to prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is a controlled substance to a person.

(C) When the physician or physician assistant, who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority, prescribes, personally furnishes, otherwise provides, or causes to be provided a prescription drug that is a controlled substance during the provision of telehealth services, the physician or physician assistant must comply with all requirements in rule 4731-37-01 of the Administrative Code.

(D) The physician or physician assistant shall conduct a physical examination of a new patient as part of an initial in-person visit before prescribing a schedule II controlled substance to the patient except as provided in paragraph (E) of this rule.

(E) As an exception to paragraph (D) of this rule, a physician or physician assistant may prescribe a controlled substance to a new patient as part of the provision of telehealth services for any of the following patient medical conditions and situations:

- (1) The medical record of a new patient indicates that the patient is receiving hospice or palliative care;
- (2) The patient has a substance use disorder, and the controlled substance is FDA approved for and prescribed for medication assisted treatment or to treat opioid use disorder.

- (3) The patient has a mental health condition and the controlled substance prescribed is prescribed to treat that mental health condition; or
- (4) The physician or physician assistant determines in their clinical judgment that the new patient is in an emergency situation provided that the following occurs:
 - (a) the physician or physician assistant prescribes only the amount of a schedule II controlled substance to cover the duration of the emergency or an amount not to exceed a three-day supply whichever is shorter;
 - (b) after the emergency situation ends, the physician or physician assistant conducts the physical examination as part of an initial in-person visit before any further prescribing of a drug that is a schedule II controlled substance.
- (F) When prescribing a controlled substance through the provision of telehealth services under one of the exceptions in paragraph (E) of this rule, the physician or physician assistant shall document one of the reasons listed in paragraph (E) for the prescribing in the medical record of the new patient in addition to the documentation already required to meet the standard of care in rule 4731-37-01 of the Administrative Code.
- (G) Nothing in this rule shall be construed to imply that one in-person physician examination demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice.
- (H) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:
 - (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; or
 - (c) "A departure from or the failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

(2) For a physician assistant:

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

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

(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.

(I) This rule shall not apply to any prescribing situations specifically authorized by the Revised Code or Administrative Code.

(J) For purposes of this rule, "patient" means a person for whom the physician or physician assistant provides healthcare services or the person's representative.



February 10, 2022

Stephanie Loucka, State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215

Ms. Loucka,

On behalf of the Ohio Association of Health Plans (OAHP), we are writing today about the Medical Board's draft telehealth rules distributed on January 6, 2022.

OAHP is the state's leading trade association representing the health insurance industry. Our member plans provide health benefits to more than 9 million Ohioans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare, Medicaid, and the Federal Insurance Marketplace. Our members offer a broad range of health insurance products to Ohioans in the commercial marketplace and are committed partners in public programs.

Telehealth is an important tool to help bridge access and affordability in healthcare, and health plans have been proactively championing and advancing innovative telehealth options for years. We know that consumers and employers are demanding access to telehealth options as they see the financial, time, accessibility, and other benefits it brings.

OAHP cautions implementing telehealth rules that could threaten access. Many times, a consumer will utilize telehealth because that is how they can access care. This can be for multiple reasons including location of patient or provider, transportation issues, or time constraints. However, if a follow-up in-person appointment is required immediately after the telehealth visit it directly undermines the utility of telehealth.

We believe the intent of HB 122 was to bridge access, therefore requiring an in-person visit immediately after a telehealth visit runs counter to this intent. Thank you for your consideration of our feedback.

Sincerely,

A handwritten signature in black ink that reads 'K O'Reilly'.

Kelly O'Reilly
President and CEO

4731-37-01

Telehealth.

(A) As used in Chapters 4730, 4731, 4759, 4761, and 4778 of the Administrative Code:

- (1) Telehealth services means health care services provided through the use of information and communication technology by a health care professional licensed in Ohio, within the professional's scope of practice, who is located at a site other than the site where the patient is receiving the services or the site where another health care professional with whom the provider of the services is consulting regarding the patient is located.
- (2) Synchronous communication technology means audio and/or video technology that permits two-way, interactive, real-time electronic communication between the health care professional and the patient or between the health care professional and the consulting health care professional regarding the patient.
- (3) Asynchronous communication technology, also called store and forward technology, means the transmission of a patient's stored clinical data from an originating site to the site where the health care professional is located. The health care professional at this distant site can review the stored clinical data at a later time from when the data is sent and without the patient being present. Stored clinical data that may be transmitted via asynchronous communication technology means video clips, sound/audio files, and photo images that may be sent along with electronic records and written records about the patient's medical condition. Asynchronous communication technology in a single media format does not include telephone calls, images transmitted via facsimile machines, and text messages, such as in electronic mail, without visualization of the patient. Photographs or video images that are visualized by a telecommunications system must be both specific to the patient's medical condition and sufficient for furnishing or confirming a diagnosis and/or a treatment plan.
- (4) Remote monitoring device means a medical device cleared or approved by the United States food and drug administration for the specific purpose which the health care professional is using it and which reliably transmits data electronically and automatically.
- (5) Health care professional means:
 - (a) a physician assistant licensed under Chapter 4730. of the Revised Code;
 - (b) a physician licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;
 - (c) a dietitian licensed under Chapter 4759. of the Revised Code;

- (d) a respiratory care professional licensed under Chapter 4761. of the Revised Code; or
 - (e) a genetic counselor licensed under Chapter 4778. of the Revised Code.
- (6) "Certified nurse practitioner" means an advanced practice registered nurse who holds a current, valid license issued under Chapter 4723. of the Revised Code and is designated as a certified nurse practitioner in accordance with section 4723.42 of the Revised Code.
- (7) "Informed consent" means a process of communication between a patient or the parent or guardian of a patient and the health care professional discussing the risks and benefits of, and alternatives to, treatment through a remote evaluation that results in the patient's or parent or guardian's agreement or signed authorization for the patient to be treated through an evaluation conducted through appropriate technology, as specified in this rule, when the health care professional is in a location remote from the patient.
- (B) A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:
 - (1) The standard of care for a telehealth visit is the same as the standard of care for an in-person visit.
 - (2) The health care professional shall follow all standard of care requirements which include but are not limited to the standard of care requirements in paragraph (C) of this rule.
 - (3) The health care professional may provide the telehealth services through the use of synchronous or asynchronous communication technology provided that the standard of care for an in-person visit can be met for the patient and the patient's medical condition through the use of the technology selected. Telephone calls, as a synchronous communication technology, may only be used for telehealth services when all of the elements of a bona fide health care visit meeting the standard of care are performed. Telephone calls that are routine or simply involve communication of information without patient interaction do not constitute a telehealth service.
 - (4) If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall do all of the following:
 - (a) The health care professional shall immediately schedule the patient for an in-person visit with the health care professional and promptly conduct

that visit or refer the patient for an in-person visit with one of the following licensed health care professionals who can provide the services in-person that are appropriate for the patient and the condition for which the patient presents:

(i) another health care professional with whom the health care professional has a cross-coverage agreement,

(ii) in the case of a physician, a physician assistant with whom the physician has a supervision agreement or a certified nurse practitioner with whom the physician has a standard care arrangement; or

(iii) in the case of a physician assistant, a physician with whom the physician assistant has a supervision agreement.

(b) The health care professional shall document the in-person visit or the referral in the patient's medical record.

(C) A health care professional must comply with all standard of care requirements to provide telehealth services to a patient including but not limited to:

(1) The health care professional shall verify the patient's identity and physical location in Ohio and communicate the health care professional's name ~~and licensure information to the patient~~ 

(2) The health care professional shall obtain the patient or the patient's parent or guardian's informed consent for treatment through telehealth;

(3) The health care professional shall provide the telehealth services in a manner that complies with the privacy and security requirements for the patient and their protected health information required by the law of this state and federal law. Also, the health care professional shall ensure that any username or password information and any electronic communications between the health care professional and the patient are securely transmitted and stored.

(4) The health care professional shall ~~request the patient's consent and, if granted, forward the medical record to the patient's primary care provider or other health care provider, if applicable, or refer the patient to an appropriate health care provider or health care facility~~ 

(5) The health care professional shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care for an in-person visit, which may include portions of the evaluation having been conducted by other Ohio licensed healthcare providers acting within the scope of their professional license;

- (6) The health care professional shall establish or confirm, as applicable, a diagnosis and treatment plan, which for those health care professionals designated as prescribers in section 4729.01 of the Revised Code, includes documentation of the necessity for the utilization of a prescription drug. The diagnosis and treatment plan shall include the identification of any underlying conditions or contraindications to the recommended treatment;
- (7) The health care professional shall promptly document in the patient's medical record the patient's informed consent to treatment through telehealth, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;
- (8) The health care professional shall provide appropriate follow-up care or recommend follow-up care with the patient's primary care provider, other appropriate health care provider, or health care facility in accordance with the minimal standards of care;
- (9) The health care professional shall make the medical record of the visit available to the patient upon request.
- (D) A health care professional must comply with the following requirements to provide telehealth services that involve consultation with another health care professional:
- ~~(1) The referring health care professional shall obtain the informed consent of the patient before seeking the telehealth services consultation with the consulting health care professional;~~ 
- (2) The consulting health care professional must meet the licensure or certification requirements in division (C) of section 4743.09 of the Revised Code; and
- (3) The health care professionals involved in the consultation must have received and reviewed all medical records of the patient relevant to the medical condition which is the subject of the consultation before the consultation occurs.
- (E) While providing telehealth services, a health care professional that is a physician or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority shall comply with the following requirements regarding prescription drugs:
- (1) the physician or physician assistant may only prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is not a controlled substance to a patient through the provision of telehealth services by complying with all requirements of this rule;

(2) the physician or physician assistant may only prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug to a patient that is a controlled substance through the provision of telehealth services by complying with the following requirements:

(a) federal law governing prescription drugs that are controlled substances;

(b) the requirements of this rule; and

(c) the requirements in rule 4731-11-09 of the Administrative Code.

(F) A health care professional that is a physician or physician assistant may provide the following additional telehealth services:

(1) A physician or physician assistant may provide telehealth services to a patient outside of this state if the physician or physician assistant confirms and documents in the medical record both of the following:

(a) the location of the patient; and

(b) that the laws of the state in which the patient is located permit the physician or physician assistant to provide telehealth services in that state.

(2) A physician or physician assistant may provide telehealth services through the use of remote monitoring devices provided that:

(a) the patient gives informed consent to the use of remote monitoring devices;

(b) the medical devices that enable remote monitoring have been cleared or approved by the United States food and drug administration for the specific purpose for which the physician or physician assistant are using it for the patient, and the remote monitoring devices otherwise comply with all federal requirements.

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

(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; or

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

(2) For a physician assistant:

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

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

(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.

(3) For a dietitian:

(a) "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 or the rules adopted by the board," as that clause is used in division (A)(1) of section 4759.07 of the Revised Code; or

(b) "A departure from, or 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 (A)(11) of section 4759.07 of the Revised Code.

(4) For a respiratory care professional:

(a) "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 or the rules adopted by the board," as that clause is used in division (A)(7) of section 4761.09 of the Revised Code; or

(b) "A departure from, or 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 (A)(10) of section 4761.09 of the Revised Code.

(5) For a genetic counselor:

(a) "Failure to comply with the requirements of this chapter, Chapter 4731. of the Revised Code, or any rules adopted by the board." as that clause is used in division (B)(2) of section 4778.14 of the Revised Code;

(b) "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 4778.14 of the Revised Code; or

(c) "A departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances whether or not actual injury to the patient is established," as that clause is used in division (B)(4) of section 4778.14 of the Revised Code.



January 26, 2022

Stephanie Loucka, Executive Director
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Re: Proposed Rule 4731-37-01; Telehealth

Dear Ms. Loucka:

Teladoc Health appreciates the opportunity to comment on the Ohio State Medical Board's proposed rules relating to telehealth. Telehealth is dynamic and evolving. Teladoc Health respects the role of the Board in considering the appropriate rules and clinical practice guidelines that are designed to be protective of public health and maintain high-quality care for patients while permissive of new technological innovations. Teladoc Health has been an active participant over the last eight years to work in a collaborative manner with the Board to ensure that perspectives other than traditional bricks-and-mortar practices are heard. Our mission is built on a simple but revolutionary idea: that everyone should have access to the best healthcare, anywhere in the world on their terms.

Teladoc Health is the world's largest telehealth company and has more than 2,400 employees, delivers health care in 175 countries and in more than 40 languages, and partners with employers, hospitals, health systems, and more than 50 health insurance plans in all 50 states, including in Ohio, to transform health care delivery. Teladoc Health provides health care services to more than 40 percent of Fortune 500 employers, as well as thousands of small businesses, labor unions and public-sector employers, which offer our virtual care services to their employees.

For context, Teladoc Health is offered as a benefit by over 9,500 Ohio employers covering over 1.8 million patients in the state. Some of these employers include: Ohio State University, Marathon Petroleum, Honda Motor Company, Kraft Heinz Company, Macy's, Procter & Gamble, and Owens Corning. Teladoc also contracts with Aetna, Molina Healthcare, and Northern Buckeye Health Plan to provide virtual care services for their commercial health plans.

While Teladoc Health appreciates the Board's efforts to protect patient safety and ensure high-quality care, we are concerned that the proposed telehealth rule would threaten access to health care via telehealth by limiting the viable options available for patients to seek care. As drafted, Proposed Rule 4731-37-01 (B)(4) states:

If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall do all of the following:

(a) The health care professional shall immediately schedule the patient for an in-person visit with the health care professional and promptly conduct that visit or refer the patient for an in-person visit with one of the following licensed health care professionals who can provide the services in-person that are appropriate for the patient and the condition for which the patient presents:

(i) another health care professional with whom the health care professional has a cross-coverage agreement,

(ii) in the case of a physician, a physician assistant with whom the physician has a supervision agreement or a certified nurse practitioner with whom the physician has a standard care arrangement; or

(iii) in the case of a physician assistant, a physician with whom the physician assistant has a supervision agreement.

(b) The health care professional shall document the in-person visit or the referral in the patient's medical record.

Teladoc Health agrees with the Board that the standard of care should be the criteria by which a physician determines the appropriateness of a telehealth visit. However, the additional requirements in subsections (a) and (b) of this proposed rule would effectively obstruct telehealth platforms from offering their services to patients in the state. Not only are these requirements clinically unnecessary, they also provide no added protection to the patient since telehealth platforms such as Teladoc Health and others already have protocols in place to ensure a patient can access the appropriate care should a telehealth visit be deemed unsuitable according to the standard of care. While the rule may appear as a sufficient safeguard for patients on paper, in practice this rule would mean that Ohio patients would have fewer telehealth providers available to them. This in turn would critically impact their ability to obtain high-quality health care where and when they need it.

As the Board contemplates good public policy that ensures patient safety as well as expanded access to health care, it is important to implement language that accommodates all forms and modalities of care and not serve to protect the business interests of Ohio bricks-and-mortar practices. Telehealth is dynamic and evolving, and – if permitted – has the ability to improve patient lives and health outcomes. Telehealth should not be restricted to a certain type of health care entity, especially when there is no clinical basis or added patient benefit.

Thank you again for the opportunity to provide comments on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read 'CDT', followed by a long horizontal line extending to the right.

Claudia Duck Tucker
Teladoc Health
Senior Vice President, Government Affairs and Public Policy

From: [Reardon, Jill](#)
To: [Loucka, Stephanie](#); [Anderson, Kimberly](#); [Smith, Nathan](#)
Subject: FW: Dr. Levy's Comments re: telemed rules
Date: Friday, January 28, 2022 4:30:10 PM

fyi

From: Jennifer Hayhurst <jhayhurst@osma.org>
Sent: Friday, January 28, 2022 12:44 PM
To: Reardon, Jill <Jill.Reardon@med.ohio.gov>
Subject: Dr. Levy's Comments re: telemed rules

Hi Jill. Me again! Dr. Alan Levy was nice enough to put his comments in writing:

Thank you for including me in this conversation. I found it a productive meeting. to summarize my comments:

1. B (4) on page 2 - I would suggest another subparagraph (iv) to read "another health care professional, or medical institution, capable of conducting an in-person visit appropriate for the diagnosis and treatment of the patient's medical condition".
2. C (1) on page 3 - I'm not sure that communicating licensure information is usually done (especially when the patient initiates contact with a particular physician). I suppose this may be warranted if the patient contacts a tele-health service provider who then connects the patient with a physician unknown to the patient. (I didn't comment on this on the call)
3. C (4) on page 3 - Begin the sentence with "If applicable" (deleting "if applicable" from line 3)
4. D (3) on page 4 - Begin the sentence with "If possible"
5. F (1) on page 5(b) - I don't believe it's necessary for the Ohio Medical Board to establish the standard of care for an Ohio Provider who is providing services to a patient in another state. that clause should be something that state identifies in THEIR standard of care
6. I have no problems with the prescribing portion of the document. I'm happy that mental health diagnosis and treatment was included as an exclusion to the in-person requirement for Schedule II treatment

Hope this helps!

Jenn

Jennifer Hayhurst

Director, Regulatory Affairs
Ohio State Medical Association
5115 Parkcenter Ave. Ste.200
Dublin, OH 43017
OSMA Office (800) 766-6762, (614) 527-6762

Cell Phone (614) 282-7926

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February 2, 2022

Ms. Stephanie Loucka
Executive Director, State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

RE: ATA ACTION COMMENTS ON PROPOSED TELEHEALTH RULES

Dear Ms. Loucka:

On behalf of ATA Action, I am writing to express our concerns about language in proposed new rule 4731-37-01 regarding telehealth and amendments to rule 4731-11-09 regarding controlled substance and telehealth prescribing.

ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, advances policy to ensure all individuals have permanent access to telehealth services across the care continuum. ATA Action supports the enactment of state and federal telehealth coverage and fair payment policies to secure telehealth access for all Americans, including those in rural and underserved communities. ATA Action recognizes that telehealth and virtual care have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

Our organization appreciates the Medical Board's attention to advancing thoughtful telehealth policy. We believe that many provisions in the proposed rules are improvements upon the state's current regulatory framework for telehealth. We were encouraged to see the revised rules on January 24th and want to thank the Board for discussing them with us and other stakeholders on the 27th. However, we still have three concerns with the Board's proposed rules, which we believe will significantly limit access to telehealth services in Ohio.

1) Definition of Asynchronous Communication Technology

Our first issue with the proposed rules comes with the definition of asynchronous communication technology (4731-37-01(A)(3)), which ATA Action finds unnecessarily restrictive and confusing.

First, as written, the definition could be interpreted to limit the kinds of “stored clinical data” that may be transmitted via asynchronous technologies to video clips, sound/audio files, and photo images. This could unnecessarily exclude other types of clinical data – such as vital signs, lab test results, patient medical histories, and/or patient descriptions of symptoms – that are often part of asynchronous telehealth visits. Second, the definition includes a reference to

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asynchronous communication technologies in a “single media format,” whose meaning – and purpose in the definition – is unclear. The ATA recommends against using undefined terms whose meanings can change over time and which can create uncertainty for providers about the permissibility of using otherwise appropriate technologies. Instead, we suggest policymakers adopt language which reiterates that the standard of care in any given telemedicine interaction must be the same as that in an in-person interaction, which the Board policy already does.

Finally, the definition singles out particular modalities – including “text messages, such as electronic mail, without visualization of the patient – from qualifying as asynchronous care. The ATA believes licensed providers should be governed by the standard of care in determining which technologies are appropriate for rendering telemedicine services in any given situation to ensure that a wide breadth of technologies can be utilized in the delivery of virtual health care without sacrificing the quality of that care. Indeed, HB 122 sought to make the maximum choice of technology available to patients and enable licensed providers to decide which modalities are appropriate to meet the standard of care for the condition presented by the patient.

For all these reasons, ATA Action recommends the Board revise the definition of asynchronous as follows:

*Asynchronous communication technology, also called store and forward technology, means the transmission of a patient’s stored clinical data from an originating site to the site where the healthcare professional is located. The health care professional at this distant site can review the stored clinical data at a later time from when the data is sent and without the patient being present. Stored clinical data that may be transmitted via asynchronous communication technology **includes but is not limited to** video clips, sound/audio files, and photo images that may be sent along with electronic records and written records about the patient’s medical condition. ~~Asynchronous communication technology in a single media format does not include telephone calls, images transmitted via facsimile machines, and text messages, such as in electronic mail, without visualization of the patient. Photographs or video images that are visualized by a telecommunications system must be both specific to the patient’s medical condition and sufficient for furnishing or confirming a diagnosis and/or a treatment plan.~~*

2) Referral to In-Person Care

Our next concern is with proposed new rule 4731-37-01(B)(4). The language reads:

4) If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall do all of the following:

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(a) The health care professional shall immediately schedule the patient for an in-person visit with the health care professional and promptly conduct that visit or refer the patient for an in-person visit with one of the following licensed health care professionals who can provide the services in-person that are appropriate for the patient and the condition for which the patient presents:

- (i) another health care professional with whom the health care professional has a cross-coverage agreement,*
- (ii) in the case of a physician, a physician assistant with whom the physician has a supervision agreement or a certified nurse practitioner with whom the physician has a standard care arrangement; or*
- (iii) in the case of a physician assistant, a physician with whom the physician assistant has a supervision agreement.*

(b) The health care professional shall document the in-person visit or the referral in the patient's medical record.

Instead of ensuring that patients only receive care of the highest quality, this rule would have the effect of making it much more difficult for telehealth providers to operate in Ohio. As currently written, this proposed rule would mandate that in order to deliver telehealth services, an Ohio-licensed provider must have both a physical location to see a patient “immediately” if necessary and cross-coverage relationships with multiple health care professionals who could deliver requisite care in person. For example, a primary care physician who determines during a telehealth visit that a patient needs to see a specialist in person for a skin condition would be required to have a cross-coverage relationship with a dermatologist located near the patient.

This requirement is not only an impractical and burdensome barrier for telehealth providers, it holds telehealth services to a higher standard than in-person care settings. When Ohio patients go to a provider’s office in person, and the provider determines that the patient needs more specialized care, the provider is not required to “schedule” an appointment with a specialist in person or even provide the patient with a referral. Further, the proposed rule makes little clinical sense when the treating physician determines during the telehealth visit that the patient needs emergency care. What value does rescheduling an appointment with an in-person provider have to someone who needs to go to the emergency room of a hospital?

ATA Action agrees with the State Medical Board that the standard of care must be the same for all health care services – regardless of whether providers render that care in person or virtually – in the interest of patient safety. We also recognize that there are some health care services which can only be addressed properly via a face-to-face interaction between a patient and his or her provider. Accordingly, our members have protocols in place to ensure that telehealth providers who determine that telehealth technologies are not sufficient to meet the standard of care can connect patients with in-person providers.

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We recommend the Board revise 4731-37-01(B)(4) to state:

“If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or that additional in-person care is necessary, the health care professional shall provide or refer a patient to appropriate in-person health care services.”

3) Storage of Patient’s User Name

Our last issue is with 4731-37-01(C)(3). The proposed rule reads:

(3) The health care professional shall provide the telehealth services in a manner that complies with the privacy and security requirements for the patient and their protected health information required by the law of this state and federal law. Also, the health care professional shall ensure that any username or password information and any electronic communications between the health care professional and the patient are securely transmitted and stored.

This language puts the onus of ensuring the secure storage and transmission of a patient’s username and password on the provider during patient-provider communications. ATA Action believes that this responsibility should fall on the facility or health care entity, not the provider.

Thank you for your consideration. We encourage you to amend the proposed rules in the interest of expanding Ohioans’ access to high-quality, affordable health care. Please let us know how we can be helpful in your efforts to adopt common-sense telehealth policy in Ohio. If you have any questions or would like to discuss further the telehealth industry’s perspective, please contact me at kzebley@ataaction.org.

Kind regards,

A handwritten signature in black ink, appearing to read 'Kyle Zebley', is written over a light blue horizontal line.

Kyle Zebley
Executive Director
ATA Action

From: [Smith, Nathan](#)
To: [Sean McGlone](#)
Cc: [Bryn Hunt](#)
Subject: RE: [EXTERNAL] informed consent provisions in the telehealth rules
Date: Monday, February 7, 2022 11:20:00 AM
Attachments: [image001.png](#)
[image002.png](#)

Hi Sean,

Thank you for your email highlighting the issues of the discussion. We would welcome any future written comments and we look forward to working with OHA as we continue the rulemaking process for the telehealth rules.

Thanks again,

Nate

From: Sean McGlone <Sean.McGlone@ohiohospitals.org>
Sent: Thursday, February 3, 2022 12:48 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Cc: Bryn Hunt <Bryn.Hunt@ohiohospitals.org>
Subject: RE: [EXTERNAL] informed consent provisions in the telehealth rules

Hi Nate. Thanks again for the discussion Tuesday morning.

We want to reiterate our appreciation for Board staff's engagement of OHA and our members early in this rule-making process.

Since our call Tuesday we have not been able to drill down with specific language to offer you to address some of the issues we discussed Tuesday and that you heard from our members last week. However, given your timeline to get materials to your Board, we thought it might be helpful to recap some of the issues that we believe warrant some additional discussion (the list below is not exhaustive of the issues discussed):

- Various references to "informed consent" throughout the draft. We discussed this more extensively Tuesday.
- Differentiating "formal" consults from "informal" consults for purposes of understanding the scope of the subsection (D), as well as the medical record review necessary in that section.
- The limitations on who referrals can be made when a health care professional determines an in-person visit is required (subsection (B)(4)). It sounded like there are some differences in perspective on this issue, even within our membership – it seems the trick will be striking a balance between ensuring patient access to care and continuity of care. In addition, some situations may not be conducive to "immediately" scheduling, as the provider may not have control over the scheduling system.
- Whether certain non-visual interaction with the patient may be considered "asynchronous" communication.

- Whether remote monitoring should be expanded to include “therapeutic” monitoring.
- Whether FDA “approval” or “clearance” is necessary in (A)(4).
- We believe certain references to the “medical record” throughout the draft need to be narrowed to the relevant telehealth encounter instead of all medical records.

Again, we just wanted to recap some of what we heard during last week’s call and subsequent follow up.

Thanks again for your work on this important issue. We look forward to continuing to work with you and your team on these rules and would be very happy to assist with any language that meets our mutual goals.

Thanks,

Sean

From: Bryn Hunt <Bryn.Hunt@ohiohospitals.org>

Sent: Tuesday, February 1, 2022 9:42 AM

To: Sean McGlone <Sean.McGlone@ohiohospitals.org>; Nathan.Smith@med.ohio.gov

Subject: RE: [EXTERNAL] informed consent provisions in the telehealth rules

Hi Nate,

Thanks for taking the time to chat with us this morning. Below is the Medicare CoP language I referenced on our call. I’ve also included a link to the interpretive guidelines which do a good job of distinguishing between informed consent to a medical or a surgical procedure and other types of informed decisions that a patient or patient's representative may need to make regarding the patient's plan of care (see <https://www.govinfo.gov/content/pkg/CFR-2007-title42-vol4/pdf/CFR-2007-title42-vol4-sec482-13.pdf> pages 90-93).

§482.13(b)(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. Interpretive Guidelines §482.13(b)(2) The right to make informed decisions means that the patient or patient’s representative is given the information needed in order to make "informed" decisions regarding his/her care

Also, here is the link to the Ohio informed consent statute for reference - <https://codes.ohio.gov/ohio-revised-code/section-2317.54> .

Again, thanks for taking the time to discuss this important issue with us. We’ll be in touch with more feedback, but please let us know if you need anything else in the meantime.

Bryn and Sean

From: Sean McGlone <Sean.McGlone@ohiohospitals.org>

Sent: Monday, January 31, 2022 3:57 PM

To: Nathan.Smith@med.ohio.gov

Cc: Bryn Hunt <Bryn.Hunt@ohiohospitals.org>

Subject: RE: [EXTERNAL] informed consent provisions in the telehealth rules

Ok, sounds great, thanks.

From: Nathan.Smith@med.ohio.gov <Nathan.Smith@med.ohio.gov>

Sent: Monday, January 31, 2022 3:56 PM

To: Sean McGlone <Sean.McGlone@ohiohospitals.org>

Cc: Bryn Hunt <Bryn.Hunt@ohiohospitals.org>

Subject: RE: [EXTERNAL] informed consent provisions in the telehealth rules

Sean,

Thanks for getting back with me - 9am tomorrow morning will work. I will send a Teams invite to you and Bryn.

Thanks,

Nate

Nathan T. Smith
Senior Legal & Policy Counsel
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From: Sean McGlone <Sean.McGlone@ohiohospitals.org>
Sent: Monday, January 31, 2022 3:46 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Cc: Bryn Hunt <Bryn.Hunt@ohiohospitals.org>
Subject: RE: [EXTERNAL] informed consent provisions in the telehealth rules

Hi Nate. Thanks for reaching out. I'd be happy to chat with you about this. I would also like to include my colleague, Bryn Hunt, in the conversation (I have cc'd her on this email).

We are available:
Tomorrow before 10am and between 11:30am-1pm
Thursday before 10am and between 2-4pm
Friday between 11am-2pm

Do any of those windows work for you?

Thanks,

Sean

Sean McGlone | Senior Vice President and General Counsel
Sean.McGlone@ohiohospitals.org



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Mission: OHA exists to collaborate with member hospitals and health systems to ensure a healthy Ohio.

Connect with OHA:



From: Nathan.Smith@med.ohio.gov <Nathan.Smith@med.ohio.gov>
Sent: Monday, January 31, 2022 3:09 PM
To: Sean McGlone <Sean.McGlone@ohiohospitals.org>
Subject: [EXTERNAL] informed consent provisions in the telehealth rules

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Sean,

Thank you for your feedback in the telehealth stakeholder meeting on Thursday. The feedback we received from participants on the call was very helpful. You shared some comments regarding informed consent and the frequency with which informed consent needed to be obtained. I was wondering if you would be willing to discuss this issue further with me as we try to make the telehealth informed consent provisions in the draft language operational. Please let me know if you have any time in the next couple days to discuss this issue as we are trying to incorporate feedback into the draft rule for the Medical Board's review at its meeting next week. My schedule is pretty flexible and I anticipate that the call will take about 15 minutes.

Sincerely,

Nate

Nathan T. Smith
Senior Legal & Policy Counsel
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**SMBO Legislative Update:
April 2022**

Recent activity:

HB 60 – Authorize medical marijuana for autism spectrum disorder (Rep. Brent and Rep. Seitz)

Of Note:

- Allows Autism Spectrum Disorder to be included in qualifying conditions.

Status: Passed House 3/2/2022. 1st Senate Health Hearing 3/30/2022

SB 261- Changes to Medical Marijuana law (Sen. S. Huffman)

Of Note:

- Transfers portions of the Medical Marijuana Program from the Board of Pharmacy to the Department of Commerce; Expands the types of qualifying medical conditions; Adds a telehealth provision; Modifies the requirement that a CTR applicant demonstrate they don't have ownership or investment interest with an entity licensed as a dispensary; Allows the medical director of a dispensary who is a licensed CTR to recommend medical marijuana.

Status: Passed Senate 12/15/2022. 1st House Government Oversight hearing 2/17/22. 2nd Government Oversight hearing 3/16/2022. 3rd House Government Oversight hearing 3/24/2022

HB 286 – Court of Common Pleas (Rep. Bill Seitz) (companion SB 189)

To generally change the venue in which appeal from an agency order is proper to the local court of common pleas.

Of note:

- Modifies the current Administrative Procedure Act by generally providing that a party adversely affected by an order of an agency may appeal from the order to the court of common pleas of the county in which the place of business of the party is located or the county in which the party is a resident.
- Removes the current provision that any party adversely affected by an order of an agency issued pursuant to any other adjudication may appeal, with certain exceptions, to the Franklin County Court of Common Pleas.

Status: Introduced in the House 5/4/2021. Reported out of House Civil Justice 6/23/2021. Re-Referred to House Rules and Reference 3/21/22. Reported out of House Rules and Reference

3/29/2022. Passed out of the House 3/30/2022. Referred to Senate Judiciary Committee 4/6/2022

SB 189 – Change venue for appeal from an agency order (Sen. Lang and Sen. McColley) (companion SB 286)

Of Note:

- To generally change the venue in which appeal from an agency order is proper to the local court of common pleas.
- Modifies the current Administrative Procedure Act by generally providing that a party adversely affected by an order of an agency may appeal from the order to the court of common pleas of the county in which the place of business of the party is located or the county in which the party is a resident.
- Removes the current provision that any party adversely affected by an order of an agency issued pursuant to any other adjudication may appeal, with certain exceptions, to the Franklin County Court of Common Pleas.

Status: Introduced in the Senate 5/26/2021. 1st Senate Judiciary hearing 6/16/2021. 2nd Senate Judiciary Hearing 9/28/2021. 3rd Senate Judiciary hearing 10/5/2021. 4th Senate Judiciary hearing 10/26/2021. 5th Senate Judiciary hearing 3/29/2022.

HB 203 – Occupational Licenses (Rep. Powell) (companion SB 131)

To require an occupational licensing authority to issue a license or government certification to an applicant who holds a license, government certification, or private certification or has satisfactory work experience in another state under certain circumstances.

Of Note:

- Requires automatic licensure of out of state applicants that meet certain criteria.

Status: Introduced in the House 3/10/2021. 1st House State & Local Government hearing 4/21/2021. 2nd House State & Local Government hearing 5/5/2021. 3rd House State & Local Government Hearing 6/10/2021. 4th House State and Local Government hearing 10/27/2021. 5th hearing House State and Local Government 1/26/2022. Reported out of House State & Local 4/6/2022

SB 131 – Occupational Licensing (Reciprocity) (Sen. Roegner and Sen. McColley) (companion HB 203)

To require an occupational licensing authority to issue a license or government certification to an applicant who holds a license, government certification, or private certification or has satisfactory work experience in another state under certain circumstances.

Of note:

- Requires automatic licensure of out of state applicants that meet certain criteria.
- Allows for the licensing authority to take disciplinary action against an applicant, deny an application and determine fitness to practice of an applicant.

Status: Introduced in the Senate 3/16/2021. 1st Senate Workforce & Higher Education hearing 5/19/2021. 2nd Senate Workforce & Higher Education hearing 5/26/2021. 3rd Senate Workforce & Higher Education hearing 3/22/2022

Actively Monitoring

HB 196 – Surgical Assistants (Rep. Kelly and Rep. Carruthers)

To Regulate the practice of surgical assistants.

Of Note:

- Creates a new license type for surgical assistants to be overseen by the Medical Board.

Status: Introduced in the House 3/9/2021. 1st House Health hearing 4/20/2021. 2nd House Health hearing 5/11/2021. 3rd House Health hearing 12/7/21. 4th House Health hearing 2/15/2022. 5th House Health hearing 3/1/2022 *Approved sub bill. OHA opposing

HB 318 – Anesthesiologist Assistants (Rep. Swearingen and Rep. Plummer)

To revise the law governing the practice of anesthesiologist assistants.

Of Note:

- Adds anesthesiologist assistants to the list of individuals authorized to prescribe drugs or dangerous drugs or drug therapy related devices during professional practice.
- Adds anesthesiologist assistant list of practitioners from which a respiratory care therapist may receive orders or prescriptions.

Status: First House Health Hearing 10/12/2021. Second House Health Hearing 2/8/2022. Third House Health Hearing 3/1/2022 *Approved sub bill

HB 509 – Revise and streamline occupational regulations (Rep. John and Rep. Fowler Arthur)

Of Note:

- Requires each occupational licensing board to prepare a report including fee structure for each license issued by the board, whether the fee structure can competitively align with neighboring states, whether the fee structure is a financial barrier for license holders.
- Requires the report be submitted to the Senate President, Speaker of the House and chairpersons of committees responsible for reviewing occupational licensing boards

Status: Passed out of the House 3/23/2022. Referred to Senate Workforce & Higher Education 3/29/2022

HB 81 – Massage Therapy (Rep. Plummer and Rep. Manchester) (companion bill SB 55)

To make changes to the laws governing massage establishments and massage therapy.

Of note:

- Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.

Status: Introduced in the House 2/9/2021. Passed out of the House 6/24/2021. Assigned to Senate Health 9/8/2021

SB 55 – Massage Therapy (Sen. Brenner) (companion bill HB 81)

To make changes to the laws governing massage establishments and massage therapy.

Of Note:

- Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.

Status: Introduced in Senate 2/9/2021. 1st Senate Health hearing 2/24/2021. 2nd Senate Health hearing 3/3/2021. 3rd Senate Health hearing 3/10/2021. 4th Senate Health hearing 3/17/2021. 5th Senate Health hearing 5/19/2021. Passed out of Senate Health Committee 5/19/2021.

HB 356 – Drugs (Rep. Loychik and Rep. Bird)

Regarding drug offenses and treatment.

Of Note:

- Proposes to reduce the abuse of prescription opioids, establish addiction treatment facilities, increase penalties for drug trafficking violations, modify penalties for drug possession, require an offender convicted of a drug possession or drug trafficking offense involving certain drugs to be subject to ten years of post-release control, allow a criminal defendant who has a severe substance use disorder involving certain drugs to be confined by a state detoxification provider while awaiting trial, create restitution work programs, and make an appropriation.
- Limits opioid prescriptions for acute pain to three days. Then, re-examination of the patient is required, and the prescriber may issue a new prescription for more than 3 days.
- Allows health related licensing board to adopt rules specifying circumstances under which a prescriber may issue an initial prescription for an opioid to treat acute pain in an amount that exceeds three days.

Status: Introduced in the House 6/21/2021. 1st House Criminal Justice hearing 11/10/2021. 2nd House Criminal Justice hearing 3/24/2022. 3rd House Criminal Justice hearing 4/6/2022

HB 476 – Create Parkinson’s disease registry; change awareness month (Rep. Bird and Rep. Lightbody)

Establish a Parkinson’s disease registry and to change the observance of “Parkinson’s Disease Awareness Month” from September to April

Of Note:

- Requires that each individual case of Parkinson’s disease be reported to the registry by the physician, physician assistant, group practice, hospital or health care facility that employs the professional who diagnosed or treated the patients Parkinson’s disease
- A health care provider may be disciplined by the provider’s licensing board for failure to comply with the bill’s reporting requirements

Status: Introduced in the House 11/1/2021. Referred to House Health 11/2/2021. 1st House Health hearing 1/25/2022. 2nd House Health hearing 2/8/2022. 3rd House Health hearing 3/29/2022. Reported out of House Health 3/29/2022. Passed out of the House 4/6/2022

SB 296 – Narcotics (Sen. Manning and Sen. S. Huffman)

Regards access to naloxone and certain narcotics testing products

Of Note:

- Adds physician assistants and advanced practice registered nurses to those who may authorize a pharmacist or pharmacy intern to dispense naloxone without a prescription.

Status: Introduced in the Senate 2/15/2022. 1st Senate Health hearing 3/16/2022. 2nd Senate Health hearing 3/23/22. 3rd Senate Health hearing 3/30/2022. 4th Senate Health hearing 4/6/2022

HB 193 – Electronic Prescriptions (Rep. Cutrona and Rep. Pavliga)

Regarding electronic prescriptions and schedule II-controlled substances.

Of Note:

- Requires that all schedule II drugs be prescribed electronically.

Status: Passed out of the House 6/23/2021. 1st Senate Health hearing 10/20/2021. 2nd Senate Health hearing 11/17/21. 3rd Senate Health hearing 1/26/2022

SB 311 – Coroners and Death Certificates (Sen. S. Huffman and Sen. Johnson)

Revise the law governing coroners and death certificates

Of Note:

- Requires that collaboration agreements between APRN's and collaborating physicians, and supervision agreements between physician assistants and supervising physicians, contain an agreement that the physician must complete and sign the medical certificate of death, regardless of coroner jurisdiction

Status: Introduced in the Senate 3/10/2022. 1st Senate Health hearing 3/30/2022. 2nd Senate Health hearing 4/6/2022

HB 64 – Regards fraudulent assisted reproduction (Rep. Powell)

To create the crime of fraudulent assisted reproduction and civil actions for an assisted reproduction procedure without consent.

Of Note:

- Prohibits a health care professional from purposely or knowingly using human reproductive material from a donor while performing an assisted reproduction procedure if the person receiving the procedure has not expressly consented to the use of that donor's material.

- Creates the crime of fraudulent assisted reproduction, making it a third-degree felony and allows for civil action against a fertility doctor within ten years of the offense.

Status: Introduced in the House 2/4/2021. 1st House Criminal Justice hearing 2/25/2021. 2nd House Criminal Justice hearing 3/17/2021. 3rd House Criminal Justice hearing 3/3/2022. 4th House Criminal Justice hearing 4/6/2022. Reported out of House Criminal Justice 4/6/2022

HB 451- Physician administered drugs (Rep. Manning, Rep. Oelslager)

To amend the law related to physician-administered drugs

Of Note:

- Prohibits a health benefit plan from requiring that physician-administered drugs be dispensed by a pharmacy, limiting coverage when such drugs are not dispensed by a pharmacy or affiliated pharmacy, or covering such drugs with higher cost-sharing if dispensed in a setting other than a pharmacy

Status: 1st House Insurance hearing 1/26/22. 2nd House Insurance hearing 2/9/2022. 3rd House Insurance hearing 3/23/2022.

HB 50 – Medical Devices (Rep. Miranda)

Enact Paige's Law re: medical identifying devices

Of Note:

- Modifies the law governing the use of medical identifying devices, including by recognizing devices containing bar or quick response codes that may be scanned to obtain medical information in an emergency

Status: Introduced in the House 2/4/2021. 1st House Health hearing 1/25/2022. 2nd House Health hearing 2/15/2022

HB 378 – Abortion Reversal (Rep. Koehler and Rep. Fowler Arthur)

Regarding pretreatment notice about the possibility of reversing a mifepristone abortion.

Of Note:

- Prohibits a physician from performing a mifepristone abortion without both informing the patient of the possibility to reverse the mifepristone abortion if she changes her mind and providing information from the Department of Health website on assistance with reversing the effects of the of the mifepristone abortion
- Criminalizes violations of the previous requirements as a misdemeanor of the first degree.
- Allows a patient who a mifepristone abortion is performed on to file a wrongful death suit against an individual who fails to inform the patient of the possibility of reversal.

Status: Introduced in the House 7/15/2021. Referred to House Health 9/16/2021. 1st House Health hearing 2/15/2022. 2nd House Health hearing 3/8/2022. 3rd House Health hearing 3/22/2022

Closely monitoring

HB 41– Exempt mental health care providers' info from Public Records Law (Rep. Lanese and Rep. Liston)

To exempt certain mental health care providers' residential and familial information from disclosure under the Public Records Law.

Of Note:

- Adds forensic mental health providers, mental health evaluation providers, and regional psychiatric hospital employees to the list of professions, consolidated in continuing law into the term “designated public service worker,” whose residential and familial information is exempted from disclosure under the Public Records Law.

Status: Passed out the House 2/4/2021. 1st Senate Health hearing 3/24/2021. 2nd Senate Health hearing 10/6/2021

HB 435 – Vaccinations (Rep. Carfagna and Rep. Seitz)

To extend certain timelines for qualified civil immunity and expand immunity to include hearing aid dealers and hearing aid fitters; to authorize emergency medical technicians to administer COVID-19 tests; to expressly cover COVID-19 vaccine injuries under the workers' compensation system.

Of Note:

- Sunsets June 30, 2023
- Provides vaccine mandate exemption for vaccines that have not received an FDA biologics license.
- Most public and private sector would be able to receive exemptions:
 - a) Medical contraindications; - shall provide a written statement from primary care provider
 - b) Natural immunity: - responsible for any costs or fees associated with demonstrating natural immunity to the employer.
 - c) Reasons of conscience, including religious convictions. -shall provide a written statement

Status: Introduced in the House 9/28/2021. Reported 9/29/2021. Re-referred to House Rules and Reference 9/29/2021.

SB 150 – Physician Contracts (Sen. Johnson and Sen. Williams)

To prohibit the use of noncompete provisions in physician employment contracts.

Of Note:

- Would prohibit the use of noncompete provisions in physician employment contracts.

Status: Introduced in the Senate 3/31/2021. 1st Senate Small Business & Economic Opportunity hearing 5/5/2021. 2nd Senate Small Business & Economic Opportunity hearing 5/12/2021. 3rd Senate Small Business & Economic Opportunity hearing 10/27/21.

SB 151 – Infant Medical Treatment (Sen. Johnson)

To establish standards for the medical treatment of certain infants and to name the act Emery and Elliot's Law.

Of Note:

- Outlines medical treatment for mothers and infants in emergency situations or infants with a disability.

Status: Introduced in the Senate 3/31/2021. 1st Senate Health hearing 6/2/2021. 2nd Senate Health hearing 9/15/2021

SB 48 – Cultural Competency (Sen. Maharath and Sen. Antonio)

To require certain health care professionals to complete instruction in cultural competency.

Of Note:

- Requires certain health care professionals to complete instruction in cultural competency and provide proof of completion at initial application for licensure and at renewal.
- Includes: dentists, nurses, pharmacists, physicians, psychologists, and social workers.

Status: Introduced in the Senate 2/3/2021. 1st Senate Health hearing 6/16/2021.

HB 160 – Health Estimates (Health care price transparency) (Rep. Holmes)

Regarding the provision of health care cost estimates.

Of Note:

- Authorizes the relevant regulatory boards to impose administrative remedies on a health plan issuer or health care provider who fails to comply with the bill's health care price transparency provisions.

Status: Introduced in the House 2/18/2021. 1st House Insurance Hearing 3/10/2021.

HB 43– Authorize public bodies to meet via video- and teleconference (Rep. Sobecki and Rep. Hoops)

To authorize public bodies to meet via teleconference and video conference.

Of Note:

- Allows public bodies to meet and hold hearings via teleconference or video conference.
- Requires public bodies to provide the public with access to meetings and hearings commensurate with the method in which the meeting is being conducted.

Status: 1st House Government Oversight hearing 2/11/2021.

SB 123 – Abortion (Sen. Roegner and Sen. O'Brien) (companion HB 598)

To enact the Human Life Protection Act to prohibit abortions based upon a condition precedent.

Of Note:

- Prohibits, as the crime of criminal abortion, a person from purposely causing or inducing an abortion by using a drug or substance or an instrument or other means.
- Provides that criminal abortion is a felony of the fourth degree.
- Provides an affirmative defense to a criminal abortion charge if the physician performed or induced the abortion, or attempted to do so, under the determination that it was necessary to prevent the woman's death or a serious risk of the substantial and irreversible impairment of a major bodily function.
- Requires the State Medical Board to revoke a physician's license to practice if the physician is guilty of abortion manslaughter, criminal abortion, or promoting abortion.

Status: Introduced in the Senate 3/9/2021. 1st Senate Health hearing 9/29/2021. 2nd Senate Health Hearing 10/27/2021.

HB 598 – Abortion (Rep. Schmidt) (companion SB 123)

To enact the Human Life Protection Act to prohibit abortions based upon a condition precedent

Of Note:

- Prohibits, as the crime of criminal abortion, a person from purposely causing or inducing an abortion by using a drug or substance or an instrument or other means.
- Provides that criminal abortion is a felony of the fourth degree.
- Provides an affirmative defense to a criminal abortion charge if the physician performed or induced the abortion, or attempted to do so, under the determination that it was necessary to prevent the woman's death or a serious risk of the substantial and irreversible impairment of a major bodily function.
- Requires the State Medical Board to revoke a physician's license to practice if the physician is guilty of abortion manslaughter, criminal abortion, or promoting abortion.

Status: Introduced in the House 3/15/2022. Referred to House Government Oversight 3/22/2022

SB 161 – Surgical Smoke (Sen. Brenner)

Regards surgical smoke.

Of Note:

- Requires that not later than one year after the effective date of enactment, each ambulatory surgical facility shall adopt and implement a policy designed to prevent human exposure to surgical smoke during any planned surgical procedure that is likely to generate surgical smoke.
- The policy shall include the use of a surgical smoke evacuation system.

Status: Introduced in the Senate 4/15/2021. 1st Senate Health hearing 9/22/2021. 2nd Senate Health hearing 11/10/2021. 3rd Senate Health hearing 3/16/2022.

SB 206 – Art & Music Therapists (Sen. Yuko and Sen. Brenner) (companion HB 359)

To license and regulate art therapists and music therapists.

Of Note:

- Creates a new license type for music therapists to be regulated under the Medical Board

Status: Introduced in the Senate 7/1/2021. Assigned to Senate Health 9/8/2021.

HB 221 – Advanced Practice Registered Nurses (Rep. Brinkman and Rep. Gross)

To modify the laws governing the practice of advanced practice registered nurses and to designate these provisions as the Better Access, Better Care Act.

Of Note:

- Would allow an APRN who has completed 2,000 clinical practice hours under a standard care arrangement the option to practice without a collaboration agreement.
- Allows an APRN who has not completed the required hours to enter into a standard care arrangement with an APRN who has completed 2,000 clinical practice hours.

Status: Introduced in the House 3/17/2021. Referred to House Health 3/23/2021.

HB 355 – Pregnancy (Rep. Boggs and Rep. Hicks-Hudson)

To authorize a pregnant minor to consent to receive health care to maintain or improve her life or the life of the unborn child she is carrying.

Of Note:

- Allows a pregnant minor to consent to receive health care, such as prenatal health care, health care during delivery, post-delivery health care, and family planning services, to maintain or improve her life or the life of the unborn child she is carrying.
- States that the bill does not remove or limit any person's responsibility under Ohio law to report child abuse or neglect.

Status: Introduced in the House 5/19/2021. Referred to House Families, Aging and Human Services 6/24/2021.

HB 359 – Art & Music Therapists (Rep. Russo and Rep. Callender) (companion SB 206)

To license and regulate art therapists and music therapists.

Of Note:

- Creates a new license type for music therapists to be regulated under the Medical Board

Status: Introduced in the House 6/24/2021. Referred to House State and Local Government 9/21/2021. Referred to House Primary & Secondary Education 6/25/2021

HB 388 – Vaccine Refusal (Rep. Jordan)

To prohibit taking certain actions against an individual because the individual refuses to be vaccinated against a disease.

Of Note:

- Prohibits certain discriminatory actions against unvaccinated people

Status: Introduced in the House 8/12/2021.

HB 402 – Ohio Midwife Practice Act (Rep. Boyd and Rep. Hicks-Hudson)

To regulate the practice of certified professional midwives and to name this act the Ohio Midwife Practice Act.

Of Note:

- Regulates the practice of certified professional midwives

Status: Introduced in the House 8/12/2021. Referred to House Families, Aging and Human Services 9/21/2021.

HB 495- Create Patient Protection Act (Representative Gross)

Of Note:

- Requires specified health care professionals (including physicians, PA's, anesthesiology assistants, limited branch licensees, acupuncturists and genetic counselors) to offer patients medical chaperones and to establish certain mandatory reporting requirements for health care professionals.
- The health care professional may refuse to conduct an exam if the patient or patient's representative declines to have a medical chaperone present during the exam

Status: Introduced in the House 11/23/2021. Referred to the House Families Aging and Human Services 12/7/2021

HB 496 – Regulate the Practice of Certified Midwives (Rep. Koehler)

To regulate the practice of certified nurse-midwives, certified midwives, and certified professional midwives

Of Note:

- Regulates the practice of certified professional midwives

Status: Introduced in the House 11/29/2021. Referred to House Families Aging and Human Services 12/7/21. 1st House Families, Aging & Human Services hearing 2/7/2022

HB 454 – Sex Alteration (Rep. Glick and Rep. Grendell)

Enact the Save Adolescents from Experimentation (SAFE) Act

Of Note:

- Bans physicians, mental health providers, or other medical health care professionals from performing gender transition procedures or referring to a medical health care professional for gender transition procedures if the individual is under 18 years old
- Any violation will be considered unprofessional conduct and subject to disciplinary action from the licensing body

Status: Introduced in the House 10/19/2021. Referred to House Families, Aging and Human Services 10/26/2021. 1st House Families, Aging and Human Services hearing 2/17/2022

Operationalizing

SB 6 – Join Interstate Medical Licensure Compact (Sen. Roegner and Sen. Steve Huffman)

Of Note:

- Actively working through implementation

Status: Passed out of the legislature 6/24/2021. Signed by Governor DeWine 7/1/2021. Required to be operational by 9/28/2022.

HB 110 – State Operating Budget (Rep. Oelslager)

Creates appropriations for FY 2022-2023.

Of Note:

- The Medical Board budget request was granted in the first version of the bill and remained in the final version.

Status: Passed out of the legislature 6/28/2021. Signed by Governor DeWine 6/30/2021. Provisions with appropriations are effective 6/30/2021. All other provisions are effective 9/30/2021.

Sub HB 51- Valuation determinations for property damage from natural events with language to reauthorize remote hearing authority for Ohio public entities. Contains emergency clause.

Of Note:

- Public bodies could choose to meet remotely through June 30 under legislation passed by the Senate on Wednesday with an emergency clause. House concurred in Senate Amendments 2/9/2022. Signed by Governor DeWine (2/17/2022). Effective date 2/17/2022

SB 9 – Regulations (Sen. McColley and Sen. Roegner)

To reduce regulatory restrictions in administrative rules.

Of Note:

- Requires certain agencies to reduce the number of regulatory restrictions in their administrative rules.

- Changes the criteria that all agencies must use when conducting a five-year review of an existing rule to match the act's criteria for elimination of regulatory restrictions

Status: Passed out of the Senate 3/10/2021. Third hearing in House Government Oversight held 10/28/2021. Passed House 3/2/2022. Senate concurred in House Amendments 3/2/2022. Signed by Governor DeWine 3/10/2022. Effective Date: 6/7/2022

Enacted but no operational changes needed

HB 6 – Modify laws governing certain professions due to COVID-19 (Rep. Roemer)

To modify the laws governing certain health professionals and educator preparation programs due to COVID-19.

Of Note:

- Allows pharmacists to administer immunization for influenza, COVID-19, and any other disease but only pursuant to prescription for persons seven or older.
- Allows pharmacists to administer immunizations for a disease to those 13 and older.
- Allows podiatrists to administer vaccinations for individuals seven and older for influenza and COVID-1.

Status: Enacted 5/14/2021. Certain provisions effective 10/9/2021.

HB 176 – Athletic Training (Rep. Carfagna and Rep. Hall)

To revise the law governing the practice of athletic training.

Of note:

- Makes changes to the law governing the practice of athletic training, including by requiring an athletic trainer to practice under a collaboration agreement with a physician or podiatrist.
- Amendment was included in the final version to prohibit an athletic trainer from administering intratendinous and intra-articular injections.

Status: Passed out of the House 5/5/2021. Passed out of the Senate 9/28/2021. Signed 10/28/2021. Effective 1/25/2022.

HB 37– Emergency Prescription Refills (Rep. Gayle Manning)

Regards emergency prescription refills.

Of Note:

- Increases from one to three the number of times that a pharmacist may dispense, without a prescription, certain drugs (dangerous drugs, other than a schedule II controlled substance) to a specific patient within a 12-month period.

Status: Passed out the House 5/5/2021. Third Senate Health hearing 10/6/2021. 1/26/22, voted out of Senate Health Committee with one technical amendment from LSC. Passed Senate 2/9/2022. House concurred in Senate Amendments 2/16/2022. Signed by Governor DeWine 3/2/2022. Effective 6/1/2022

HB 138 – Emergency Medical Services (Rep. Baldrige)

Regarding the scope of emergency medical services provided by emergency medical service personnel.

Of Note:

- Eliminates the enumeration of specific services that may be provided by emergency medical services (EMS) personnel.
- Requires the State Board of Emergency Medical, Fire, and Transportation Services to establish the scope of practice for EMS personnel through rulemaking.
- Permits EMS personnel to comply with a do-not-resuscitate order issued by a physician assistant or advanced practice registered nurse.
- Requires the medical director or cooperating physician advisory board of each EMS organization to establish protocols for EMS personnel to follow when providing services at all times.

Status: Passed out of the House 6/16/2021. 1st Senate Health hearing 9/29/2021. 2nd Senate Health hearing 10/20/2021. 3rd Senate Health hearing 2/9/2022. 4th Senate Health hearing. Reported out of Senate Health 3/2/2022. Passed out of the Senate 3/16/2022. House Concurred in Senate Amendments 3/23/2022. Waiting for Governor DeWine's signature