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**POLICY COMMITTEE MEETING**  
**June 10, 2020 via Videoconference**

<p><b>Members:</b> Amol Soin, M.D., Chair Robert Giacalone, R.Ph., J.D. Mark Bechtel, M.D. Sherry Johnson, D.O.</p> <p><b>Other Board Members present:</b> Michael Schottenstein, M.D. Kim Rothermel, M.D. Bruce Saferin, D.P.M. Michael Gonidakis, Esq. Betty Montgomery Jonathan Feibel, M.D. Harish Kakarala, M.D.</p>	<p><b>Staff:</b> Stephanie Loucka, Executive Director Kimberly Anderson, Chief Legal Counsel Nathan Smith, Senior Legal and Policy Counsel Jonithon LaCross, Legislative Liaison Benton Taylor, Board Parliamentarian</p>
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Dr. Soin called the meeting to order at 9:02 a.m.

### **Rule Spreadsheet and Schedule**

Ms. Anderson stated that the Rule Spreadsheet and Schedule has been provided to the Committee members. Ms. Anderson stated that the legal staff continues to make good progress through the rules and they continue to be a focus.

### **Legislative Update**

**House Bill 432 and Senate Bill 246:** Mr. LaCross stated that these licensure reciprocity bills have not been labeled as priorities in either house. Mr. LaCross will keep the Committee abreast of developments regarding these bills.

**House Bill 263:** Mr. LaCross stated that this bill would require the Board to create a specific list of disqualifying felony offenses; an applicant with a conviction for a felony on the list would be disqualified from licensure. Mr. LaCross contrasted this with the current practice in which the Board evaluates each applicant individually and makes a determination regarding licensure. The bill also states that any conviction that is more than five years old cannot be used for disqualification, and it removes the consideration of moral turpitude or character when making decisions for licensure.

Mr. LaCross stated that the Medical Board worked with other health care boards while this bill was in committee. At one point it had been agreed that an amendment developed by the board would be included in the bill prior to it passing committee. However, following a long delay the bill was designated a priority by the Speaker and it passed committee without amendments.

Mr. LaCross stated that the Board will continue to work on this bill and engage with the Senate when it moves to that body. Mr. LaCross stated that the boards have already been in contact with the Senate, which has indicated that the bill will not be fast-tracked.

**House Bills 641 and 650:** Mr. LaCross stated that these bills concern the treatment of specific conditions with medical marijuana; one is for autism spectrum disorder and the other is for opioid use disorder. Mr. LaCross stated that there is little push in either chamber to move these bills.

**Senate Bill 178:** Mr. LaCross stated that this bill would allow podiatrists to administer flu vaccine to patient seven years and older. This bill has been reviewed by Dr. Saferin and the Board and there does not seem to any concern about it from the medical community. The purpose of the bill is to provide greater access to the flu vaccine.

**Senate Bill 303:** Mr. LaCross stated that this bill will allow pharmacists to consult directly with physician assistants and advanced practice nurses who are prescribing to patients. The Board of Pharmacy favors this bill, as does most of the medical community.

Ms. Montgomery asked if the Board has taken a position on the pharmacy consultation bill. Mr. LaCross stated that prior to the COVID-19 pandemic there had been a plan to determine how to properly engage regarding that bill, but the Board has not taken a position at this time.

**House Bill 484:** Mr. LaCross stated this bill concerning athletic trainers was amended in the House and is unlikely to move in the Senate prior to the legislative recess. The bill requires athletic trainers to practice in collaboration agreements with physicians and podiatrists.

**House Bill 606:** Mr. LaCross stated that this bill creates a tort liability exemption for any health care practitioner who accidentally transmits COVID-19 and they cannot be held civilly liable. In response to a question from Dr. Feibel, Mr. LaCross stated that the bill will also create immunity for physicians who have been asked to perform actions outside their specialty. For example, physicians who were asked by their hospital to work in the emergency department during the emergency even though they have never practiced emergency medicine will be protected.

**Senate Bill 1:** Mr. LaCross stated that this bill would reduce regulatory restrictions for cabinet-level agencies. Which does not include the Medical Board. However, the bill also states that any Governor's Order must undergo JCARR review after 14 days, and this would affect the Board's licensees. Mr. LaCross stated that this bill is going into conference committee.

**Medical Board Stances on Pending Legislation:** Ms. Montgomery commented that there are several bills on which the Board should have an opinion, but has not taken a position on either in favor or against. Mr. Gonidakis stated that historically the Board has taken positions on many bills, but has done so less often over the last several months. Ms. Montgomery stated that when she served as a legislator, they heard from the Medical Board regularly. Ms. Montgomery stated that the Board should have a policy for weighing in on legislation so it has a voice at the appropriate time with policy-makers. Dr. Feibel agreed that the Board should have a greater presence on the bills that affect their licensees.

Dr. Soin was grateful for this feedback and stated that the Board can work on creating mechanism and methods for commenting on pending legislation that would affect the Board. Mr. LaCross also thanked the Committee and stated that he will meet with Ms. Loucka and Ms. Reardon to address these concerns further.

**House Bill 679:** Mr. LaCross stated that this telehealth services bill, which passed out of committee yesterday, will codify the ability to practitioners to use telemedicine. Other parts of the bill deal with Medicaid and maintains the facility fee for using telemedicine. The bill applies not only to physicians, but also to other practitioners such as dietitians, psychologists, clinical nurses, occupational therapists, physical therapists, and audiologists. Respiratory care professionals are not currently

included, but their association is working to change that so that they can manage things like albuterol usage via telemedicine. Initial visits to a practitioner would be allowed to occur by telemedicine if the visit meets the same standard of care as an in-person visit. If passed, the Board will be able to implement rules regarding the use of telemedicine.

Ms. Loucka noted that this bill moved very quickly through the House. Unfortunately, the Board had not been aware that the Ohio State Medical Association (OSMA) was providing testimony last week, at that testimony led to many of the sub-amendments that are detailed in the memo. The sub-bill was released yesterday, and the staff has not yet done a thorough analysis of it, though there is analysis of the bill as introduced. Ms. Loucka asked the Committee for guidance on how to proceed on this issue.

The Committee discussed this topic thoroughly. Dr. Bechtel commented that Ohio's elderly population is probably at the greatest risk for coronavirus, but many of them are not tech-savvy and may not be able to use telemedicine by way of computers and cameras. Dr. Bechtel stated that allowing use of telephone without a video component may help ensure that elderly and other vulnerable populations have access to care.

Dr. Johnson agreed with Dr. Bechtel, stating that many in southeastern Ohio have spotty internet service and telephones are the only way they have to communicate. Dr. Johnson stated that it is very important that health care practitioners continue to provide services for economically-challenges patients.

Ms. Montgomery stated that it is critical that the Board have a presence working with all allied health professionals affected by the telehealth issue. Ms. Montgomery also noted that there was some concern in the bill about a disparity between Medicaid and other telehealth services. Ms. Montgomery stated that patients not be subject to disparate treatment of a limiting of the quality of medical care simply because someone is on Medicaid. Mr. LaCross stated that the sub-bill adopted yesterday addresses many of these concerns.

Dr. Schottenstein agreed with previous comments about use of the telephone. Dr. Schottenstein stated that some psychiatric patients may be prone to anxiety about being on a video call. In general, Dr. Schottenstein did not favor restricting a doctor's ability to consult with a patient over the telephone.

Mr. Gonidakis commented that if enacted, this represents a significant policy shift for Ohio, and he expressed concern that the Board does not seem to have a seat at the table in the legislature. Ms. Loucka shared these concerns and stated that the Board will work on building on relationships in the House and staying in front of issues. Ms. Loucka agreed with Ms. Montgomery that these are unique times and things are moving quickly due to departure dates and deadlines in the legislature.

Dr. Feibel suggested that these issues may warrant a special meeting of the Committee so that it can stay on top of developments. Dr. Feibel commented that some medical specialties may be more conducive to telemedicine than others. Dr. Feibel stated that it is helpful to save a patient from having to go to a doctor's office during a pandemic, but the Board should be careful and thoughtful about making it the new standard of care. Dr. Feibel expressed concern that some will take advantage of being able to bill for a simple, short telephone call with a patient.

Dr. Soin agreed with Dr. Feibel's concerns and was opposed to telephone or email visits to physicians in certain situations. Dr. Soin stated that such provisions seem to conflict with other parts of the bill concerning facility fees and liability waivers. Dr. Soin pointed out that there are existing mechanisms within CMS and insurance payors to compensate for telephone encounters and those systems should

be left in place. Dr. Soin opined that telephone visits should be allowed only in cases in which the patient has a documented lack of video capability.

Mr. Giacalone agreed that telephone visits may make sense for the elderly population, but opined that the Board should be judicious in what it does. Mr. Giacalone noted past experiences with online prescribing and felt that the Board should not fall back into a similar situation. Mr. Giacalone felt that telephone visits would work for certain populations and certain medical specialties, but it should not be universal.

Dr. Bechtel agreed that video is the optimal means of communicating remotely and stated that telephone should only be used when use of video is documented to be impossible. Dr. Bechtel shared concerns that telephone visits could be abused and used as a way of generating income by having minimal conversations that would normally be simply part of a physician's daily work.

Ms. Loucka commented that it will be important for the Board to having rule-making authority to establish parameters for telemedicine as it relates to issues such as office-based opioids treatment, treatment for weight-loss, and recommendations for medical marijuana.

Ms. Loucka continued that the bill as introduced required a patient's initial visit to a physician to be in person and at least one in-person visit each year subsequent to that. Mr. LaCross stated that the sub-bill alters this requirement and allows the initial visit to be over the telephone so long as the visits meets the same standard of care that an in-person visit would. The sub-bill also outlines criteria that a telephone visit would have to meet.

Dr. Feibel opined that in most medical specialties, an initial visit by telephone could never meet the same standard of care of an in-person visit. Dr. Soin agreed, stating that the initial visit is critical not only for the physical examination but also for establishing a strong physician/patient relationship.

Ms. Loucka suggested that a sub-group of Board members focused on the telemedicine issue be established for the staff to work with between meetings. Dr. Soin, Mr. Gonidakis, Dr. Bechtel, Ms. Montgomery, and Dr. Feibel volunteered to be on the sub-group. Ms. Anderson stated that if the sub-group meets, it may be required to be a public meeting with notice given to the public. Dr. Soin stated that the staff can begin with individual consultations and then have a public meeting if that is deemed necessary.

**House Bill 45:** Mr. LaCross stated that there was some concern with this bill regarding the scope and registration of surgical technicians. The associations and hospitals are in favor of full licensure for surgical technicians rather than registration. This would allow the Board to properly regulate surgical technicians as it does all its licensees. Dr. Feibel stated that the Board should examine the merits of registration and whether there needs to be separate licensure.

**House Bill 492:** Dr. Schottenstein asked if there has been any movement on this bill concerning physician assistants. Dr. Schottenstein expressed concern that the bill waters down qualifications for physician assistants while simultaneously increasing their level of responsibility. Mr. LaCross stated that there is no intention in the legislature to move this bill at this time.

### **Rules for Initial Circulation**

Ms. Anderson asked that the proposed hearing rules in Chapter 4731-13 be withdrawn from the Common Sense Initiative (CSI) so that it can be amended to address some concerns and refiled. Ms.

Anderson also asked that the exposure prone invasive procedures be circulated to interested parties for review.

**Dr. Bechtel moved to withdraw Rule 4731-13-13 from CSI review and include it with the initial circulation of other rules from Chapter 4731-13, as amended, for initial review by interested parties; and to circulate rules from Chapter 4731-17, as amended, for initial review by interested parties. Mr. Giacalone seconded the motion. All Committee members voted aye. The motion carried.**

### Rules to File with CSI

Ms. Anderson stated that no comments were received on the personal information system rules and one comment was received on the radiologist assistant rules. Ms. Anderson believed that the statute on radiologist assistants addresses some of the informed consent issues because it requires radiologist assistants to wear a badge identifying themselves at all time and to work under the supervision of a radiologist. The Committee has also been provided with a detailed memo on the dietetics rules.

**Dr. Bechtel moved to recommend that proposed radiologist rules from Chapter 4774-1; the proposed personal information systems rules from Chapter 4731-9; and the proposed dietetics Rules 4759-4-04 and 4759-4-08 as amended, be filed with CSI. Ms. Montgomery seconded the motion. All Committee members voted aye. The motion carried.**

### CSI Updates

Mr. Smith stated that that Rule 4759-6-02 had been ready for filing with the Joint Committee on Agency Rule Review (JCARR) in Fall 2019. However, Senate Bill 221 became effective and changed the requirements for incorporation by reference, which are references to external documents. Senate Bill 221 requires such things as including the date for the version of the external document and that it be posted on the website. Some deficiencies in the Board's external references were noted in Rule 4759-6-02, so the rule's language has been amended to address that. In addition, an enforcement mechanism has been added that will make violation of the rule a violation of minimal standards of care.

Mr. Smith stated that the Dietetics Advisory Council has reviewed these amendments and recommend that the Board adopt them.

**Dr. Bechtel moved to recommend approval of proposed amended rule 4759-6-02 for refiling with CSI. Mr. Giacalone seconded the motion. All Committee members vote aye. The motion carried.**

### Death Certificate Position Statement

Ms. Anderson asked for the Committee's approval to amend the Board's death certificate position statement to update all the statute and rule references, as well as a statement specifically regarding death certificates related to COVID-19, based on guidance from the Centers for Disease Control (CDC).

**Ms. Montgomery moved to approve the updated position statement on death certificates for filing on the Board's website. Dr. Bechtel seconded the motion. All Committee members voted aye. The motion carried.**

## Weight-Loss Rules FAQ's

Ms. Anderson stated that the medication Belviq, a controlled substance for chronic weight maintenance, has been withdrawn from the market. Since Belviq is one of the two medications mentioned by name in the Board FAQ's on chronic weight loss, Ms. Anderson asked the Committee's approval to amend the FAQ's by removing references to Belviq.

**Bechtel moved to update the weight-loss rules FAQ's on the Board's website as discussed. Mr. Giacalone seconded the motion. All Committee members voted aye. The motion carried.**

## Microneedling

Ms. Anderson stated that she wished to introduce this topic to the Committee this month and have a more robust discussion next month. In December 2019, the Ohio State Cosmetology and Barber Board made changes in their rules for cosmetologists and aestheticians which clarified that procedures such as microneedling and cool sculpting is not permitted in their scope of practice. The Cosmetology Board did not opine on whether microneedling is a medical task which can be delegated under the Medical Board's delegation rules, or if it is a medical procedure which cannot be delegated and must be performed by a practitioner for whom it is within their scope of practice.

Ms. Anderson spoke about this matter with Dr. Bechtel, and his initial opinion was that microneedling is a medical procedure and not a medical task because there is risk of harm to patients. The Board's legal staff is currently researching how other states have addressed this issue. So far the consensus seems to be that other states consider microneedling to be a medical procedure, but it appears that other state medical boards have not weighed in on the issue. Ms. Anderson stated that the legal staff will continue researching and getting information from practitioners.

Dr. Bechtel stated that microneedling involves a platelet-rich infusion in which blood is drawn from the patient, spun in a centrifuge, and then injected into an area such as acne, scars, or under the scalp. This procedure involves a risk of bleeding and there has been reports of nerve damage. Dr. Bechtel noted a recent incident in New Mexico in which blood was mixed up and patients were potentially exposed to blood-borne pathogens. This incident illustrates the risks that are involved with microneedling. Dr. Bechtel was concerned about delegating this procedure to an unlicensed person. In response to a question from Dr. Kakarala, Ms. Anderson stated that cool sculpting is also outside the scope of practice of a cosmetologist or anesthetist.

Ms. Anderson stated that this topic will be brought back to the Policy Committee for discussion at a future meeting.

## Adjourn

**Dr. Bechtel moved to adjourn the meeting. Ms. Montgomery seconded the motion. All Committee members voted aye. The motion carried.**

The meeting adjourned at 10:08 a.m.

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**MEMORANDUM**

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Update

DATE: June 29, 2020

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Attached are the updated rule schedule and rule spreadsheet. Please note that several rules were filed with JCARR and the public hearing is scheduled for July 23, 2020.

**Action Requested: No action requested**

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# Legal Dept. Rules Schedule

As of 6/22/20

## RULES AT CSI

### Comment Deadline 12/20/19

Military Rules for all license types

### Comment Deadline 2/28/20

4731-36-04

### Comment Deadline 5/27/20

4731-18 – Light Based Medical Device Rules

### Comment Deadline 6/12/20

4731-10-CME Rules

### Approved to File with CSI

4731-11-02	4731-11-03	4731-11-04
4731-11-04.1	4731-11-07	4731-11-11
4774-1-01	4759-4-04	4759-4-08
4774-1-02	4759-6-02	
4774-1-03		
4774-1-04		
4731-8-01		
4731-8-02		
4731-8-03		
4731-8-04		
4731-8-05		
4731-8-06		

## **RULES READY FOR INITIAL CIRCULATION**

Hearing rules-4731-13-01-4731-13-36  
Exposure Prone Invasive Procedures

## RULES AT JCARR

### Filed 6/19/20 – Hearing Scheduled 7/23/20

4730-1-01	4730-1-05	4730-1-06
4730-1-07	4730-1-08	4730-2-01
4730-2-04	4730-2-05	4730-2-06
4730-2-07	4730-2-10	4730-4-01
4730-4-02	4731-11-01	4731-11-14
4731-33-01	4731-33-02	4731-35-01
4731-35-02	4761-5-01	4761-5-02
4761-5-04	4761-5-06	4761-6-01
4761-7-04	4761-9-01	4761-9-04
4761-9-05	4761-9-07	4761-10-03

### **No Change Rules-Filed with JCARR**

4730-1-01	Effective 9/16/20
4730-1-05	Effective 9/17/20
4730-2-01	Effective 9/16/20
4761-5-02	Effective 9/17/20
4761-5-06	Effective 9/16/20

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	Notes
4730-1-01	Regulation of Physician Assistants - Definitions		06/12/19	07/16/19	11/07/19	06/18/20	No change rule			09/18/20	06/18/25	
4730-1-05	Quality Assurance System		06/12/19	07/16/19	11/07/19	06/19/20	No change rule			09/18/20	06/29/25	
4730-1-06	Licensure as a physician assistant	03/22/19	06/12/19	12/04/19		06/18/20	07/23/20			09/30/18	09/30/23	
4730-1-06.1	Military provisions related to certificate to practice as a physician assistant	03/22/19	06/12/19	12/04/19						09/30/15	09/30/20	
4730-1-07	Miscellaneous Provisions		06/12/19	07/16/19	11/07/19	06/18/20	07/23/20			09/30/18	09/30/23	
4730-1-08	Physician assistant delegation of medical tasks and administration of drugs		06/12/19	07/16/19	11/07/19	06/18/20	07/23/20			07/31/16	07/31/21	
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			11/30/18	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			11/30/18	11/15/23	
4730-2-06	Physician Assistant Formulary		06/12/19	07/16/19	11/07/19	06/18/20	07/23/20			06/30/14	12/27/19	extension granted from 6/30/19
4730-2-07	Standards for Prescribing		06/12/19	07/16/19	11/07/19	06/18/20	07/23/20			9/30/18	12/27/19	extension granted from 6/30/19
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			09/30/18	09/30/23	
4730-4-01	Definitions	05/09/19		11/15/19	05/20/20	06/18/20	07/23/20			04/30/19	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					
4730-4-03	Office Based Treatment for Opioid addiction									04/30/19	04/30/24	
4730-4-04	Medication assisted treatment using naltrexone									04/30/19	04/30/24	
4731-1-01	Limited Practitioners - Definition of Terms									03/30/20	03/30/25	
4731-1-02	Application of Rules Governing Limited Branches of Medicine or Surgery									07/31/19	07/31/24	
4731-1-03	General Prohibitions										08/31/23	
4731-1-04	Scope of Practice: Mechanotherapy									12/31/18	12/31/23	
4731-1-05	Scope of Practice: Massage Therapy				04/24/19	Refiled 8/20/19 4/29/19	06/05/19		10/16/19	11/05/19	11/05/24	
4731-1-06	Scope of Practice: Naprapathy									08/31/18	08/31/23	
4731-1-07	Eligibility of Electrologists Licensed by the Ohio State Board of Cosmetology to Obtain Licensure as Cosmetic Therapists Pursuant to Chapter 4731 ORC and Subsequent Limitations									12/31/18	12/31/23	

Rule Number	Rule Description	Sent for Initial Comment	Board Approval to File with CSI	CSI filing	CSI recommendation	JCARR filing	Rules Hearing	JCARR Hearing	Board Adoption	New Effective Date	Current Review Date	Notes
4731-1-08	Continuing Cosmetic Therapy Education Requirements for Registration or Reinstatement of a License to Practice Cosmetic Therapy									09/30/19	09/30/24	
4731-1-09	Cosmetic Therapy Curriculum Requirements										08/31/23	
4731-1-10	Distance Education									01/31/19	01/31/24	
4731-1-11	Application and Certification for certificate to practice cosmetic therapy									03/30/20	03/30/25	
4731-1-12	Examination									11/30/16	11/30/21	
4731-1-15	Determination of Standing of School, College or Institution									12/31/18	12/31/23	
4731-1-16	Massage Therapy curriculum rule (Five year review)									01/31/19	11/30/21	
4731-1-17	Instructional Staff									05/31/19	05/31/24	
4731-1-18	Grounds for Suspension, Revocation or Denial of Certificate of Good Standing, Hearing Rights									03/30/20	03/30/25	
4731-1-19	Probationary Status of a limited branch school									03/30/20	03/30/25	
4731-1-24	Massage Therapy Continuing Education	03/09/16		10/26/16	04/24/19	04/29/19	06/05/19			Withdrawn 8/30/19		
4731-1-25	Determination of Equiv. Military Educ. For CT/MT	03/22/19	06/12/19	12/04/19						12/31/15	12/31/20	
4731-2-01	Public Notice of Rules Procedure									12/07/17	12/07/22	
4731-4-01	Criminal Records Checks - Definitions									09/30/19	09/30/24	
4731-4-02	Criminal Records Checks									09/30/19	09/30/24	
4731-5-01	Admission to Examinations									06/09/17	06/09/22	
4731-5-02	Examination Failure; Inspection and Regrading									06/09/17	06/09/22	
4731-5-03	Conduct During Examinations									06/09/17	06/09/22	
4731-5-04	Termination of Examinations									06/09/17	06/09/22	
4731-6-01	Medical or Osteopathic Licensure: Definitions									07/31/19	07/31/24	
4731-6-02	Preliminary Education for Medical and Osteopathic Licensure									07/31/19	07/31/24	
4731-6-04	Demonstration of proficiency in spoken English									06/09/17	06/09/22	
4731-6-05	Format of Medical and Osteopathic Examination									07/31/19	07/31/24	
4731-6-14	Examination for physician licensure									07/31/19	07/31/24	
4731-6-15	Eligibility for Licensure of National Board Diplomats and Medical Council of Canada Licentiates									07/31/19	07/31/24	

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	Notes
4731-6-21	Application Procedures for Certificate Issuance; Investigation; Notice of Hearing Rights									07/31/19	07/31/24	
4731-6-22	Abandonment and Withdrawal of Medical and Osteopathic Licensure Applications									07/31/19	07/31/24	
4731-6-30	Training Certificates									07/31/19	07/31/24	
4731-6-31	Limited Preexamination Registration and Limited Certification									07/31/19	07/31/24	
4731-6-33	Special Activity Certificates									07/31/19	07/31/24	
4731-6-34	Volunteer's Certificates									07/31/19	07/31/24	
4731-6-35	Processing applications from service members, veterans, or spouses of service members or veterans.			12/04/19						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								04/21/16	04/21/21	
4731-8-02	Definitions	04/29/20								04/21/16	04/21/21	
4731-8-03	Procedures for accessing confidential personal information	04/29/20								04/21/16	04/21/21	
4731-8-04	Valid reasons for accessing confidential personal information	04/29/20								04/21/16	04/21/21	
4731-8-05	Confidentiality Statutes	04/29/20								07/31/16	07/31/21	
4731-8-06	Restricting & Logging access to confidential personal information	04/29/20								04/21/16	04/21/21	
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						02/02/18	02/02/23	
4731-10-02	Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement	10/25/19		05/26/20						05/31/18	05/31/23	
4731-10-03	CME Waiver	10/25/19		05/26/20						05/31/18	05/31/23	
4731-10-04	Continuing Medical Education Requirements for Restoration of a License	10/25/19		05/26/20						05/31/18	05/31/23	
4731-10-05	Out-of-State Licensees	10/25/19		05/26/20						05/31/18	05/31/23	
4731-10-06	Licensure After Cutoff for Preparation of Registration Notices	10/25/19		05/26/20						05/31/18	05/31/23	
4371-10-07	Internships, Residencies and Fellowships	10/25/19		05/26/20						05/31/18	05/31/23	
4371-10-08	Evidence of Continuing Medical Education	10/25/19		05/26/20						05/31/18	05/31/23	
4731-10-09	Continuing Medical Education Requirement for Mid-term Licensees	10/25/19		05/26/20						05/31/18	05/31/23	
4731-10-10	Continuing Medical Education Requirements Following License Restoration	10/25/19		05/26/20						05/31/18	05/31/23	
4731-10-11	Telemedicine Certificates	10/25/19		05/26/20						05/31/18	05/31/23	
4731-11-01	Controlled substances; General Provisions Definitions				11/14/19	06/18/20	07/23/20			12/23/18	12/07/22	

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	Notes
4731-11-02	Controlled Substances - General Provisions	07/26/19								04/30/19	12/31/20	
4731-11-03	Schedule II Controlled Substance Stimulants	07/26/19								12/31/15	12/31/20	
4731-11-04	Controlled Substances: Utilization for Weight Reduction	07/26/19								02/29/16	02/28/21	
4731-11-04.1	Controlled substances: Utilization for chronic weight management	07/26/19								12/31/15	12/31/20	
4731-11-07	Research Utilizing Controlled Substances	07/26/19								09/30/15	09/30/20	
4731-11-08	Utilizing Controlled Substances for Self and Family Members									08/17/16	08/17/21	
4731-11-09	Prescribing to persons the physician has never personally examined.									03/23/17	03/23/22	
4731-11-11	Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).	07/26/19								12/31/15	12/31/20	
4731-11-13	Prescribing of Opioid Analgesics for Acute Pain									08/31/17	08/31/22	
4731-11-14	Prescribing for subacute and chronic pain			3/21/19	11/14/19	06/18/20	07/23/20			12/23/18	12/23/23	
4731-12-01	Preliminary Education for Licensure in Podiatric Medicine and Surgery									06/30/17	06/30/22	
4731-12-02	Standing of Colleges of Podiatric Surgery and Medicine									06/30/17	06/30/22	
4731-12-03	Eligibility for the Examination in Podiatric Surgery and Medicine (see note below)									04/19/17	04/19/22	
4731-12-04	Eligibility of Licensure in Podiatric Medicine and Surgery by Endorsement from Another State									06/30/17	06/30/22	
4731-12-05	Application Procedures for Licensure in Podiatric Medicine and Surgery, Investigation, Notice of Hearing Rights.									06/30/17	06/30/22	
4731-12-06	Visiting Podiatric Faculty Certificates									06/30/17	06/30/22	
4731-12-07	Podiatric Training Certificates									06/30/17	06/30/22	
4731-13-01	Conduct of Hearings - Representative; Appearances									07/31/16	07/31/21	
4731-13-02	Filing Request for Hearing									07/31/16	07/31/21	
4731-13-03	Authority and Duties of Hearing Examiners									09/30/18	07/31/21	
4731-13-04	Consolidation										04/21/21	
4731-13-05	Intervention										04/21/21	
4731-13-06	Continuance of Hearing									09/30/16	09/30/21	
4731-13-07	Motions									09/30/18	04/21/21	
4731-13-07.1	Form and page limitations for briefs and memoranda									09/30/18	09/30/23	
4731-13-08	Filing									07/31/16	07/31/21	
4731-13-09	Service									07/31/16	07/31/21	
4731-13-10	Computation and Extension of Time									07/31/16	07/31/21	

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	Notes
4731-13-11	Notice of Hearings									07/31/16	07/31/21	
4731-13-12	Transcripts									07/31/16	07/31/21	
4731-13-13	Subpoenas for Purposes of Hearing	05/09/19	06/12/19							07/31/16	07/31/21	
4731-13-14	Mileage Reimbursement and Witness Fees										04/21/21	
4731-13-15	Reports and Recommendations									07/31/16	07/31/21	
4731-13-16	Reinstatement or Restoration of Certificate									07/31/16	07/31/21	
4731-13-17	Settlements, Dismissals, and Voluntary Surrenders									04/21/16	04/21/21	
4731-13-18	Exchange of Documents and Witness Lists									07/31/16	07/31/21	
4731-13-20	Depositions in Lieu of Live Testimony and Transcripts in place of Prior Testimony									07/31/16	07/31/21	
4731-13-20.1	Electronic Testimony									07/31/16	07/31/21	
4731-13-21	Prior Action by the State Medical Board									04/21/16	04/21/21	
4731-13-22	Stipulation of Facts									04/21/16	04/21/21	
4731-13-23	Witnesses									09/14/16	09/30/21	
4731-13-24	Conviction of a Crime									04/21/16	04/21/21	
4731-13-25	Evidence									07/31/16	07/31/21	
4731-13-26	Broadcasting and Photographing Administrative Hearings									04/21/16	04/21/21	
4731-13-27	Sexual Misconduct Evidence									04/21/16	04/21/21	
4731-13-28	Supervision of Hearing Examiners									04/21/16	04/21/21	
4731-13-30	Prehearing Conference									04/21/16	04/21/21	
4731-13-31	Transcripts of Prior Testimony									04/21/16	04/21/21	
4731-13-32	Prior Statements of the Respondent									04/21/16	04/21/21	
4731-13-33	Physician's Desk Physician									04/21/16	04/21/21	
4731-13-34	Ex Parte Communication									07/31/16	07/31/21	
4731-13-35	Severability									04/21/16	04/21/21	
4731-13-36	Disciplinary Actions									07/31/16	07/31/21	
4731-14-01	Pronouncement of Death									06/30/16	06/30/21	
4731-15-01	Licensee Reporting Requirement; Exceptions									11/17/17	11/17/22	
4731-15-02	Healthcare Facility Reporting Requirement									11/17/17	11/17/22	
4731-15-03	Malpractice Reporting Requirement									11/17/17	11/17/22	
4731-15-04	Professional Society Reporting									11/17/17	11/17/22	
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									11/17/17	11/17/22	
4731-16-04	Other Violations									11/17/17	11/17/22	
4731-16-05	Examinations									11/17/17	11/17/22	
4731-16-06	Consent Agreements and Orders for Reinstatement of Impaired Practitioners									11/17/17	11/17/22	
4731-16-07	Treatment Provider Program Obligations									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	Notes
4731-16-08	Criteria for Approval									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	
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									12/31/16	12/31/21	
4731-17-02	Universal Precautions									11/30/16	11/30/21	
4731-17-03	Hand Washing										08/17/21	
4731-17-04	Disinfection and Sterilization									12/31/16	12/31/21	
4731-17-05	Handling and Disposal of Sharps and Wastes										08/17/21	
4731-17-06	Barrier Techniques										08/17/21	
4731-17-07	Violations									11/09/16	11/30/21	
4731-18-01	Definitions	01/10/18	01/20/20	05/12/20								Chapter 18 rules were
4731-18-02	Use of Light Based Medical Devices	01/10/18	01/20/20	05/12/20						05/31/02	06/30/05	reviewed by CSI for
4731-18-03	Delegation of the Use of Light Based Medical Devices	01/10/18	01/20/20	05/12/20						06/30/00	06/30/05	anti-trust. Determination
4731-18-04	Delegation of phototherapy and photodynamic therapy	01/10/18	01/20/20	05/12/20						05/31/02	05/31/07	rec'd 12/219
4731-20-01	Surgery Privileges of Podiatrist - Definition of Foot									05/31/18	05/31/23	
4731-20-02	Surgery: Ankle Joint									05/31/18	05/31/23	
4731-22-01	Emeritus Registration - Definitions									08/31/17	08/31/22	
4731-22-02	Application									08/31/17	08/31/22	
4731-22-03	Status of Registrant									05/12/17	05/12/22	
4731-22-04	Continuing Education Requirements									05/12/17	05/12/22	
4731-22-06	Renewal of Cycle of Fees									05/12/17	05/12/22	
4731-22-07	Change to Active Status									08/31/17	08/31/22	
4731-22-08	Cancellation of or Refusal to Issue an Emeritus Registration									05/12/17	05/12/22	
4731-23-01	Delegation of Medical Tasks - Definitions									11/30/16	11/30/21	
4731-23-02	Delegation of Medical Tasks									11/30/16	11/30/21	
4731-23-03	Delegation of Medical Tasks: Prohibitions									08/17/16	08/17/21	

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	Notes
4731-23-04	Violations									08/17/16	08/17/21	
4731-24-01	Anesthesiologist Assistants - Definitions									07/31/19	07/31/24	
4731-24-02	Anesthesiologist Assistants; Supervision									07/31/19	07/31/24	
4731-24-03	Anesthesiologist Assistants; Enhanced Supervision									07/31/19	07/31/24	
4731-24-05	Military Provisions Related to Certificate to Practice as an Anesthesiologist Assistant			12/04/19						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	
4731-25-07	Accreditation of Office Settings									05/31/18	05/31/23	
4731-25-08	Standards for Surgery									09/30/19	09/30/24	
4731-26-01	Sexual Misconduct - Definitions									06/30/16	06/30/21	
4731-26-02	Prohibitions									06/14/16	06/14/21	
4731-26-03	Violations; Miscellaneous									06/30/16	06/30/21	
4731-27-01	Definitions									02/04/19	02/02/24	
4731-27-02	Dismissing a patient from the medical practice									05/31/19	05/31/24	
4731-27-03	Notice of termination of physician employment or physician leaving a practice, selling a practice, or retiring from the practice of medicine									05/31/19	05/31/24	
4731-28-01	Mental or Physical Impairment									08/31/17	08/31/22	
4731-28-02	Eligibility for confidential monitoring program									08/31/18	08/31/23	
4731-28-03	Participation in the confidential monitoring program									08/31/18	08/31/23	
4731-28-04	Disqualification from continued participation in the confidential monitoring program									08/31/18	08/31/23	
4731-28-05	Termination of the participation agreement for the confidential monitoring program									08/31/18	08/31/23	
4731-29-01	Standards and procedures for operation of a pain management clinic.									06/30/17	06/30/22	
4731-30-01	Internal Management Definitions									09/23/18	09/23/23	
4731-30-02	Internal Management Board Metrics	07/26/19								09/23/18	09/23/23	
4731-30-03	Approval of Licensure Applications					05/07/20				10/17/19	10/17/24	
4731-31-01	Requirements for assessing and granting clearance for return to practice or competition. (concussion rule)					04/10/19	05/13/19			11/30/19	11/30/24	
4731-32-01	Definition of Terms									09/08/17	09/08/22	

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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			04/30/19	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					
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	01/18/19		03/21/19	11/14/19	06/18/20	07/23/20					
4731-35-02	Standards for managing drug therapy	01/18/19		03/21/19	11/14/19	06/18/20	07/23/20					
4731-36-01	Military provisions related to education and experience requirements for licensure	03/22/19	06/12/19	12/04/19								
4731-36-02	Military provisions related to renewal of license and continuing education	03/22/19	06/12/19	12/04/19								
4731-36-03	Processing applications from service members, veterans, or spouses of service members or veterans.	03/22/19	06/12/19	12/04/19								
4731-36-04	Temporary license for military spouse	02/11/20	02/12/20	02/14/20								
4759-2-01	Definitions	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-4-01	Applications	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-4-02	Preprofessional experience	04/19/18	07/11/18	09/25/18							08/28/24	
4759-4-03	Examination	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-4-04	Continuing Education	08/27/19								11/30/19	11/30/24	
4759-4-08	Limited permit	8/27/19 4/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-4-09	License certificates and permits	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-4-12	<i>Consideration of military experience, education, training and term of service</i>	03/22/19	06/12/19	12/04/19						11/30/19	11/30/24	
4759-4-13	<i>Temporary license for military spouse</i>	03/22/19	06/12/19	12/04/19						11/30/19	11/30/24	
4759-5-01	Supervision of persons claiming exemption									08/28/19	08/28/24	
4759-5-02	Student practice exemption	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-5-03	Plan of treatment exemption	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-5-04	Additional nutritional activities exemption										07/01/24	
4759-5-05	Distribution of literature exemption										07/01/24	
4759-5-06	Weight control program exemption										07/01/24	
4759-6-01	Standards of practice innutrition care	04/19/18	07/11/18	09/25/18						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	Notes
4759-6-02	Standards of professional performance	04/19/18	07/11/18	09/25/18							12/18/17	
4759-6-03	Interpretation of standards	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-9-01	Severability	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4759-11-01	Miscellaneous Provisions	04/19/18	07/11/18	09/25/18						11/30/19	11/30/24	
4761-2-03	Board Records									02/28/19	02/28/24	
4761-3-01	Definition of terms									02/28/19	02/28/24	
4761-4-01	Approval of educational programs									02/28/19	02/28/24	
4761-4-02	Monitoring of Ohio respiratory care educational programs									02/28/19	02/28/24	
4761-4-03	Recognition of military educational programs for active duty military members and/or military veterans			12/04/19						11/15/18	11/15/23	
4761-5-01	Waiver of licensing requirements pursuant to division (B) of section 4761.04 or the Revised Code	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20			04/24/13	04/24/18	
4761-5-02	Admission to the Ohio credentialing examination	04/23/19	06/12/19	11/06/19	01/10/20	06/19/20	No change rule			09/19/20	06/19/25	
4761-5-04	License application procedure	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20			08/12/13	08/15/18	
4761-5-06	Respiratory care practice by polysomnographic technologists	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	No change rule			09/18/20	06/18/25	
4761-6-01	Limited permit application procedure	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20			02/28/19	02/28/24	
4761-7-01	Original license or permit, identification card or electronic license verification									02/28/19	02/28/24	
4761-7-03	Scope of respiratory care defined										11/15/23	
4761-7-04	Supervision			11/06/19	01/10/20	06/18/20	07/23/20				11/15/23	
4761-7-05	Administration of medicines										11/15/23	
4761-8-01	Renewal of license or permits	03/22/19	06/12/19	12/04/19							08/15/18	
4761-9-01	Definition of respiratory care continuing education			11/06/19	01/10/20	06/18/20	07/23/20				02/28/24	
4761-9-02	General RCCE requirements and reporting mechanism	03/22/19	06/12/19	12/04/19							05/06/15	
4761-9-03	Activities which do not meet the Ohio RCCE requirements									02/28/19	02/28/24	
4761-9-04	Ohio respiratory care law and professional ethics course criteria			11/06/19	01/10/20	06/18/20	07/23/20				02/28/24	
4761-9-05	Approved sources of RCCE			11/06/19	01/10/20	06/18/20	07/23/20				02/28/24	
4761-9-07	Auditing for compliance with RCCE requirements			11/06/19	01/10/20	06/18/20	07/23/20				05/06/15	
4761-10-01	Ethical and professional conduct									02/28/19	02/28/24	
4761-10-02	Proper use of credentials										11/15/23	
4761-10-03	Providing information to the Board	04/23/19	06/12/19	11/06/19	01/10/20	06/18/20	07/23/20				05/06/15	
4761-12-01	Initial application fee			12/04/19						06/04/14	05/06/15	
4761-15-01	Miscellaneous Provisions									02/28/19	02/28/24	





**MEMORANDUM**

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Light-Based Medical Device Rules

DATE: July 2, 2020

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On May 12, 2020, the proposed amended rules regarding light-based medical devices (Rules 4731-18-01 through 4731-18-04) were filed with Common Sense Initiative and circulated to interested parties for comments. The Business Impact Analysis and the proposed rules are attached for your review. The Board received comments from fourteen different individuals and entities. A spreadsheet summary and the comments are attached for your review.

Three of the comments, including comments from the Ohio Association of Physician Assistants raise concerns that the proposed rules are too restrictive with respect to physician assistants. Concerns are also raised that the Physician Assistant Policy Committee comments have not been fully considered by the Board. The next PAPC meeting is scheduled for August 17, 2020 and these rules will be on the agenda. I will plan to bring the PAPC comments back to the Board at the September meeting.

In the meantime, I would appreciate any feedback regarding the received comments and any proposed changes for the rules.

**Action Requested: No action requested**

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**Comments - Light Based Medical Devices -4731-18**

Name	Email	Organization	Comments
Tammy Hands	<a href="mailto:janssenlasers@gmail.com">janssenlasers@gmail.com</a>	Janssen Lasers	Wants us to include non-medical trained technicians
Jason Lichten, MD	<a href="mailto:doctor@Ohioplastic.com">doctor@Ohioplastic.com</a>	Central Ohio Plastic Surgery	I just do not understand why the board does not address the use of lasers for Tattoo removal or IPL applications which are commonly delegated in other states. Also, could these applications along with hair removal and vascular be delegated to licensed aestheticians with the same training and supervision requirements?
Alex Thiersch	<a href="mailto:Alex@americanmedspa.org">Alex@americanmedspa.org</a>	American Medspa Association	(1) 4731-18-01(B) definition of phototherapy does not include red-blue LED light treatments for acne and skin redness; (2) 4731-18-01(C) definition of ablative and 4731-18-01 (D) non ablative does not account for an intra-epidermal ablative procedure which may excise a portion of the epidermis but is not expected to excise the dermo-epidermal junction; (3) The supervision and delegation requirements are unduly restrictive and do not follow common practices in other states; (4) Recommend a tiered approach where procedures are grouped by risk and chance of complication or injury; (5) Training-recommendation is to require a supervising physician to individually review the potential delegate's training, education, skill and assess competency.
Martha Hickmann, M.D.	<a href="mailto:mhickmann50@gmail.com">mhickmann50@gmail.com</a>		Opposes delegation of light based medical devices for non-ablative procedures and phototherapy and photodynamic therapy by non-physicians due to concerns about serious complications.
Eric Plinke	<a href="mailto:Eric.Plinke@dinsmore.com">Eric.Plinke@dinsmore.com</a>	Dinsmore	Provided comments dated 1.17.18. Definition of vascular laser is not clear. Are all vascular lasers light based medical devices. See 4731-18-01(J) and 4731-18-03(A).
Amanda Nelson, CT	<a href="mailto:cosmetictherapyohio@gmail.com">cosmetictherapyohio@gmail.com</a>	Cosmetic Therapy Association	Include laser hair removal as part of the scope of practice for cosmetic therapists and do not require delegation and supervision by a physician.
Mona Foad, M.D.; Jessica Watkins, PA; Megan Niese, PA; Anna Donovan, CNP		Mona Dermatology	Submitted comments in 2018; PAs should not be held to same supervisory requirements as RNs or LPNs. Change the rules to not require physician supervision pre and post evaluation for PAs; eliminate requirement for 100% onsite physician supervision for PAs so long as physician is available by phone and within a certain distance in case complications arise; expand vascular laser delegation to include other laser types for dermatologic uses, including fractionalized laser for cosmetic purposes.
Rishi Gandhi, M.D.	<a href="mailto:rishi.gandhi@gmail.com">rishi.gandhi@gmail.com</a>		Dermatologist is concerned with permitting PA, CNP, RN or medical assistant to perform nonablative laser procedures. High concern for irreversible harm to patients including ulcers, hyperpigmentation and scarring. Recommend restriction of use of lasers and light devices to board certified physicians.
Jeff Wargo, M.D.	<a href="mailto:jwarg75@gmail.com">jwarg75@gmail.com</a>		Concerned with non-physicians performing nonablative laser procedures. Same as Dr. Gandhi.
Matthew Molenda M.D.	<a href="mailto:molenda@braviaderm.com">molenda@braviaderm.com</a>	Bravia Dermatology	Dermatologist supports delegation of all nonablative lasers to PAs. Does not support delegation of ablative lasers and not supportive of expanding laser use to RNs, LPNs, or cosmetic therapists.
Frank Papay MD; Allison Vidimos, MD, Shilpi	<a href="mailto:Barnhab@ccf.org">Barnhab@ccf.org</a>	Cleveland Clinic	Concerns with delegation of non-ablative vascular device, pulsed dye laser and intense pulsed light to non-physicians. Physicians utilizing these devices undergo specialty training in dermatology. Eight hours of training is not sufficient and will result in harm to patients. Two articles are attached for review.
Elizabeth Adamson, Executive Director		OAPA	Stands by 2/1/18 comments. In addition, rules are in conflict with and overly restrictive with the intent of 4730.19(B)(1) and (2); 4730.20(A)(8) and 4730.21. Board is in violation of 4730.06 and 4730.07 regarding PAPC input. The changes in 4730 since the time these rules were originally put in place have resulted in less physician oversight than what is laid out in the rules. The rules discuss registered nurses and it is not clear if this also includes advanced practice registered nurses.
Kelly Ott-Statzer, CT			Cosmetic therapist is concerned that the rules will result in further restrictions to CT practice, which is more limited than Kentucky. CT states she did laser tattoo removal in KY. Requests to postpone any changes to this rule until occupational licensing issues are addressed in HB 452.
Antoinette Sepsi, CT	<a href="mailto:inot1980@icloud.com">inot1980@icloud.com</a>		Rule changes will be harmful to CTs. Will raise anti-trust issues. Delay rule change until occupational licensing issues are addressed in HB 452.



commit to and comply with minimum standards and requirements widely accepted as safe practices.

Your current efforts fall squarely in AmSpa's purview and address issues that AmSpa has been tackling for more than six years. No one knows more about the underlying concerns in your proposal than AmSpa. With a database and corresponding legal analysis of medical spa laws in all 50 states, connections with nearly every medical spa in the country, and relationships with industry executives and key opinion leaders throughout aesthetics, we are well positioned to assist you in leading the country in keeping this fast-growing, exciting industry safe for the public.

### **The Underlying Issue**

Before we address the specific proposals, it is important to understand the underlying problem that this industry faces. The fact is that the overwhelming number of medical spas and aesthetic clinics offer services with very few incidents, side effects or bad outcomes. This is an overwhelmingly safe industry that offers incredibly popular and manifestly safe procedures. But as the industry has grown and become lucrative, we have seen a number of unsupervised medical aesthetic centers, often run by entrepreneurs as opposed to physicians, enter the industry. Often, these businesses try to follow the rules but find it difficult to find the relevant regulations to follow. And because many of the procedures offered in aesthetics are "non-invasive" and require little downtime, some of these businesses operate with limited medical oversight, if any at all. We refer to these businesses as "rogue medical spas," and they are, unfortunately, the root of most of the problems this industry faces.

In your proposed rules, you accurately identify that laser treatments are often the primary culprit in terms of injury. Many of the problems occur because businesses do not treat laser and energy-based treatments as medical treatments. Instead, because they are easy to operate and, if performed properly, have little risk of complication, they are treated like spa services and offered without medical supervision. This is often done out of ignorance, not malice, but regardless, it is 100% the wrong approach. These are medical facilities offering medical treatment using medical devices. Accordingly, laser, light and energy-based treatments must be treated as medical procedures.

The real problem here is that rogue medical spas don't treat their services as medical treatments, but rather as a commodity to be sold in order to make a profit. These businesses therefore do not have proper delegation and supervision protocols in place. But the solution here is much more simple than many in this industry assume: We need to explicitly define, through legislation or rulemaking, that these treatments are medical in nature and must be overseen by physicians, not laypeople. Once physicians (or formally delegated mid-levels such as nurse practitioners or physician assistants) take over responsibility for these treatments, they assume responsibility for ensuring they are performed safely by trained and qualified practitioners. This is the same standard as any medical treatment—while treatments may be delegated, it is the duty of the physician to ensure all treatments meet the applicable standard of care.

## **Comments on Proposed Rules**

The proposed rules seek to provide training and supervision requirements for laser and light-based medical procedures. This is a laudable goal overall and one that we support. As written, though, the current proposal will likely not prevent the activity it seeks to stop, and will unduly burden many trained physicians and licensed professionals who are currently operating in a safe and compliant manner.

### ***Definitions***

The definitions used for many of the specific light-based procedures are too specific and leave out many common laser and light based treatments. Additionally, the specific definitions will have the effect of preventing the development and innovation of new laser or light-based treatments by Ohio physicians. As an example, section 4731-18-01 (B) defines phototherapy as one of two specific treatments, but it does not allow for the common red and blue LED light treatments often used to treat acne or reduce redness. Additionally, section 4731-18-01 (C) defines “ablative” as excising below the dermo-epidermal junction, and section (D) defines “non-ablative” as not excising below the epidermal surface of the skin. This leaves an undefined gap in the definitions for an intra-epidermal ablative procedure, which may excise a portion of the epidermis but is not expected to excise to the dermo-epidermal junction.

### ***Supervision and Delegation***

The supervision and delegation requirements are unduly restrictive and do not follow practices common in the majority of states. An appropriate patient examination is critical to ensuring the high standards necessary to the practice of medicine. However, requiring that the physician personally perform this examination greatly underutilizes Ohio’s highly trained and skilled advanced practitioners, such as physician assistants (PAs) and nurse practitioners (NPs). In most states, these advanced licensees are permitted to perform patient examinations and prescribe treatments when working in a supervisory or collaborative relationship with a physician. If the medical board were to adopt a rule allowing these types of delegations, it would free the physician to focus on more complex and taxing cases and permit the advanced licensees the ability to practice to the level of their training, education and skill, as their counterparts in other states are able to.

Similarly, the requirement for physicians to be on site to supervise is unduly restrictive to their practice and excessive in light of many of the more common low-risk laser and light procedures. For these types of procedures, it is common for the physician to provide supervision while being readily available to respond to complications, but not necessarily on the physical premises. Further, many states permit the physician to delegate the supervision of the procedure to appropriately trained PAs and NPs who are physically on site. The current proposed rule will unnecessarily use up the physician’s time and reduce the total availability of medical care in Ohio.

### ***Ablative and Non-Ablative Procedures***

In excluding trained medical assistants from performing any non-ablative light or energy-based procedures, you have identified a pressing issue that must be addressed, but unfortunately we don't believe the solution proposed targets the real problem facing the industry. The problem here is not that medical assistants or other unlicensed professionals are unable to safely administer these procedures, but rather that physicians and business owners allow these procedures without proper training, delegation and supervision procedures in place. In other words, the problems herein are not caused by treatments being performed by trained individuals under proper supervision—they are caused by treatments being performed without any supervision at all.

Indeed, nationally we have seen many of these procedures offered safely and effectively when provided by trained health professionals under the supervision of a physician trained in the procedures. Like all other medical procedures, physicians should be able to delegate these procedures to individuals who are skilled, trained and experienced in the procedure. But like other procedures, before this happens the physician must perform a sufficient exam, implement proper protocols and engage in appropriate supervision.

The solution here is to clearly state that all non-ablative laser, light and energy-based aesthetic procedures are *medical procedures*, and that the physician (or mid-level practitioner, as appropriate) must utilize the same standard of care as they would for any medical procedure. By disseminating and implementing this rule, we will place the onus on the physician to prevent these procedures from taking place in unsupervised settings by individuals not trained or qualified to perform them in the first place.

Furthermore, restricting ablative procedures only to physicians does not comport with the practice environment elsewhere in the country. In most states, physicians are permitted to exercise their professional judgment and may delegate these types of procedures to appropriately prepared PAs and NPs, provided there is onsite physician supervision.

With all dermatologic procedures, our recommendation is to adopt a tiered approach where procedures are grouped by risk and chance of complication or injury. Under this approach, only higher level and advanced licensees would be permitted to perform the riskiest procedures, and licensed practical nurses (LPNs) and unlicensed persons would only be permitted to perform the least risky.

### ***Training and Education***

Proper training and education in light and other energy-based procedures is critical to maintaining high levels of patient care. However, the proposed rules currently are unduly onerous and would make it exceedingly difficult for non-physicians to meet the requirements on an ongoing basis. Many devices are multi-mode and able to provide a number of different non-ablative treatments. Additionally, it is extremely common for practices to own multiple types of laser and light devices

from multiple manufacturers. Skills and knowledge in a certain procedure can translate across multiple similar devices, and knowledge and skill in one device can translate to its use in a number of differing procedures.

As stated above, the problem, here is not the lack of training, but rather that these procedures are sometimes performed without any physician supervision whatsoever. By requiring that a physician be involved in the process, it becomes the physician's responsibility to ensure delegates are properly trained and supervised in the procedures they are performing.

Accordingly, our recommendation is to require that the supervising physician review the prospective delegate's pertinent training, education and skill, and assess their competency. This assessment may include observing the person perform a procedure, but the frequency and requirement should be left to the physician's judgment. Training can take many forms—including classroom, hands-on and proctored demonstrations—but the specific form and sufficiency of a particular person's acquired skills should remain for the supervising physician to judge.

### **Conclusion**

AmSpa welcomes the opportunity to work all stakeholders in this process. We are glad that the State of Ohio has recognized that laser and light procedures need to be further regulated. However, we cannot support your proposed rules in their current form. We have been researching, training and educating the industry for more than six years, and we have access to advisors and professionals who have been in the space for more than 20 years. We have the respect and confidence of over half of the existing medical spas in the U.S. We believe that by working together, Ohio will be the leader on this unique, but fast-growing industry, and other states will quickly follow Ohio's guidance. We look forward to hearing from you on how we can help shape the regulations to structure a complaint medical spa industry.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Alex Thiersch', written in a cursive style.

---

Alex R. Thiersch, CEO, AmSpa

**From:** [Martha Hickmann](#)  
**To:** [Anderson, Kimberly](#)  
**Subject:** Comment on Use of Light based medical devices  
**Date:** Tuesday, May 26, 2020 8:05:17 PM

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Re: Use of light-based medical devices

Rule 4731-18-03 Delegation of the use of light-based medical devices for specified non-ablative procedures

Rule 4731-18-04 Delegation of phototherapy and photodynamic therapy

I oppose the delegation of the use of light-based medical devices for specified non-ablative procedures and the delegation of phototherapy and photodynamic therapy by personnel other than a physician. I am aware of the serious complications of these procedures as I have gone to multiple education conferences where the detrimental effects of improperly performed procedures are detailed. I would never want a procedure performed on myself or a relative unless done by a physician due to the potential of a serious adverse event.

Sincerely,

Martha Hickmann, MD, FAAD

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**From:** [Plinke, Eric](#)  
**To:** [Anderson, Kimberly](#); [CSIPublicComments](#)  
**Subject:** Comments to SMBO Light Based Rules Amendments OAC 4731-18  
**Date:** Wednesday, May 27, 2020 3:19:55 PM  
**Attachments:** [4731-18.pdf](#)

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I have reviewed the revisions to the proposed rules as provided by email dated May 13, 2020. I provided comments to the original proposed rule amendments to the Board's Light Based Rules at OAC 4731-18 dated January 17, 2018. As an attorney representing many provider types who will be subject to and required to comply with these rules, I have the following additional comment to the most recent revisions as follows:

While the addition of the definition of "vascular laser" in the revised rules at 18-01(J) is helpful, I do not know the scope of the definition as it uses broad terms not set forth elsewhere in the rule ("lasers" and "intense pulsed light apparatuses") and lacks possible qualifying language such as "means light based medical devices in the form of lasers and intense pulsed light apparatuses whose . . . ." This results in uncertainty and ambiguity as to which devices are subject to the rule and which are not. Additionally, the references to wavelengths in the last sentence to that definition also confuses the intent of the scope of term. My concern here is that I do not whether the added definition of "vascular laser" is intended to be a sub-category of the definition of "light based medical device" such that all types of "vascular lasers" must meet the technical requirements of the definition of "light based medical device" or not. If the later, then the definition of "vascular laser" greatly broadens the scope of the rule beyond the technical requirements of devices meeting the definition of "light based medical device."

If the intent is that all "vascular lasers" are "light based medical devices," I suggest making this more clear as to scope of the rules. My reading is that "vascular lasers" do not have to meet those definitions – which greatly broadens the rule. However, this conflicts with the title of 18-03 which contains the qualifier and reads "Delegation of the use of light based medical devices for specified non-ablative procedures." I believe the Rules of Construction are that words used in titles are not part of the law and, as a further example of the confusion here, the text of 18-03(A), which governs the delegation of vascular lasers for non-ablative procedures, does not use the term "light based medical device" as a qualifier to "vascular laser" in the same way that the term is used in 18-03(B) in qualifying delegation of hair removal. Given the structure of the definition of "vascular laser" and lack of qualifiers in 18-01(J) and 18-03(A), I am uncertain of the scope and intent of the rule.

Thank you for your time in reviewing this comment. Please let me know if you need anything additionally from me.

Thanks,  
Eric

The logo for Dinsmore, featuring the word "Dinsmore" in a blue, sans-serif font with a stylized blue triangle above the letter 'i'.

**Eric J. Plinke**  
Partner

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**From:** [Cosmetic Therapy Association of Ohio](#)  
**To:** [Anderson, Kimberly](#)  
**Cc:** [CSIPublicComments](#)  
**Subject:** CTAO Comments on Changes to Use of Light Based Medical Devices  
**Date:** Wednesday, May 27, 2020 1:53:48 PM  
**Attachments:** [CTAO Comments on Proposed Light Based Medical Device Procedure Rules JCARR.pdf](#)

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Hello,

Please see the attached letter providing Cosmetic Therapy Association of Ohio's stance on the proposed changes to the use of light based medical devices.

Be aware that covid-19 disease has radically changed our businesses and the way medicine is practiced. Although changes were made quickly to adjust to the social and sanitary requirements, most independently owned laser hair removal companies were negatively impacted and may take a long time to settle back into a stable economy. As we are the experts who diligently dedicate our livelihoods to providing the safest and most effective treatments, we are seeking any changes that can help in our medically licensed profession gaining autonomy in the singular task of hair removal.

Sincerely,  
Amanda Nelson, CT  
President  
The

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the Phish Alert Button if available.

\_\_\_\_\_or click

**From:** [Tammy Hands](#)  
**To:** [Rodriguez, Judith](#)  
**Subject:** Re: FW: Seeking Comments on Light Based Rules  
**Date:** Thursday, May 14, 2020 4:10:50 PM  
**Attachments:** [image001.png](#)  
[image003.png](#)  
[image004.png](#)

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Hello Judith

Thank you for the opportunity to give my input on the topic of Medical Light Based Devices.

My name is Tammy Hands, Distributor and Certified Trainer for Janssen Lasers. I have been in this Industry since 1999. My experience includes, Operating my own Laser Clinic and Beauty Spa, Hands on Treatments with Clients, Equipment Sales, providing Certified Training and Ongoing Support.

Over the past several years, I have seen many changes in this Industry. Which include:

1. The Laser Equipment is constantly being improved. The equipment is extremely user friendly in current times, compared to many years ago. Not only has the equipment become more User Friendly, but it is also much more gentle on the Clients / Patients, hence much less chance of negative side effects. Some side effects, which are rare, could be a blister or scabbing. These types of side effects could last a few days to a week. Very superficial and not long lasting.
2. User Friendly Equipment. Since the equipment has become so user friendly, the settings on the equipment are extremely easy to prepare for the treatments. Many years ago the equipment required much more attention to detail to prepare the equipment for treatments. The vast extent to set the equipment up for each Client / Patient, could result in a greater chance of error, which is very rare to happen with the modern user friendly equipment of today. Resulting in very rare negative side effects.
3. Predictable Treatments. Now that thousands of treatments have been performed over the past few decades, we have a greater understanding of the outcome and results of the equipment on our Clients / Patients. There is extensive research showing the treatments are safe, reliable, with amazing positive results.

One of the biggest issues facing the Laser and Light Based Industry in the past and present years, was whether or not the Equipment should be used by Medical or Non-Medical Persons. Allow me to say that all of Canada allows Laser and Light Based equipment to be operated by Non-Medical Trained Technicians. Many Countries in Europe

also allow Non-Medical Trained Technicians to operate and perform treatments for their Clients. All U.S States except New Jersey and Ohio also allow Non-Medical Trained Technicians to operate and perform the treatments.

The decisions to allow Non-Medical Trained Technicians to operate the Lasers and Light Based Devices, was carefully decided and agreed upon by Groups and Individuals, such as yourselves. from Medical Boards in every State of the U.S. As you can see, Ohio and New Jersey are the only 2 States that have not re-visited the Laws of Medical Device Usage and Operation since 2004. This Industry is changing very quickly and greatly improving to provide Clients / Patients with safe, reliable treatments without the negative side effects once associated with the Lasers and Light Based Equipment.

The Medical Board needs to consider whether or not these treatments should be considered Medical or Non-Medical Treatments.

Let's consider these factors:

a). Tattoo Artists have been performing Tattoo Treatments for decades. They are well trained in their Industry.

They inject, with needles, permanent ink under the layers of skin. The ink is a foreign substance to the body.

There could be a great risk for infection, the body rejecting the ink, bleeding, blisters, negative side effects, etc.

However, there is rarely any of these side effects. The tattoos are performed by Non-Medical Trained Tattoo Artists.

I'm sure you will agree, tattooing is quite invasive, yet Non-Medical.

The Equipment for Tattoo Removal Laser is a lot less invasive than actually getting a Tattoo.

The Tattoo Removal Laser

has settings for:

1. Skin Type (determines proper skin color for the treatment to protect Client's skin)
2. Low to High Energy Power Levels (helps protect the skin and tissue, by setting to lower energy)
3. Emergency Stop Button (shuts off the equipment immediately if needed to protect the Client, Operator and Equipment)
4. Speed Settings (slow to fast, so operator can go slower and more careful with Clients)

The Equipment for Hair Removal, Skin Rejuvenation, Spider Veins, Pigmentation, Acne, etc, has these same User Friendly,

Safety Settings as well. This Equipment includes: Lasers, IPL, Photo-Light, Light Based, etc.

Another example of Non-Medical Trained Technicians:

Aestheticians work in Beauty Spas. They perform many different types of Beauty Treatments, Such as:

a) Hair Removal by waxing (wax is lathered onto the skin and ripped off with cloth strips. Sometimes ripping off the actual skin)

Also bruising the skin and burns from the hot wax. Could be a very invasive treatment and performed by Non-Medical Persons.

Lasers and Light Based Devices have cool tips for comfort and help prevent the hot Laser from potentially burning the skin.

Much safer than traditional Waxing for Hair Removal.

b) Facials (hot steam blowing on the skin, Technician probing the skin, squeezing and extracting blemishes. Can cause bruising, soreness and redness from treatments.

Lasers and Light Based Devices have the cool tips to avoid any burning from the Laser. The Light penetrates the skin and destroys the bacteria, so no need for painful squeezing and extracting of the blemishes. Great for Acne Treatments.

There are so many well Trained and Certified individuals just waiting for the opportunity to offer these well needed treatments to their Clients. They are Non-Medical Trained Technicians. Most of these individuals have years of experience in their field already offering similar treatments to their Clients. The Laser and Light Based Equipment is the next step for these individuals to expand and excel in their Industry!

Ohio currently only allows Medical Professionals to operate and perform treatments with Laser and Light Based Devices. However, these treatments are not considered Medical Treatments by all other U.S States, Canada and Europe.

According to all other Medical Boards, they consider these treatments to be of a Beauty need and not necessarily a Medical need.

Of course Medical Professionals are still offering these Treatments in their Medical Facilities. There are many Clients / Patients that prefer to visit a Doctor, Dermatologist, Nurse, etc for these type of Treatments. However, the prices are much higher when performed in a Medical Facility by a Medical Professional, which limits a large portion of the population who have lower incomes.

Laser and Light Based Treatments are amazing and should not be limited to populations with higher incomes. The Non-Medical Trained Technicians can offer lower prices to their Clients. This allows people with lower incomes to enjoy such needed treatments as:

1. Tattoo Removal (unsightly tattoos, gang tattoos, prison tattoos, mistake tattoos, etc)
2. Hair Removal (unsightly hair, facial hair, excessive hair growth, etc)
3. Skin Rejuvenation (wrinkle reduction, spider vein removal, brown spot removal)
4. Acne Treatments (unsightly facial pimples, sores, blackheads, etc)

At this time, I encourage you to consider Non-Medical Trained Technicians the opportunity to expand into the Laser and Light Based Devices. As there is a large desire from the public to have their services performed outside of the Medical offices of Doctors.

Thank you for allowing my input on your proposed ruling. I am available to discuss matters in greater detail if you desire.

I can be reached at 416-435-3212.

Sincerely,  
Tammy Hands  
Janssen Lasers Distributor

On Wed, May 13, 2020 at 9:58 AM [Judith.Rodriguez@med.ohio.gov](mailto:Judith.Rodriguez@med.ohio.gov)  
<[Judith.Rodriguez@med.ohio.gov](mailto:Judith.Rodriguez@med.ohio.gov)> wrote:

**The State Medical Board of Ohio has filed proposed actions concerning rules with the Common Sense Initiative Office. The proposals are available for your comment.**

A state rule-making agency may propose to adopt a new rule, amend or rescind an existing rule, or propose to continue a rule without any changes. Executive Order 2011-01K and Sections 107.62 and 121.82, Ohio Revised Code, require state agencies to draft rules in collaboration with stakeholders, assess and justify any adverse impact on the business community, and provide an opportunity for the affected public to provide input on the proposed rules. The Business Impact Analysis for the proposed rules discusses the purpose of the rule and identifies the nature of the adverse impact on licensees. The Common Sense Initiative review must be completed before the rules can begin the formal rule-making process through the Joint Committee on Agency Rule Review.

***At this time, public comment is being sought on the proposed actions for the following rules. The rule number is a link to the rule and the Business Impact Analysis filed with the Common Sense Initiative.***

Rule 4731-18-01      Definitions

Rule 4731-18-02      Use of light based medical devices

Rule 4731-18-03      Delegation of the use of light based medical  
devices for specified non-ablative procedures

Rule 4731-18-04      Delegation of phototherapy and photodynamic  
therapy

**Comments on the proposed rules must be received no later than May 27,**

**2020** Please provide comments to both of the following:

**Medical Board** at: [Kimberly.Anderson@med.ohio.gov](mailto:Kimberly.Anderson@med.ohio.gov)

AND

**Common Sense Initiative Office** at:  
[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

Judy Rodriguez

Public Services Manager

State Medical Board of Ohio

30 East Broad Street, 3rd Floor

Columbus, Ohio 43215

o: 614-466-4999

w: [med.ohio.gov](http://med.ohio.gov)



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**From:** [Jason Lichten](#)  
**To:** [Rodriguez, Judith](#); [Anderson, Kimberly](#); [CSIPublicComments](#)  
**Subject:** RE: Seeking Comments on Light Based Rules  
**Date:** Wednesday, May 27, 2020 3:27:47 PM  
**Attachments:** [AD3115F247F8469091258B98F23F1C58.png](#)  
[0E0D98E993DA4CFBB96E7CAE9B6498C6.png](#)  
[EB65E6846A56455C9F95A3649BFCD258.png](#)

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~~Subject: Seeking Comments on Light Based Rules~~ or IPL

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**From:** [Judith.Rodriguez@med.ohio.gov](mailto:Judith.Rodriguez@med.ohio.gov)  
**Sent:** Wednesday, May 13, 2020 9:58 AM  
**To:** [Barry T. Doyle \(todayle@aol.com\)](mailto:todayle@aol.com); [beth collis](#); [Bruce B. Whitman \(bbwhitmanlaw@aol.com\)](mailto:bbwhitmanlaw@aol.com); [Damion Clifford](#); [Deborah R. Lydon \(lydon@dinslaw.com\)](mailto:lydon@dinslaw.com); [Doug Graff](#); [Eric Plinke](#); [James Leo](#); [James McGovern \(jmcgovern@grafflaw.com\)](#); [Jeffrey Jurca \(jjurca@jurcalashuk.com\)](mailto:jjurca@jurcalashuk.com); [Jennifer Belt \(jbelt@slk-law.com\)](#); [Joe Feltes](#); [John R. Irwin](#); [Levi Tkach](#)

[Long; Matthew Harney](#); [Melissa Wervev Arnold \(chapter@ohioaap.org\)](mailto:chapter@ohioaap.org); [Ohio Association of Physician Assistants \(OAPA@OhioPA.com\)](#); [Rumberg Jimelle Ph. D.](#); [Steve Landerman](#); [Trimbath John \(jdtpac@adelphia.net\)](mailto:TrimbathJohn(jdtpac@adelphia.net))

**Subject:** FW: Seeking Comments on Light Based Rules

**The State Medical Board of Ohio has filed proposed actions concerning rules with the Common Sense Initiative Office. The proposals are available for your comment.**

A state rule-making agency may propose to adopt a new rule, amend or rescind an existing rule, or propose to continue a rule without any changes. Executive Order 2011-01K and Sections 107.62 and 121.82, Ohio Revised Code, require state agencies to draft rules in collaboration with stakeholders, assess and justify any adverse impact on the business community, and provide an opportunity for the affected public to provide input on the proposed rules. The Business Impact Analysis for the proposed rules discusses the purpose of the rule and identifies the nature of the adverse impact on licensees. The Common Sense Initiative review must be completed before the rules can begin the formal rule-making process through the Joint Committee on Agency Rule Review.

***At this time, public comment is being sought on the proposed actions for the following rules. The rule number is a link to the rule and the Business Impact Analysis filed with the Common Sense Initiative.***

- |                                 |  |
|---------------------------------|--|
| <a href="#">Rule 4731-18-01</a> | Definitions  |
| <a href="#">Rule 4731-18-02</a> | Use of light based medical devices   |
| <a href="#">Rule 4731-18-03</a> | Delegation of the use of light based medical devices for specified non-ablative procedures |
| <a href="#">Rule 4731-18-04</a> | Delegation of phototherapy and photodynamic therapy  |

**Comments on the proposed rules must be received no later than May 27, 2020**

Please provide comments to both of the following:

**Medical Board** at: [Kimberly.Anderson@med.ohio.gov](mailto:Kimberly.Anderson@med.ohio.gov)

AND

**Common Sense Initiative Office** at: [CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

Judy Rodriguez  
Public Services Manager

State Medical Board of Ohio  
30 East Broad Street, 3rd Floor  
Columbus, Ohio 43215  
o: 614-466-4999  
w: [med.ohio.gov](http://med.ohio.gov)





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May 26, 2020

Attn: Kimberly Anderson  
State Medical Board of Ohio  
30 E Broad Street  
Columbus, OH 43215

To the members of the Policy Committee of the State Medical Board of Ohio::

Thank you for providing the opportunity to receive and consider clinician feedback regarding the proposed rules **4731-18-01**, **4731-18-02**, **4731-18-03**, and **4731-18-04** of the Ohio Administrative Code.

We submitted commentary in 2018 and have unchanged opinions today regarding the proposed rules. We are a leading dermatology practice in the greater Cincinnati area committed to our ability to comprehensively treat our patients. We are proud to be a practice that is progressive in utilizing technological advancements that enhance our ability to give care. We have reviewed the adjusted proposed rules and continue to believe that several key adjustments are needed to render these rules useful for clinical practice while still maintaining excellent safety standards for Ohio's patients.

- 1) Physician assistants should not be held to the same supervisory requirements as an RN or LPN due to their more extensive education and training than that of our delegate types. Specifically, we propose that **physician assistant** application of light-based devices **not require physician pre and post evaluation**. This is based on the following logic:
  - a) Current supervisory agreements for Ohio PAs allow for a supervising physician to supervise their PAs as it pertains to their practice, education and training. The proposed supervision required for PAs in regards to light based therapies creates a much more restrictive framework than is customary to PAs in the practice of minimally invasive medical procedures.
  - b) We are strong proponents for meeting the proposed required 8 hours of education, observation of 15 procedures, and performance of 20 procedures under direct physician oversight. Given those prerequisites, this level of ongoing supervision strikes us as much more exhaustive than necessary.
  - c) The requirement of a physician to assess the patient pre and post is cumbersome and wastes valuable physician time. Considering many applications of vascular lasers take seconds to minutes, it would defy the utility for delegating the procedure to another individual in the first place.
    - i) We will present an example to illustrate this issue. Many busy dermatology clinics utilize pulsed dye laser frequently to treat common warts, for example. Physicians and PAs have separate schedules of dozens of patients per day. For a physician to evaluate a patient on behalf of that PA prior to laser treatment and after treatment (for a simple, low risk procedure) is to disrupt patient flow, decrease access to care, and take away from a PA's ability to comprehensively treat their patients.



- 2) We feel on-site physician supervision **should not be required 100% of the time for PA laser use**. PAs and physicians often have schedules that do not overlap, and in regard to laser use in a busy dermatology practice, this law would create complexities in scheduling that significantly decrease patient access to care.

Therefore we would propose the following adjustments to be made:

Instead of 100% on site physician supervision, the physician must be available by phone at all times and within an appropriate mile radius in the event of complications.

- 3) Vascular laser delegation should be **expanded to include other laser types for dermatologic uses**, including fractionated laser for cosmetic purposes, provided the same rigorous education and competency measures are met.

In summary, PAs are committed to team practice with physicians and other healthcare providers. Today, PAs are still held to obsolete requirements despite the PA profession being well established. Ohio state law requirements, including these rules, should support the Optimal Team Practice policy passed in 2017 by the American Academy of PAs (AAPA). Optimal Team Practice occurs when PAs, physicians and other healthcare professionals collaborate to provide quality care without burdensome administrative constraints.

We thank you again for the opportunity to provide our insight on matters that significantly impact our practice in dermatology and aesthetic medicine.

Sincerely,

Dr. Mona S. Foad, MD, MHS FAAD

Board Certified Dermatologist

Jessica P. Watkins, PA-C

Megan Niese, PA-C

Anna Donovan, C-NP

**From:** [Rishi Gandhi](#)  
**To:** [Anderson, Kimberly](#)  
**Subject:** Light Based Procedure Rule # 4731-13  
**Date:** Tuesday, May 26, 2020 9:14:51 PM

---

Dear Kimberly Anderson:

I am a board certified dermatologist and fellowship trained cosmetic dermatologic surgeon. It is with serious concern that I am writing about the Light based procedure rule #4731-13 that would permit non physicians (PA/NP/RN/MA) with the authority to perform nonablative laser procedures.

These nonablative light and laser devices require extensive knowledge of laser tissue interaction and laser physics. These difficult and challenging scientific topics are usually taught in dermatology residency or advanced procedural fellowships.

Without proper education and supervised training there is high concern for unintended and irreversible harm to patients including: burns, hyperpigmentation, and scarring. The liability for mistakes and unintended harm is enormous. IPL and Laser hair removal are the largest reasons for patients to initiate a lawsuit towards their cosmetic clinician.

I have treated several of these complications from outside offices where the patient believed they were seeing a skilled laser expert. In many cases, these required extensive amounts of time, money, and more importantly, patient distress.

In order to protect the public and our patients, I strongly urge the state Medical Board of Ohio to restrict the use of laser and light devices to board certified medical doctors.

Rishi Gandhi MD  
Ohio License# 35.097602

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Rishi K. Gandhi, MD FAAD



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**From:** [Jeff Wargo](#)  
**To:** [Anderson, Kimberly](#)  
**Subject:** Light Based Procedure Rule # 4731-13  
**Date:** Wednesday, May 27, 2020 12:24:14 PM

---

Dear Kimberly Anderson:

I am a board certified internist and chief dermatology resident at Wright State. It is with serious concern that I am writing about the Light based procedure rule #4731-13 that would permit non physicians (PA/NP/RN/MA) with the authority to perform nonablative laser procedures.

These nonablative light and laser devices require extensive knowledge of laser tissue interaction and laser physics. These difficult and challenging scientific topics are usually taught in dermatology residency or advanced procedural fellowships.

Without proper education and supervised training there is high concern for unintended and irreversible harm to patients including: burns, hyperpigmentation, and scarring. The liability for mistakes and unintended harm is enormous. IPL and Laser hair removal are the largest reasons for patients to initiate a lawsuit towards their cosmetic clinician.

I have seen these complications where the patient believed they were seeing a skilled laser expert at a medi-spa. In many cases, these required extensive amounts of time, money, and more importantly, patient distress.

In order to protect the public and our patients, I strongly urge the state Medical Board of Ohio to restrict the use of laser and light devices to board certified medical doctors.

Jeffrey Wargo MD

57.030409

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**From:** [Matthew Molenda, MD](#)  
**To:** [Anderson, Kimberly](#)  
**Subject:** Light-Based Medical Device Rules  
**Date:** Tuesday, May 26, 2020 6:01:31 PM

---

Hello Ms. Anderson,

I would like to put in my comments regarding [Light Based Medical Device Rules](#). I am a board certified dermatologist. I wanted to pass along my comments on what I support, and what I do not support.

**SUPPORT:**

-I think that delegation of all non-ablative lasers (not just non-ablative vascular lasers), such as those that are could safely be delegated to Physician Assistants.

**DO NOT SUPPORT:**

-I am not supportive of expanding laser use to RNs, LPNs, or cosmetic therapists due to safety issues and complication issues they may not be equipped to deal with.

-I am not supportive of ablative lasers being delegated to non-physicians due to increased concerns for scarring and infection.

Thank you for considering these comments.

Dr. Matt Molenda

--

Matthew A. Molenda, MD, FAAD, MBA, FACMS, FASDS  
Dermatology and Dermatologic Surgery

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**From:** [Barnhart, Blair](#)  
**To:** [Anderson, Kimberly](#); [CSIPublicComments](#)  
**Subject:** Medical Board - Light Based Rules  
**Date:** Wednesday, May 27, 2020 2:16:01 PM  
**Attachments:** [5\\_26\\_2020 Article Fractionated Laser Skin Resurfacing Treatment Complications\\_A Review \(002\).pdf](#)  
[5\\_26\\_2020 article Intense Pulsed Light for Skin Rejuvenation, Hair Removal, and Vascular Lesions\\_A Patient Satisfaction Study and Review of the Literature.pdf](#)  
[5\\_27\\_2020 FINAL Medical Board Rule Light based product 2pm.pdf](#)

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Dear Ms. Anderson:

Attached please find the comments of Cleveland Clinic along with two articles referenced in the letter. Should you have any questions, please don't hesitate to contact us.

Thank you for your consideration of our comments.

~blair



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

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May 26, 2020

Kimberly Anderson  
State Medical Board of Ohio  
30 E. Broad Street, 3<sup>rd</sup> Floor  
Columbus, OH 43215

Dear Ms. Anderson:

The Ohio Association of Physician Assistants (OAPA) would like to submit the following comments to proposed amendments to rules OAC 4731-18-01, 4731-18-02, 4731-18-03 and 4731-18-04 as requested by the State Medical Board of Ohio (here-to-fore referred to as the "Board") on May 13, 2020.

OAPA believes these rules as proposed by the Board are in conflict with and extremely overly restrictive to the intent of ORC 4730.19(B)(1) and (2), 4730.20(A)(8), and 4730.21 as OAPA referred to in previous comments submitted to the Board on February 1, 2018:

*"As you are aware, physician assistants (PAs) were included in the administrative rules for the use of light-based medical devices when they were originally promulgated in 2000. Since then, ORC 4730 has been amended several times greatly expanding the PAs scope of practice; commensurate to PAs education and training; which included less settling and oversight by the medical board in determining the specific services a PA may provide by restructuring the process of approving supervisory agreements and eliminating special services plans, while affording the supervising physician more authority to determine a PA scope of practice at the practice level or by the healthcare facilities policies in which the supervising physician and PAs practice."*

Furthermore, OAPA believes the Board may be in violation of ORC 4730.06 and 4730 .07 for the following reasons;

These proposed amended rules, commonly referred to as Light Based Medical Devices (LBMD) rules, as reported by the Board, were initially discussed by the Policy Committee of the Board on January 13, 2016. The Board's staff communicated with a panel of medical experts experienced in the application of LBMD which submitted written and verbal comments on the existing rule 4730-18 and suggested how to improve the rules. Subsequently, the board staff drafted proposed rules. During the drafting process, the Board's staff met with Dr. Bechtel, a member of the Board, and the panel of experts to develop and review the draft of the proposed rules. Dr. Bechtel also provided additional input on supervision and appropriate LBMD education and training from an "informal" survey from doctors and residents within his own practice at the Ohio State University Wexler Medical Center.

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

On January 17, 2018, the Board circulated the draft of the proposed rules to interested parties and licensees and received 47 written responses. Amongst these comments, was a comment from an attorney representing chiropractors of potential litigation based on the perception the proposed rules would constrain the market for chiropractors use of non-ablative LBMDs. On March 14, 2018, the Policy Committee of the Board made changes to the proposed rules and submitted them to the full board for their approval. The proposed rules as approved by the Board were sent to Common Sense Initiative on June 15, 2018. It seems that forewarning of potential litigation and the Board's request of Common Sense Initiative's antitrust review of the proposed rules is the apparent reason why there has been a two-year delay in the process of promulgating these rules.

What the Board failed to do prior to seeking public comment on these proposed rules, which OAPA believes constitutes a breach in the Board's statutory responsibilities, was to include the Physician Assistant Policy Committee (PAPC) of the State Medical Board in any formal discussions and/or seek recommendations from the PAPC in accordance with ORC 4730.06 and 4730.07. OAPA believes the aforementioned statutes clearly articulates the PAPC has the **"statutory rights and responsibility"** to review and submit recommendations to the Board on any proposed rules pertaining to the scope of practice of physician assistants and the supervisory relationship between physician assistants and supervising physicians. It was not until February 12, 2018 when Mr. Nathan Smith, staff member of the Board, presented the proposed rules to the PAPC, at which time PAPC member Mr. Robert Zaayer, PA-C *"expressed concern that this would require a special services type approval and that would be a step backward from where we are currently with PA's ability to perform services that are within their supervising physicians practice."* Mr. Smith indicated he would continue to consider comments and adjust these rules accordingly. OAPA has researched all of the minutes of the PAPC and the Board meetings from February 2018 to date, and cannot find even a single reference to any further inclusion of, and/or comments on recommendations from the PAPC to the Board proposing amendments to these draft rules that would be consistent with the current tenants of PA scope of practice that is determined at the practice level by the supervising physician.

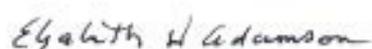
OAPA also believes ORC 4730 is quite clear in conveying the current practice of a physician assistant is performed under the **"supervision, control and direction of the supervising physician"** with less oversight by the Board which is laid out in ORC 4730.19, 4730.20 and 4730.21. The proposed rules place arbitrary numbers on the procedures the physician assistant must observe the supervising physician perform, the number of procedures the physician assistant must perform with **"over the shoulder supervision"** of the supervising physician, and thereafter the supervising physician must provide **"on-site supervision at all times"**. The proposed rules encumbers the supervising physicians privilege and statutory authority to determine scope of practice at the practice level.

OAPA would also like to bring the Board's attention a comment that is on page 5 of the May 12, 2020 submission of the proposed rules to Common Sense Initiative which expresses concerns regarding the rules' lack of regulation of nurse practitioners and the interplay of the rules with the Ohio Nursing Board's regulation of nurse practitioners' application of LBMD. OAPA is likewise concerned by the lack of clarity in the rules as it pertains to advanced practice registered nurses. OAPA would like to believe the limitation placed on a "registered nurse's" scope of practice in the proposed rules would also include advanced practice registered nurses. If the Nursing Board of Ohio does not agree that advanced practice nurses must adhere to the restricted protocols for LBMD applications as other registered nurses, OAPA feels that would place physician assistants at extreme disadvantage to obtain employment in certain medical/surgical specialties that utilize LBMD to provide service to their patients. OAPA does not choose to express any concern regarding the scope of practice of a licensed practical nurse or cosmetologist at this time as it pertains to LBMD.

OAPA stands by our previous comments to the proposed rules submitted on February 1, 2018 and is prepared to work with the Board to assure that these proposed rules, or any other future rules, remain consistent with the current tenants of ORC 4730 that afford the supervising physician the authority to determine a physician assistant scope of practice at the practice level. OAPA would also like to inform the Board that OAPA has finally reached the point where we can no longer stand by and be tolerant of the Board's continually overlooking the Physician Assistant Policy Committee, and not seeking their input in matters of importance to the physician assistant profession. Because there is no specific statutory direction on the application of LBMD, OAPA may need to seek potential litigation rather than a legislative relief if the Board and OAPA cannot come to a mutual resolution to address this issue.

OAPA greatly appreciates the opportunity to comment on these proposed rules. If you have any questions or need further information, please do not hesitate to contact us.

Sincerely,



Elizabeth W. Adamson  
Executive Director

**From:** [Kelly Statzer](#)  
**To:** [CSIPublicComments](#)  
**Cc:** [Anderson, Kimberly](#)  
**Subject:** RE: Light-Based Procedures  
**Date:** Wednesday, May 27, 2020 1:38:50 PM

---

Dear Sir/Madam:

I am a Cosmetic Therapist who has been practicing in Ohio for five years. I have been looking for full-time work in Ohio for the past year. I was recently laid off the beginning of March from a job in Kentucky where I performed Laser Tattoo Removal. Kentucky has less restrictions than Ohio. I have been looking for work in Ohio, closer to my home, for the last two years and have been unsuccessful due to the restrictions passed down by the State Medical Board of Ohio. Without taking into consideration the new mandates handed out from the Medical Board, the current proposal will restrict us even further.

I encourage you to vote NO on May 27<sup>th</sup> on the changes for 4731-18 – Light-based Therapy. I encourage you to **postpone** these matters and address all of the issues in this regulatory change when the House Bill 452 changes are made for licensed Cosmetic Therapists. Here are my reasons: (1) The regulations, as written, will be challenged by the FTC because they impose a restraint of trade against Cosmetic Therapists – similar to North Carolina Dental Examiners v FTC. (2) These regulations would devastate the Cosmetic Therapists as most of us would all be fired

and replaced by Nurses or Physician Assistants. (3)  
Encouraging Med Spa owners to raid hospitals for  
Nurses and Physician Assistants is BAD PUBLIC  
POLICY, especially in the middle of this COVID-19  
pandemic.

All of these matters can be addressed in House Bill 452  
review of CT license.

Thank you for your consideration,

Kelly Ott-Statzer, CT

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**From:** [Anderson, Kimberly](#)  
**To:** [Antoinette Sepsi](#)  
**Cc:** [vickie aboutface-ctc.com](#); [CSIPublicComments](#)  
**Subject:** RE: Common sense initiative and House Bill 452  
**Date:** Thursday, May 28, 2020 8:47:00 AM  
**Attachments:** [CSI DET ORC 107.56 Light Based Medical Device Procedures.pdf](#)

---

Ms. Sepsi:

Thank you for your comments. They will be shared with the Board. Please note that CSI has completed an anti-trust review of these rules. I have attached the determination for your information.

Kimberly C. Anderson  
Chief Legal Counsel  
State Medical Board of Ohio  
30 E. Broad Street, 3rd Floor  
Columbus, Ohio 43215-6127  
O: 614-466-7207  
C: 614-230-9077  
[Kimberly.Anderson@med.ohio.gov](mailto:Kimberly.Anderson@med.ohio.gov)  
[Med.ohio.gov](http://Med.ohio.gov)

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

From: Antoinette Sepsi <[inot1980@icloud.com](mailto:inot1980@icloud.com)>  
Sent: Thursday, May 28, 2020 8:33 AM  
To: Anderson, Kimberly <[Kimberly.Anderson@med.ohio.gov](mailto:Kimberly.Anderson@med.ohio.gov)>  
Cc: [vickie aboutface-ctc.com](mailto:vickie aboutface-ctc.com) <[vickie@aboutface-ctc.com](mailto:vickie@aboutface-ctc.com)>  
Subject: Common sense initiative and House Bill 452

Good Morning Kimberly Anderson,

I'm asking that the Common Sense Initiative vote to POSTPONE the proposed changes for 4731-18 – Light-based Therapy. I encourage you to seek input from licensed Cosmetic Therapists (Whose jobs would be in jeopardy) and please make changes to 4731-18 when the House Bill 452.

Consider these reasons:

(1) The regulations, as written, will be challenged by the FTC because they impose a restraint of trade against Cosmetic Therapists – similar to FTC v North Carolina Dental Examiners.

(2) These (proposed) new regulations would devastate the careers of Cosmetic Therapists, who would all be replaced by nurses, physician assistants and “cosmetic assistants”. Med Spa owners would be forced to hire away nurses and physician’s assistants from hospitals to man their light based hair removal devices. Creating a further shortage of those resources. All we seek is, a level playing field and regulations adjusted to reflect that.

All of these matters can be addressed in a review of House Bill 452 for the CT licensees.

Thank you for your consideration,  
Antoinette Sepsi, C.T.  
440-888-0226

Sent from my iPhone

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# Common Sense Initiative

**Mike DeWine**, Governor  
**Jon Husted**, Lt. Governor

**Carrie Kuruc**, Director

## Business Impact Analysis

Agency, Board, or Commission Name: State Medical Board of Ohio

Rule Contact Name and Contact Information:

Kimberly C. Anderson (email: Kimberly.Anderson@med.ohio.gov); phone: 614-466-7207

Regulation/Package Title (a general description of the rules' substantive content):

Light based procedures

Rule Number(s): 4731-18-01 Definitions; 4731-18-02; Use of light based medical devices; 4731-18-03 Delegation of the use of light based medical devices for specified non-ablative procedures; 4731-18-04 Delegation of phototherapy and photodynamic therapy

Date of Submission for CSI Review: May 12, 2020

Public Comment Period End Date: May 27, 2020

Rule Type/Number of Rules:

New/ X rules

No Change/      rules (FYR?     )

Amended/   x   rules (FYR?yes     )

Rescinded/      rules (FYR?     )

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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CSIPublicComments@governor.ohio.gov

### **Reason for Submission**

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

**Which adverse impact(s) to businesses has the agency determined the rule(s) create?**

**The rule(s):**

- a.  **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b.  **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c.  **Requires specific expenditures or the report of information as a condition of compliance.**
- d.  **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

### **Regulatory Intent**

2. **Please briefly describe the draft regulation in plain language.**

*Please include the key provisions of the regulation as well as any proposed amendments.*

#### **4731-18-01: Definitions**

- Consolidates all definitions in the chapter and adds new definitions including: “phototherapy” (B), “phototherapy devices” (C), “photodynamic therapy” (D), “ablative dermatologic procedure” (E), “non-ablative dermatologic procedure”, “physician” (G), and “delegation” (H).

#### **4731-18-02 Use of light based medical devices**

- Lays out framework for physician delegation of the application of light based medical devices.
- Paragraph (B) states that a physician shall not delegate application of light based medical devices for ablative procedures.

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- Paragraphs (C), (D), and (E) provide for the delegation of the application of light based medical devices for specific types of non-ablative procedures according to the requirements in subsequent rules.

**4731-18-03: Delegation of the use of light based medical devices for specified non-ablative procedures**

- Paragraph (A) adds the ability of physicians to delegate vascular laser non-ablative dermatologic procedures to a physician assistant, R.N., or L.P.N. if specified conditions are met including: physician evaluates patient before and after the first application of the vascular laser; delegate has completed eight (8) hours of education; observed fifteen (15) procedures; performed twenty (20) procedures under direct physical oversight of physician; and physician provides on-site supervision.
- Paragraph (B) retains current rule on laser hair removal delegation by a physician, but adds robust education and training requirements including eight (8) hours of education; observation of fifteen (15) procedures; and performance of twenty (20) procedures under direct physical oversight of physician.

**4731-18-04: Delegation of phototherapy and photodynamic therapy**

- Paragraph (A) adds specificity to physician delegation of the application of phototherapy in the treatment of hyperbilirubinemia in neonates to include a physician assistant, R.N., and L.P.N. This paragraph also requires training and on-site physician supervision.
- Paragraph (B) also adds specificity to physician delegation of phototherapy for psoriasis and other skin diseases to include a physician assistant, R.N., L.P.N., and certified medical assistant who has successfully completed training. This paragraph requires on-site physician supervision as well.
- Adds photodynamic therapy delegation by a physician to a physician assistant, R.N. and L.P.N. in paragraph (C) with the requirements that the delegate complete training and that the physician provides on-site supervision.
- Requires reporting of adverse events and failure of treatment by all delegates, and requires physician to personally evaluate patient when this occurs in paragraph (D).
- Lays out the disciplinary framework for violations of (A), (B), (C), and (D).

**3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The Medical Board is authorized to issue rules by R.C. 4730.07, R.C. 4731.05, and R.C. 4731.15. There is no specific statutory direction on the application of light based medical devices. However, the general rulemaking authority to regulate the practice of medicine and

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[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

surgery gives the Medical Board authority to amend its rules in the evolving area of light based medicine in the practice of medicine and surgery.

- 4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

*If yes, please briefly explain the source and substance of the federal requirement.*

The proposed regulations do not implement a federal requirement, nor are they being adopted or amended in connection with administering or enforcing a federal law or participating in a federal program.

- 5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

The question is not applicable.

- 6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

The public purpose of the proposed rules is to ensure public safety in the practice of medicine and surgery and the competent application of certain light based medical devices.

- 7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of these regulations will be measured by the safe application of certain light based medical devices with minimal adverse events; the rules being written in plain, understandable language; licensee compliance with the rules; and minimal questions from the licensees about the proposed rules.

- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No. The rules are not being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931.

### **Development of the Regulation**

- 9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

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On January 13, 2016, the Policy Committee of the Medical Board discussed the light based medical device rules in chapter 4731-18 and recommended that technical and medical expertise related to light based procedures be obtained.

Subsequently, Board staff communicated with an initial panel of five medical experts with experience in the application of light based medical devices. The expert panel included Dr. Mark Bechtel, Dr. Stephen Smith, Dr. Georgann Poulos, Dr. Eric Bernstein, and Dr. Ronald Siegle. These experts provided verbal or written comments on the existing Chapter 4731-18 rules and suggestions how to improve the rules. Doctors Smith and Poulos provided additional written comments to the initial circulation draft of the proposed rule as well.

Board staff also conducted extensive research into the regulation of light based medical device procedures by other states, adverse events involved in application of light based medical devices, and the light based medical device procedures themselves.

After obtaining the required technical and medical information through consultation with the expert panel and independent research, Board staff drafted the proposed rules. During the drafting process, Board Staff met with Dr. Bechtel, a member of the Board and the expert panel, to develop and review the draft of the proposed rules. Dr. Bechtel provided additional input for the draft on the issues of supervision and appropriate light based medical device education and training from his informal survey of doctors and residents associated with his practice with The Ohio State University Wexner Medical Center.

On January 10, 2018, the Board's Policy Committee publicly reviewed, discussed, and approved the proposed rules for initial circulation with a few amendments that did not change the overall substance of the rule. Board staff then circulated the proposed rules for comment to interested parties and all licensed doctors, physician assistants, and cosmetic therapists.

**10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

In response to the initial circulation, the Board received 46 written comments which can be categorized as follows:

1. Seven comments were generally supportive of the rules with no suggested changes.
2. Three comments raised questions and expressed concerns about the rules' lack of regulation of nurse practitioners and the interplay of the rules with Nursing Board regulation of nurse practitioners' application of light based medical devices.
3. Two comments were concerned with the definition of phototherapy for the treatment of hyperbilirubinemia in neonates. Two other comments expressed concern that the definition was too narrow for cosmetic procedures not regulated in these rules.
4. Five comments sought a definition or clarification of the term "vascular laser".

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5. Seven comments supported expanding the application of non-ablative light based medical devices beyond vascular lasers for dermatologic procedures and hair removal. Five of these seven comments supported expanding delegation to fractionated lasers often used for cosmetic procedures.
6. Four comments opposed expanding delegation of light based medical devices beyond hair removal to vascular lasers, or did not support physician's delegating the application of light based medical devices at all.
7. Two comments favored delegating light based medical device procedures to only physician assistants due to their more extensive education and training than that of other delegates. Two other comments were in favor of delegation to physician assistants and nurses, but not cosmetic therapists.
8. Three comments advocated delegating all light based medical device procedures, including ablative procedures, to physician assistants.
9. Three comments encouraged extending delegation of phototherapy and photodynamic therapy to cosmetic therapists.
10. Eight comments favored expanding off-site physician supervision beyond cosmetic therapists to all other delegates.
11. Nine comments did not agree with the requirements that the physician personally see patients before and after the initial application of a light based medical device, and sought to eliminate the initial evaluation, the follow-up evaluation, or both.
12. One comment requested clarification on whether the phrase "the physician has seen and personally evaluated the patient" allows for video or picture review by the physician instead of the physician being in the same room as the patient.
13. Five comments sought various changes to the rule's delegation of phototherapy in the treatment of hyperbilirubinemia in neonates.
14. One comment advocated extending the delegation of light based medical devices to tattoo removal, and allowing non-medical technicians to perform these procedures along with laser hair removal, skin rejuvenation, and acne treatment.
15. One comment argued that the rules' limited delegation of non-ablative dermatologic procedures was too restrictive and could possibly be in violation of antitrust laws.
16. Four comments had questions about or suggested changes to the new training requirements for delegates applying light based medical devices.
17. One comment inquired into whether delegates who had been lawfully practicing laser hair removal could be exempted from the rule's new education and training requirements. One other comment suggested a grandfather clause for practitioners who had been performing photodynamic therapy for years without regulation.

Board staff also met with two additional Board members, Dr. Andrew Schachat and Dr. Kim Rothermel, to discuss the effect of the proposed rules in their fields of ophthalmology and

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pediatrics respectively. Dr. Schachat expressed concern about the danger of delegating light based medical device procedures for purposes other than dermatologic ones due to the great potential for patient harm in areas like ophthalmology. Dr. Rothermel reported concerns in the hospital community about regulating phototherapy in the treatment of jaundice beyond what the hospital protocols were already successfully accomplishing.

On February 12, 2018, the initial circulation draft of the proposed rules was presented to the Physician Assistant Policy Committee (“PAPC”) where comments were received regarding the application of phototherapy in the treatment of jaundice by hospital protocol, and regarding the amount and frequency of appropriate training and education to delegates. Based on the comments received from Board members and members of the PAPC as well as written comments provided by interested parties and licensees during the initial circulation of the proposed rules, the following changes were made to the proposed rules:

1. Added definition of vascular laser;
2. Clarified and distinguished definition of phototherapy applied in the treatment of jaundice in infants versus application in the treatment of psoriasis and similar skin diseases.
3. Simplified delegation of phototherapy in the treatment of jaundice in infants by aligning it with hospital standards of care found in their existing protocols and policies.
4. Clarified that the physician evaluation provisions are per type of procedure delegated rather than per procedure, and that the evaluation must occur in person by the physician rather than through video or photograph.
5. Explained the specific education requirements; and clarified that the training must be done per type of procedure rather than per delegating physician.
6. Added a clause that would allow delegates who had been successfully applying a specific type of light based medical device procedure for hair removal to be exempted from education and training requirements if they provided a written certification from a delegating physician stating that the delegate has received sufficient education and training to competently apply that type of light based medical device procedure for hair removal.

**11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

The Board consulted with a panel of medical experts to develop the rules. These experts used their own experience and medical texts to guide the development of the rule.

**12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn’t the Agency consider regulatory alternatives?**

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The Medical Board considered a multitude of comments across a wide spectrum of opinion regarding the degree of regulation desired and the types of light based medical devices that should be delegated by physicians.

- 13. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The Medical Board did not consider a performance-based regulation because these proposed rules do not define the required outcome and instead seek to prevent adverse events.

- 14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

Medical Board staff reviewed the proposed regulations and all relevant Medical Board related Ohio Administrative Code chapters to assure there was no duplication of existing Ohio regulations.

- 15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The rules will be posted on the Medical Board's website and notice of the rules will be circulated to the interested parties. Medical Board staff members will be available to answer questions regarding the rule. Board staff will be made aware of the rule's provisions so that the rule can be fairly, consistently, and predictably applied to the regulated community.

### **Adverse Impact to Business**

- 16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

- a. Identify the scope of the impacted business community; and**
- b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**
- c. Quantify the expected adverse impact from the regulation.**

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.*

The impacted business community includes physicians utilizing light-based medical devices in their practice, licensees to whom tasks are delegated such as physician assistants, registered nurses, licensed practical nurses and cosmetic assistants. The nature of the adverse impact is the eight hours of basic education that must be completed for the delegation of non-ablative

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procedures and laser hair removal. In addition, the physicians will need to have the delegated licensees observe 15 procedures and then provide direct physical oversight of 20 procedures before the licensees can perform on their own. In addition, physicians who violate these rules are subject to disciplinary action and fines up to \$20,000 from the Medical Board.

**17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

The Medical Board determined that the regulatory intent justifies the adverse impact to the regulated business community because the Board endeavors to protect patients and ensure the competent application of the specified light based medical devices. In these proposed rules, the Board is expanding the ability of physicians to delegate the application of certain light based medical devices which helps rather than harms the regulated business community.

**Regulatory Flexibility**

**18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

No, the regulation does not provide exemptions or alternative means of compliance for small business. All practitioners utilizing light-based medical devices need to follow the same regulations for patient safety.

**19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

Due process requires the Medical Board to consistently apply its rules such that all licensees using light-based medical devices are equally treated.

**20. What resources are available to assist small businesses with compliance of the regulation?**

Medical Board staff members are available by telephone and e-mail to answer questions.

## Chapter 4731-18 Surgery Standards-Light Based Procedures

### 4731-18-01 Standards for Surgery Definitions

~~(A) The surgeon of record in an operative case shall personally:~~

~~(1) Evaluate the patient sufficiently to formulate an appropriate preoperative diagnosis; and~~

~~(2) Select the operation to be performed in consultation with the patient or with a person authorized to act on his patient's behalf; and~~

~~(3) Determine, based on his surgeon's own evaluation, and, as necessary, on consultation with other physicians involved in the patient's care, that the patient is a fit candidate for the operation to be performed; and~~

~~(4) Assure that the patient or a person authorized to act on his patient's behalf gives informed consent before the surgery begins; and~~

~~(5) Comply with division (B)(6) of section 4731.22 of the Revised Code; and~~

~~(6) Perform or personally supervise the surgery, except those portions of the surgery, if any, which are performed or supervised by another qualified surgeon with the informed consent of the patient.~~

~~(B) Management of postoperative medical care is the responsibility of the surgeon of record. The surgeon of record shall fulfill this responsibility by:~~

~~(1) Personally performing the postoperative medical care; or~~

~~(2) Delegating postoperative medical care to another physician or physicians who are qualified by training and experience to provide the level of care required, provided that the surgeon of record shall remain primarily responsible for the patient's overall care unless the patient and the other physician have agreed in advance to shift that responsibility to the other physician; or~~

~~(3) Delegating defined aspects of the postoperative medical care to appropriately trained and supervised allied health care personnel in compliance with applicable standards, provided that the surgeon of record shall retain personal responsibility for the quality of the care rendered by personnel who are under his supervision and control. The surgeon of record shall obtain the patient's fully informed consent, or the consent of a person authorized to act on the patient's behalf, in advance of surgery, before delegating aspects of patient care to allied health care personnel under this paragraph. The surgeon of record need not obtain the patient's informed consent for aspects of care to which the patient has already consented, such as consent to~~

treatment and care by hospital personnel under an informed consent form signed upon the patient's admission to the hospital; or

~~(4) Delegating defined aspects of the postoperative medical care to licensees of other health regulatory boards who are licensed to independently provide the scope of practice and the level of care required, provided that the surgeon of record shall remain primarily responsible for the patient's overall care and must examine the patient during the postoperative period.~~

~~(C) This rule shall not be read to transfer any responsibility which currently rests with any other physician, allied health care provider, or institution to the surgeon of record.~~

~~(D) This rule shall not be read to prohibit or interfere with the appropriate training of medical students and physicians in post graduate training programs, or other personnel.~~

~~(E) The provisions of this rule requiring consultation with or obtaining the informed consent of the patient or a person legally authorized to act on his patient's behalf do not apply to the extent they would prevent the performance of surgery or other procedures under emergency circumstances.~~

As used in this chapter of the Administrative Code:

(A) "Light based medical device" shall mean 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  $1.0 \times 10^6$  nm [ten to the sixth power] and that is manufactured, designed, intended or promoted for ~~in vivo~~ 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. 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 and must be in a location that under normal conditions is not more than sixty minutes travel time from the cosmetic therapist's location.
- (J) “Vascular laser” means 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 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 ~~(C)~~(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 in person to determine whether the proposed application of the specific vascular laser is appropriate;

(4) The physician has seen and evaluated the patient in person 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 authorizing the service; or,

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

(6) 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 (8) 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 (15) 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 (20) 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 (a) 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 (b) and (c) must be completed by the delegate once for each specific type of vascular laser procedure delegated regardless of the number of delegating physicians;
- (7) The physician provides on-site supervision at all times that the person to whom the delegation is made is applying the vascular laser; and,
- (8) 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 ~~only~~ for the purpose of hair removal ~~and~~ 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; ~~and~~
  - (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; ~~and~~
  - (3) The physician has seen and ~~personally~~ evaluated the patient in person to determine whether the proposed application of ~~a~~ the specific light based medical device is appropriate; ~~and,~~
  - (4) The physician has seen and ~~personally~~ evaluated the patient in person following the initial application of ~~a~~ 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; ~~and,~~
  - (5) The person to whom the delegation is made is one of the following:
    - (a) A physician assistant ~~registered~~ licensed ~~pursuant to~~ under Chapter 4730. of the Revised Code ~~and with whom the physician has a board approved supplemental~~

~~utilization plan allowing such delegation~~ an effective supervision agreement authorizing the service; or,

(b) A cosmetic therapist licensed ~~pursuant to~~ under Chapter 4731. of the Revised Code; or,

(c) A registered nurse or licensed practical nurse licensed ~~pursuant to~~ under Chapter 4723. of the Revised Code; ~~and,~~

(6) 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 (8) 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 (15) 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 (20) 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 (a) 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 (b) and (c) 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 (2) years through a lawful delegation by a physician, shall be exempted from the education and training requirements of (a), (b), and (c) 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 (60) days after the effective date of this provision, and a copy of the certification shall be retained by each delegating physician and each delegate.

(7) 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,

(8) The physician supervises no more than two persons pursuant to this rule at the same time.

(C) Notwithstanding paragraph (B)(7) 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 ~~(A)~~(B) of this rule is a cosmetic therapist licensed ~~pursuant to~~under Chapter 4731. of the Revised Code 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 board; ~~and~~

(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), ~~or (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.

(H) A violation of paragraph (D) of this rule by a cosmetic therapist shall constitute "A 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.

(I) 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.

#### **4731-18-04 Delegation of phototherapy and photodynamic therapy**

(A) ~~A physician authorized pursuant to Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may delegate to any appropriate person the application of light based medical devices cleared or approved by the United States food and drug administration for phototherapy in treatment of hyperbilirubinemia in neonates~~ only if all the following conditions are met:

- (1) The use of the light based medical device for this treatment is within the physician's normal course of practice and expertise.
- (2) The delegation and application of light based medical devices for phototherapy for this treatment is performed pursuant to hospital rules, regulations, policies, and protocols.

(B) ~~A physician authorized pursuant to Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may delegate to any appropriate person the application of a light based medical device that is a fluorescent lamp phototherapy device that is cleared or approved by the United States food and drug administration for treatment of psoriasis and similar skin diseases~~ only under if all the following conditions are met: A fluorescent lamp phototherapy device is a device that emits ultraviolet light through the use of one or more fluorescent bulbs and is approved by the United States food and drug administration for phototherapy in the treatment of psoriasis or similar skin diseases.

- (1) The use of the light based medical device for this treatment is within the physician's normal course of practice and expertise.

- (2) The physician has seen and personally evaluated the patient to determine whether the proposed application of phototherapy is appropriate;
  - (3) 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 authorizing the service;
    - (b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code; or
    - (c) A certified medical assistant who has successfully completed and documented the completion of basic training on psoriasis and similar skin diseases and clinical training in the administration of the phototherapy device for the specific skin disease being treated; and
  - (4) The physician provides on-site supervision at all times that the person to whom the delegation is made is applying the phototherapy.
- (C) A physician may delegate the application of light based medical devices cleared or approved by the United States food and drug administration for photodynamic therapy for dermatologic purposes only if all the following conditions are met:
- (1) The use of the light based medical device for this treatment is within the physician's normal course of practice and expertise.
  - (2) The physician has seen and personally evaluated the patient to determine whether the proposed application of photodynamic therapy is appropriate;
  - (3) 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 authorizing the service; or,
    - (b) A registered nurse or licensed practical nurse licensed under Chapter 4723. of the Revised Code;
  - (4) The person to whom the delegation is made completes basic training on photodynamic therapy and clinical training in the administration of photodynamic therapy for the specific disease or disorder being treated;
  - (5) The completion of this training is documented by the person to whom the delegation is made; and
  - (6) The physician provides on-site supervision at all times that the person to whom the delegation is made is applying the photodynamic therapy.
- (D) Any person to whom a lawful delegation of phototherapy or photodynamic therapy has been made shall immediately report to the supervising physician any clinically significant side effect following the application of the phototherapy or photodynamic therapy 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. A violation of division (A)(2), (B)(2), or (C)(2) 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 (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.



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**MEMORANDUM**

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: CSI Comments regarding CME Rules

DATE: July 2, 2020

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On May 26, 2020, the amended rules regarding CME were filed with the Common Sense Initiative and circulated to interested parties for comment. A copy of the Business Impact Analysis is attached for your review.

The Board received comments from five entities, all related to Rule 4731-10-02. A spreadsheet listing the comments and copies of the comments are attached for your review.

The Academy of Medicine of Cleveland and Northern Ohio, Ohio Osteopathic Association, Ohio Academy of Family Physicians, Ohio Psychiatric Physicians Association and the Ohio State Medical Association all indicated opposition to the change to Rule 4731-10-02 which requires one hour of mandatory CME on the topic of duty to report misconduct.

In addition, the Ohio Osteopathic Association indicated opposition to the added allowance of Category 2A credits for osteopathic physicians as a condition of licensure. The OOA requests that the current language be restored to the original language of Rule 4731-10-02.

With respect to the comments objecting to mandatory, topic-specific CME, it is important to note that this rule amendment was made pursuant to one of the recommendations of the Strauss Working Group. Thus, I am not recommending a change to this provision of the rule.

With respect to the concerns raised by the OOA, I propose deleting paragraph (A)(3) referencing Category 2-A CME credits.

In addition, two technical fixes are requested to Rule 4731-10-02:

1. Add "CME" after category 1 in paragraph (A)(1)(c);
2. Change "category 1" to category 1-A in paragraph (A)(2)(b).

A copy of the rule with the proposed edits is attached for your review.

**Action Requested: Approve amendments to Rule 4731-10-02(A)(1)(c), (A)(2)(b) and delete paragraph (A)(3) and provide information to CSI.**

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June 15, 2020

Kimberly Anderson, Chief Legal Counsel  
State Medical Board of Ohio  
Sent via email: [Kimberly.Anderson@med.ohio.gov](mailto:Kimberly.Anderson@med.ohio.gov)

Dear Ms. Anderson:

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO) would like thank the State Medical Board of Ohio (SMBO) for the opportunity to provide our comments on the proposed changes to Ohio Administrative Code 4731-10-02, Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement.

The AMCNO opposes mandatory Continuing Medical Education as a condition for licensure. We believe that physician educational needs should be determined by the physician, and we support the concept that it is a physician's responsibility to establish the curriculum for continued self-education based upon their type of practice, specialty and patient mix. Requiring mandatory CME could result in many physicians spending time and money on education that has no relation to the patients they see instead of focusing on CME activities that more appropriately address topics related to their professional practice.

In addition, physicians have a limited amount of time available for CME activities and content- mandated CME may be detrimental in that it competes for time needed for education that actually does apply to the physician's practice.

The AMCNO understands the issues that resulted in the SMBO's proposal on the topic of reporting physician misconduct and we agree that physicians should be made aware of all situations that require reporting.

To that end, the AMCNO agrees with and supports the Ohio State Medical Association's suggestion that a broader educational effort aimed at educating Ohio's physicians about their duty to report, not only physician misconduct, but other reporting obligations outlined in Ohio law such as reporting requirements surrounding abuse, neglect and felonies could be developed by the SMBO. We also agree with the OSMA that a broader educational piece that is easily accessible on the board's website, and promoted by state and local medical associations, would provide more comprehensive and relevant information related to a physician's duty to report.

Thank you for giving us the opportunity to comment on this proposed rule change. We look forward to working with the SMBO on this issue.

Sincerely,

Thomas E. Collins, MD, FACEP, FAEMS

President, The Academy of Medicine of Cleveland & Northern Ohio

**From:** [Matt Harney](#)  
**To:** [Anderson, Kimberly](#)  
**Subject:** Comment from the OOA regarding 4731-10-02  
**Date:** Friday, June 19, 2020 4:43:05 PM

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Hi Kim,

On behalf of approximately 7,000 osteopathic physicians and 1,000 osteopathic medical students, the Ohio Osteopathic Association (OOA) would like to address major concerns regarding certain proposed changes regarding CME for licensure in 4731-10-02.

Firstly, **the OOA is opposed to the addition of a “duty to report misconduct” CME topic as a requirement for licensure.** Within the American Osteopathic Association’s (AOA) *Rules and Guidelines for Professional Conduct*, an osteopathic physician already “has an obligation to pursue a patient’s best interests and to be an advocate for the patient.” The AOA’s *Code of Ethics* and *Osteopathic Oath* further reinforce the enduring priority of patient protections.

Additionally, **the OOA opposes the added allowance of Category 2-A credits for osteopathic physicians as a condition of licensure.** For the osteopathic profession, Category 2 credit not only removes the osteopathic requirement but is of lesser educational value.

It is the understanding of the OOA that the primary animus behind reducing the CME requirement per licensure cycle (from 100 total hours with 40 Category 1 hours to 50 Category 1 hours) was to eliminate the requirement of lesser-quality CME. **This would not achieve that goal for osteopathic physicians.**

Further, this would effectively remove the authority of the OOA to certify osteopathic CME in the state of Ohio, as Category 2 credit can be provided by non-osteopathic accrediting bodies.

**Osteopathic medicine is a separate and distinctive philosophy and practice of medicine and wellness.** Osteopathic physicians receive additional education and training on the musculoskeletal system and manipulation. One of the tenets of the osteopathic profession is the body is a unit; made up of body, mind, and spirit. This distinctive osteopathic philosophy is expressly recognized throughout Ohio statute and federal law, including within this section of Ohio Revised Code. House Bill 166 (the current budget bill) initiated changes to the number of requisite CME hours for licensure, but there was purposefully no intention to modify certifying bodies. The proposed language would effectively do just that. Further, the OOA already has a process in place for DOs that could convert otherwise Category 2 credit to Category 1 in rare circumstances if certain requirements are met--such as a lack of similar subject matter for AOA Category 1 CME offerings.

We’ve been down this path before as the OOA had previously filed a lawsuit against the SMBO to maintain certification of osteopathic CME in the state. **Quality**

**continuing medical education is important to the osteopathic profession, as DOs were the first medical practitioners to require CME as a condition of re-licensure back in the 1940s.** Much of this is due to the distinctive philosophy of the profession. Osteopathic physicians receive an additional 200 hours of neuromusculoskeletal medicine education and are trained to provide osteopathic manipulative treatment for patients. Further, DOs educate and train with a fundamentally unique, holistic approach that encompasses a mind, body, and spirit approach to wellness.

Again, there was no reference in the budget bill regarding certification issues and what type of credit is allowed. This type of change was not the legislative intent.

Thus, we ask for the current language to be restored: **A licensee shall be required to complete 50 hours of Category 1 CME as certified by their respective state professional associations and approved by the board. Certification is a process whereby the Ohio Osteopathic Association defines its respective CME program requirements.** Protecting the authority of the Ohio Osteopathic Association to certify osteopathic CME in the state and require Category 1 credit for licensure will undoubtedly protect the health and safety of the public.

I'm happy to discuss this matter further. Thank you for your time.

Matt Harney, MBA  
Executive Director  
Ohio Osteopathic Association  
614.299.2107 *office*  
405.503.6258 *cell*



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**From:** [Ann Spicer](#)  
**To:** [CSIPublicComments](#); [Anderson, Kimberly](#)  
**Cc:** [A McMaster](#); "[sarah sams](#)"; [JHayhurst@osma.org](#)  
**Subject:** Comments on Requisite Hours of CME for License Renewal or Reinstatement  
**Date:** Wednesday, May 27, 2020 2:14:33 PM

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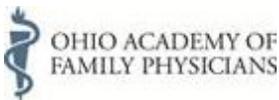
Our comments on mandated content specific CME on duty to report remain the same as they were when I sent them to you back on October 28, 2019. The Ohio Academy of Family Physicians objects to a mandate of content specific CME as a condition of licensure. The State Medical Board has already instituted our earlier suggestion that a licensee acknowledge duty to report responsibilities by verifying with a checkbox on their license application/renewal.

In addition, OAFP sought permission to reprint Tessie Pollack's duty to report article in the June 2020 issue of The Ohio Family Physician magazine, a publication that reaches all 5,200 of our members. We will continue to educate our members about this issue but mandating CME on duty to report is unnecessary and opens the floodgates for CME requirements on hot button topics that often diminish in urgency over time. It is a mistake to go down this path and we object to the rule language as drafted.

Thank you for your consideration.

Ann

**Ann M. Spicer | Executive Vice President**  
**Ohio Academy of Family Physicians**  
4075 N. High St. | Columbus, OH 43214  
Direct: 614.914.5625 | Main: 614.267.7867 | Fax: 614.267.9191  
[aspicer@ohioafp.org](mailto:aspicer@ohioafp.org) | [www.ohioafp.org](http://www.ohioafp.org)



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**From:** Ann Spicer  
**Sent:** Monday, October 28, 2019 4:29 PM  
**To:** 'Kimberly.Anderson@med.ohio.gov' <Kimberly.Anderson@med.ohio.gov>  
**Subject:** Comments on Requisite Hours of CME for License Renewal or Reinstatement

Kim –

The Ohio Academy of Family Physicians submits the following comments on proposed revisions to 4731-10-02 Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement.

The Ohio Academy of Family Physicians has a long-standing policy of opposing the mandate of content specific CME as a condition of licensure. Physicians are professionals

who should have the ability to choose what CME they need to provide appropriate care within their unique practice setting for their patients.

With the State Medical Board's recent support of the reduction of CME for licensure of MDs, DOs, and DPMS, this ability to select pertinent and appropriate CME for the individual licensee's practice and patient population is even more important. Given the scope of topics on which physicians need to stay current, mandating the completion of one hour of CME every two years on this single issue seems excessive. We certainly agree that it is vitally important that licensees understand and abide by the licensee's duty to report misconduct provisions of the law, but think that devoting one hour out of the required 50 every two years is extreme. Could not the same goal be accomplished by a statement on the licensure application reiterating the licensee's duty to report misconduct with a checkbox that the licensee must check verifying that they have read and understand (to be completed every licensing cycle)?

Over the years, content specific CME as a condition of licensure has been proposed many, many times on a variety of hot button topics. Topics tend to address an current issue that may diminish in urgency over time or is adequately addressed in other ways. If all of these topics were mandated, physicians would be locked into very specific areas of learning which address a hot topic at the time but may or may not be beneficial to them and their practice long-term or even immediately. Yes, physicians need to understand and follow the duty to report misconduct provisions of section 4731.224 of the Ohio Revised Code, but we question whether mandating one hour of CME on this topic every two years is the best way to ensure understanding and compliance now and into the future.

Thank you for your consideration.

Ann

**Ann M. Spicer | Executive Vice President**

**Ohio Academy of Family Physicians**

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PHYSICIANS  
ASSOCIATION

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*Dedicated to promoting the highest quality care for people with mental disorders and to serving the professional needs of Ohio's psychiatric physicians.*

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Cleveland

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Columbus

Newsletter Editor  
**Henry Nasrallah, MD**  
Cincinnati

Executive Director  
**Janet Shaw, MBA**

Administrative Assistant  
**Michelle Mazza**

June 12, 2020

Kimberly Anderson  
Chief Counsel  
State Medical Board of Ohio  
30 East Broad Street, 3<sup>rd</sup> Floor  
Columbus, OH 43215

Dear Ms. Anderson:

Thank you for the opportunity to comment on several proposed rules, including 4731-10-02 which would require one hour of continuing medical education (CME) on the topic of a licensee's duty to report misconduct. On behalf of the more than one thousand psychiatrists who are members of the Ohio Psychiatric Physicians Association (OPPA), I am writing to express our opposition to mandated topic-specific CME for licensure.

The OPPA believes that physicians should select and engage in CME based on their own needs and professional learning gaps. Over the years, topic-specific CME as a condition of licensure has been proposed many times. The topics tend to be issues of importance in the moment that may or may not be relevant over time. Such topics can often be addressed in other ways, including information available on websites, news articles addressing the topic of concern and a listing of available CME offerings on the proposed issue to be addressed.

Physicians need to understand and follow 4731.224 of the Ohio Revised Code that requires reporting of professional misconduct. We believe that continued information about this requirement of Ohio law, shared by their professional organizations, is a much better way of helping physicians to understand compliance of duty to report.

The OPPA recognizes the importance of this duty to report and will take steps to educate (and remind) its members now and in the future.

Sincerely,

Megan Testa, MD  
President

3510 Snouffer Road  
Suite 101  
Columbus, Ohio 43235-4217  
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(614) 481-7559 Fax

E-mail:  
oppa@ohiopsychiatry.org

Website:  
www.ohiopsychiatry.org

**From:** [Jennifer Hayhurst](#)  
**To:** [Anderson, Kimberly](#)  
**Cc:** [CSIPublicComments](#)  
**Subject:** OSMA Comments regarding proposed CME rule changes  
**Date:** Friday, June 12, 2020 3:06:40 PM  
**Attachments:** [2019.11.7 CME mandate misconduct medical board.pdf](#)

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Kim,

Good afternoon. Regarding the proposed CME rule changes the board is currently considering, I have attached the OSMA's November 2019 comment letter. Our position remains the same regarding the proposed changes to Ohio Administrative Code 4731-10-02, Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement. The OSMA has existing policy against the medical board mandating topic-specific CME.

If you have any questions, please feel free to contact me.

Have a great weekend!

Jennifer

**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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**\*\*\* DRAFT - NOT YET FILED \*\*\***

4731-10-02

**Requisite hours of continuing medical education for license renewal or reinstatement.**

(A) During a registration period, a licensee shall be required to complete fifty hours of CME. A licensee must complete a minimum of one hour of CME, approved by the board, on the topic of a licensee's duty to report misconduct under section 4731.224 of the Revised Code. The remainder shall be completed by participating in the following:

- (1) Educational activities recognized by the American medical association as category 1 pursuant to its CME categorization system, and
  - (a) Are certified for category 1 CME credit by the Ohio state medical association
  - (b) Are certified for category 1 CME credit by an institution or organization accredited by the Ohio State Medical Association or the Accreditation Council for Continuing Medical Education; or
  - (c) Have been awarded category 1 CME credit directly by the American medical association.
- (2) Educational activities recognized by the American osteopathic association as category 1-A pursuant to its CME categorization system, and
  - (a) Are certified for category 1-A CME credit by the Ohio osteopathic association
  - (b) Are certified for category 1-A CME credit by an institution or organization accredited by the Ohio osteopathic association or the American osteopathic association; or
  - (c) Have been awarded category 1-A CME credit directly by the American osteopathic association
- ~~(3) Educational activities recognized by the American osteopathic association as category 2-A pursuant to its CME categorization system~~
- (4) Educational activities certified for category 1 CME credit by the Ohio foot and ankle medical association
- (5) Educational activities certified for continuing education contact hours by a provider approved by the council on podiatric medical education
- (6) Internships, residencies, or fellowships accredited by the accreditation council for graduate medical education, the American osteopathic association, or the council on podiatric medical education. Credit shall be earned at a rate of one hour of CME for each week of participation.

**\*\*\* DRAFT - NOT YET FILED \*\*\***

4731-10-02

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- (7) Pursuant to section 4745.04 of the Revised Code, providing health care services in Ohio, as a volunteer, to indigent and uninsured persons, up to a maximum of three hours per registration period.
- (B) If a licensee has not completed the requisite hours of CME, a licensee is not eligible for license renewal or license reinstatement until such time as the requisite hours have been completed. Any CME undertaken after the end of a registration period and utilized for purposes of renewing or reinstating a suspended license cannot also be utilized to meet the CME requirement of the current registration period.
- (C) Licensees who are not working in the medical profession or who are retired from practice but wish to renew or reinstate their licenses shall meet the CME requirements of section 4731.282 of the Revised Code and this chapter of the Administrative Code.
- (D) Licensees residing or practicing out of the state who wish to renew or reinstate their licenses must meet the CME requirements of section 4731.282 of the Revised Code and this chapter of the Administrative Code even though not currently residing or practicing in Ohio.
- (E) During a volunteer registration period, every holder of a volunteer's certificate shall be required to complete one hundred fifty hours of CME pursuant to the requirements of section 4731.295 of the Revised Code. Seventy-five hours must meet the criteria established in paragraph (A)(1) of this rule. If a holder of a volunteer's certificate has not completed the requisite hours of CME, a holder is not eligible for certificate renewal until such time as the requisite hours have been completed. Any CME undertaken after the end of a volunteer registration period and utilized for purposes of renewing a suspended certificate cannot also be utilized to meet the CME requirement of the current volunteer registration period.
- (F) During a clinical research registration period, every holder of a clinical research faculty certificate shall be required to complete seventy-five hours of CME pursuant to the requirements of section 4731.293 of the Revised Code. Such hours must meet the criteria established in paragraph (A)(1) of this rule. If a holder of a clinical research faculty certificate has not completed the requisite hours of CME, a holder is not eligible for certificate renewal until such time as the requisite hours have been completed. Any CME undertaken after the end of a clinical research registration period and utilized for purposes of renewing a suspended certificate cannot also be utilized to meet the CME requirement of the current clinical research registration period.
- (G) During a conceded eminence registration period, every holder of a certificate of conceded eminence shall be required to complete fifty hours of CME pursuant to the requirements of section 4731.297. Such hours must meet the criteria established in paragraph (A)(1) of this rule. If a holder of a certificate of conceded eminence

**\*\*\* DRAFT - NOT YET FILED \*\*\***

[4731-10-02](#)

3

has not completed the requisite hours of CME, a holder is not eligible for certificate renewal until such time as the requisite hours have been completed. Any CME undertaken after the end of a conceded eminence registration period and utilized for purposes of renewing a suspended certificate cannot also be utilized to meet the CME requirement of the current conceded eminence registration period.



# Common Sense Initiative

**Mike DeWine**, Governor  
**Jon Husted**, Lt. Governor

**Carrie Kuruc**, Director

## Business Impact Analysis

Agency, Board, or Commission Name: State Medical Board of Ohio

Rule Contact Name and Contact Information:

Kimberly Anderson, Chief Counsel, [kimberly.Anderson@med.ohio.gov](mailto:kimberly.Anderson@med.ohio.gov)

Regulation/Package Title (a general description of the rules' substantive content):

Physician continuing medical education rules

Rule Number(s): 4731-10-10-01, 4731-10-02, 4731-10-03, 4731-10-04, 4731-10-05, 4731-10-06, 4731-10-07, 4731-10-08, 4731-10-09, 4731-10-10, 4731-10-11

Date of Submission for CSI Review: May 26, 2020

Public Comment Period End Date: June 12, 2020

**Rule Type/Number of Rules:**

New/\_\_\_ rules

No Change/\_\_\_ rules (FYR? \_\_\_)

Amended/ X rules (FYR? \_\_\_)

Rescinded/ X rules (FYR? \_\_\_)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

## **Reason for Submission**

- 1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

**Which adverse impact(s) to businesses has the agency determined the rule(s) create?**

**The rule(s):**

- Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- Requires specific expenditures or the report of information as a condition of compliance.**
- Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

## **Regulatory Intent**

- 2. Please briefly describe the draft regulation in plain language.**

*Please include the key provisions of the regulation as well as any proposed amendments.*

### **4731-10-01**

- Adds definitions for applicable registration periods for holders of clinical research faculty certificates and certificates of conceded eminence
- Amends or deletes definitions to promote consistency and clarity

### **4731-10-02**

- Makes the rule consistent with the statute by requiring physicians to complete fifty hours of CME and defines the type of activities that are eligible for credit
- Requires one hour of CME on the topic of a licensee's duty to report misconduct under section 4731.224 of the Revised Code pursuant to recommendations from the Governor's working group on reviewing the Medical Board's handling of the investigation involving Richard Strauss recommended the following:

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*The Medical Board should require that physician continuing education requirements toward maintaining a medical license include training on the duty to report pursuant to Ohio Revised Code § 4731.224, including, as necessary, revising the Medical Board's rules contained in Ohio Administrative Code Ch. 4731-10, "Licensing; Continuing Education."*

- Defines the type of CME that must be completed by holders of clinical research faculty certificates, certificates of conceded eminence, and volunteer's certificates

#### **4731-10-03**

- Clarifies that the waiver provisions apply to holders of clinical research faculty certificates, certificates of conceded eminence, and volunteer's certificates
- Removes restrictions on the granting of waivers in order to provide the board with more discretion

#### **4731-10-04**

- Clarifies the intent of this provision but no substantive change

#### **4731-10-05**

- Propose to rescind as provision is now in proposed 4731-10-02(D)

#### **4731-10-06**

- Propose to rescind as it reflects the prior process of mailing renewal applications and the use of staggered renewal system.

#### **4731-10-07**

- Propose to rescind as the provision has been amended and moved to 4731-10-02(A)(2)

#### **4731-10-08**

- Clarifies that that this rule applies to holders of clinical research faculty certificates, certificates of conceded eminence, and volunteer's certificates, and makes other textual changes

#### **4731-10-09**

- Propose to rescind as proration will no longer be necessary. Effective October 16, 2019, initial licenses will be issued for a full two years.

#### **4731-10-10**

- Propose to rescind as staff believes it is unnecessary considering the other provisions of the rules, and the fact that the total number of CME hours has been reduced from one hundred to fifty. Applicants for restoration are required to prove that CME has been completed within the prior twenty-four months prior to the restoration application, and if an applicant has not, then the

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applicant must do so before restoration. As a result, after restoration, licensees have generally met the applicable requirement at the time of the next renewal. It should also be noted that rule currently applies to less than two hundred individuals per year.

#### **4731-10-11 Telemedicine Certificates**

- Propose to rescind as telemedicine licenses will be abolished effective October 16, 2019

#### **3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

Statutory authority: 4731.295, 4731.281, 4731.05

Amplifying statutes: 4731.281, 4731.296, 4731.295, 4731.294, 4731.293, 4731.292, 4731.291, 4731.282

#### **4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

*If yes, please briefly explain the source and substance of the federal requirement.*

No.

#### **5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not applicable.

#### **6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Continuing medical education is statutorily required by Revised Code Section 4731.282. The amendment to Rule 4731-10-02 fulfills Governor DeWine's recommendation to include required education on reporting misconduct. In addition, the rules protect the public by ensuring that physicians are up to date on current medical knowledge and procedures.

#### **7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of these regulations will be measured by physician licensees completing the requisite number of continuing education hours; the rules being written in plain,

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understandable language; licensee compliance with the rules; and minimal questions from the licensees about the proposed rules.

**8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No.

**Development of the Regulation**

**9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

Interested parties that have requested notification of proposed rule changes, including the Ohio Academy of Family Physicians, Ohio State Medical Association, Cleveland Clinic Foundation, Ohio Osteopathic Association, Ohio Foot and Ankle Association, were notified via email on 10/29/19.

**10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

The Board received three comments. Ann Spicer, Executive Vice-President of the Ohio Academy of Family Physicians and Susan Hubbell, M.D., President of the Ohio State Medical Association objected to the addition of content specific CME to Rule 4731-10-02, OAC. James Young, MD, Chief Academic Officer for the Cleveland Clinic proposed using “credits” rather than “hours” in rules 4731-10-10, 4731-10-02 and 4731-10-08, OAC.

Section 4731.282, Ohio Revised Code, the statute which authorizes the CME rules utilizes the term “hours”, rather than “credits. The specific content in proposed Rule 4731-10-02, OAC, conforms to Governor DeWine’s recommendation to include required education on reporting misconduct.

**11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

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[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

The proposed rules are not amenable to scientific data.

**12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

No alternative regulation was considered because no problems have been encountered with the current rules.

**13. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The proposed rules are performance based.

**14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The Medical Board is the only state agency that licenses physicians.

**15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The rule will be posted on the Medical Board's website. Medical Board staff members are available by telephone and e-mail to answer questions.

**Adverse Impact to Business**

**16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

**a. Identify the scope of the impacted business community; and**

The business community impacted is composed of physician licensees regulated by the Medical Board.

**b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**

The adverse impact is that licensed physicians will be required to expend money for taking mandated continuing medical education.

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- c. **Quantify the expected adverse impact from the regulation.**  
*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.*

The cost of continuing medical education varies greatly based upon the vendors, ranging from no cost to thousands of dollars, depending on the type and length of the course.

**17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

It is essential that the Medical Board and the general public is assured that physician licensees are up to date on medical knowledge and procedure, as well as Governor DeWine’s recommendation that licensees are aware of their obligations to report violations of the Medical Practices Act.

**Regulatory Flexibility**

**18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

There is no exemption or alternative means based upon the size of the business, as continuing medical education is required by statute. Rule 4731-10-03 does allow for a waiver if the physician is unable to complete the education due to illness, accident, or absence from the state.

**19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

Fines for failing to complete continuing medical education are statutory, per Revised Code Section 4731.282.

**20. What resources are available to assist small businesses with compliance of the regulation?**

Board staff is available to answer questions regarding the rule. The rules are posted and are available on the Board’s website.

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[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

To: Amol Soin, Chair, Policy Committee, SMBO

Cc: Dr. Michael Schottenstein, President SMBO

Stephanie Loucka, Executive Director SMBO

Kimberly Anderson, Chief Legal Counsel SMBO

7/6/2020

Dr. Soin,

I am responding to the Ohio Osteopathic Association (OOA) opposition to the added allowance of the American Osteopathic Association (AOA) Cat. 2A credits for osteopathic physicians as a condition of licensure and their request to restore the original language stating: A licensee shall be required to complete 50 hours of Category 1 CME as certified by their respective state professional associations and approved by the board. Certification is a process whereby the Ohio Osteopathic Association defines its respective CME program requirements.

The AOA has Cat. 1A, 1B, 2A, & 2B credits. Basically, Cat. 1 CME credits are AOA accredited sponsors and AOA Cat. 2 credits are AMA PRA Cat. 1 CME's sponsored by AACME accredited providers. The OOA has the same categories with the addition of Cat. 1C. To receive Cat. 1C credits, the osteopathic physician completes the OOA Application for Category 1-C Credit form which is a request for Category reclassification from Category 2 to Category 1-C. The OOA fee for processing this form is \$25.00. Please be aware, this is the OOA process which was mentioned in the letter. It is in place because, in the past, this process was required of Ohio Osteopathic physicians prior to the acceptance of the AOA Cat. 2A credits.

If the AOA Cat. 2A credits, which are AMA PRA Cat I credits, are no longer recognized then osteopathic physicians who complete allopathic credits (i.e. CME programs, Residency or Fellowship training) will, once again, be required to complete the OOA Cat 1C credit form and pay the \$25.00 fine to meet the CME requirement.

I am concerned that the deletion of the paragraph 4731-10-02 (A)(3) referencing AOA category 2-A CME credits and the restoration of the original language may be an unnecessary burden and not fair to some osteopathic physicians especially if allopathic options meet their CME needs.

I would suggest we keep the language as is and not make any revisions.

I look forward to our discussion concerning this matter in the Policy meeting on 7/8/2020.

Please feel free to contact me with any questions.

Sincerely,

Dr. Sherry Johnson

State Medical Board of Ohio



## MEMORANDUM

TO: State Medical Board of Ohio Members  
FROM: Stephanie Loucka, Executive Director  
RE: Telehealth Legislation, Sub House Bill 679  
DATE: June 17, 2020

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### **Introduction**

As was discussed in the June Medical Board Policy meeting, HB 679 was introduced in the House of Representatives at the end of May. The bill was fast tracked through the House Insurance Committee. There was an amendment accepted during committee that then created a Sub Bill. This Sub bill was voted out of the House Insurance committee and on by the full House on June 10<sup>th</sup>. The Medical Board did not have the opportunity to weigh in on the bill as it made its way through the House.

Sub House Bill 679 will be introduced in the Senate and referred to Committee. The House and Senate are now in Summer recess. We will work with various members of the Senate throughout the summer.

You can view the entire text of the bill here:

<https://www.legislature.ohio.gov/legislation/legislation-summary?id=GA133-HB-679>

### **Legal Analysis**

Board counsel authored two memos for analysis (attached). The first memo is on HB 679, as introduced. The second memo is on Sub HB 679, as passed by the House. The memo on the Sub bill supplements the original memo.

### **Stakeholder input**

Several organizations gave [testimony](#) before the House Insurance Committee on June 9<sup>th</sup>: Testimony from the OSMA is attached to this memo. It appears as if the House accepted the suggestions of the OSMA.

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### **Issues for Board consideration:**

There are a variety of issues for Board consideration. While staff can likely surmise the Board's position on most items below, given the importance of the bill, staff would like Board input. Additionally, staff encourages Board members to share any relevant thoughts on telehealth (not just those listed below), as staff will then convey those thoughts in legislative meetings.

Items of note in the Sub bill:

**Applicability to particular health care issues or existing telehealth requirements:** The bill does not account for existing Medical Board telehealth statutes. Specifically, the Board has in person visit requirements for various public health concerns (prescribing; medical marijuana; office based opiate treatment).

- Should Board staff advocate to keep existing provision?
- Are there additional provisions to add?
- Should existing provisions change?

**Initial Visit:** The amended sub bill removed the requirement of the initial visit to be in-person.

- Is the Board comfortable with the as amended elimination of in-person visits?

**Standard of care:** The bill is not clear on the Board's ability to establish standard of care for telehealth.

- Should Board staff advocate for explicit rule making authority to define standard of care for telehealth provided by Board licensees (beyond the basic requirements spelled out in the bill)? It appears as if tele-dentistry sought and received this clarification.

**Out of state telehealth:** The bill creates a conflict with the more restrictive, existing Board statutes on the provision of out of state telehealth services.

- Is the Board comfortable with the more relaxed requirements in HB 679?

**Billing practices:** Communications for which licensees can bill are expanded in the sub bill. Additionally, the methodology for accounting for time for phone and email communications are changed.

- Is the Board comfortable with the bill's requirements for billing practices?

**Equal application of Board regulations:** As introduced by the House, the bill created specific provisions in the Medicaid statutes. These conflicted with other provisions. While resolved in the amended sub bill, Board staff will work to ensure that these consistencies remain clarified so that services can be rendered equally regardless of payor.

## **Next steps for the Board**

**Board feedback:** Board staff will collect feedback provide a summary back to the Board.

- Board feedback CAN include items not covered in the legislation (but maybe should be covered in future versions)
- If there is conflict in feedback, or Board members would like more dialogue before the next Board meeting, staff can notice an Ad Hoc Telehealth Subcommittee of Policy
- Given the major change in health care delivery offered by telehealth, the Board should consider either a standing Telehealth agenda item in Policy Committee or a monthly Telehealth Committee as new laws and rules get crafted and operationalized

**Written position:** Given the major shift in health care delivery created by HB 679, Board staff recommends the Medical Board have a written position on the bill to share with legislators. After staff receives feedback from Board members, a draft statement will be created for review.

**Stakeholder outreach:** Board staff will work with all licensee associations, as well as other state healthcare boards to better understand the positions and interests of the various groups.

**Legislative strategy:** Board staff will create a list of issues to lobby once input is received from the Board; general outreach to Senate members will begin immediately. Once the bill is introduced in the Senate, staff will get the Board's statement to the Senate Bill sponsors as well as the committee chair and committee members that will be hearing the legislation. We will set up times to meet with the committee staff and sponsors as well as the appropriate senate chamber staff to brief them. Most likely, the bill will be heard in the Senate Insurance and Financial Institutions Committee:



MEMORANDUM

TO: Michael Schottenstein, MD, President, State Medical Board of Ohio  
Members, State Medical Board of Ohio

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

DATE: June 3, 2020

RE: Legal Analysis of HB 679 Telehealth Services and its Impact on Medical Board  
(Draft protected by Attorney-Client privilege and Attorney Work Product  
doctrine)

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This memorandum provides a legal analysis of the following questions regarding the impact of House Bill 679 Telehealth Services on the Medical Board:

- (1) What is the jurisdiction of the Board related to this bill?
- (2) What would be the impact on other Board statutes and rules? (4731-11-09, prescribing rules, etc.)
- (3) Are there legal concerns with standard of care and the ability to bring a standard of care action?

**Jurisdiction of the Medical Board related to this bill**

Proposed section 4743.09(B) in HB 679 states that “Each health care professional licensing board shall permit a health care professional under its jurisdiction to provide the professional's services as telehealth services in accordance with this section. The board may adopt any rules it considers necessary to implement this section.”

The proposed statute defines “health care professional licensing Board” to include the State Medical Board; and also states that “health care professional” includes these Medical Board licensees: physicians (M.D., D.O., and D.P.M), physician assistants, and dietitians. Proposed sections 4730.60 and 4759.20 provide that PAs and dietitians respectively may provide telehealth services in accordance with proposed section 4743.09. Section 4743.09 is proposed to replace R.C. 4731.2910 which dealt with Fees for Telemedicine Services for physicians and PAs.

Section 4743.09(C) lists the following requirements for the provision of telehealth services:

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- (1) A health care professional shall conduct an initial in-person visit with a patient before providing telehealth services to the patient, except that the professional may waive this requirement if the professional determines that a situation is critical and an in-person visit is not practical.
- (2) A health care professional may deny a patient telehealth services and, instead, require the patient to undergo an in-person visit.
- (3) When providing telehealth services, a health care professional shall use technology with secure video capabilities . A health care professional shall ensure that any username or password information and any electronic communications between the professional and a patient are securely transmitted and stored.
- (4) A health care professional shall conduct at least one in-person visit each year with each patient who receives telehealth services from the professional, except that the professional may waive this requirement if the professional determines that a situation is critical and an in-person visit is not practical.
- (5) In the case of a health care professional who is a physician, physician assistant, or advanced practice registered nurse, both of the following apply:
  - (a) The 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.
  - (b) The professional may provide 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.

Thus, HB 679 provides the Medical Board jurisdiction and authority to implement the bill's requirements through its rules.

HB 679 also amends R.C. 5164.95 which is the Ohio Department of Medicaid statute on Standards for Payment of Telehealth Services. Proposed R.C. 5164.95(C)(1) states that physicians (M.D., D.O., and D.P.M.), physician assistants and dietitians are among the practitioners that "are eligible to render telehealth services covered pursuant to his section." However, the Medical Board is not given any explicit statutory jurisdiction or rulemaking power regarding telehealth services by these Medical Board licensees providing services payable by Medicaid.

While it is assumed that the requirements of 4743.09 are applicable regardless of payor, there are differences between the two proposed sections. Section 4743.09(C)(3) requires the health care professional to "use technology with secure video capabilities", but section 5164.95(D)(1) only states that "any electronic communications between the practitioner and patient" be securely transmitted and stored. Further, proposed R.C. 5164.95 provides detail as to the types of health care services for which Medicaid will render payment that is not included in the more general language of section 4743.09.

Any Medical Board rules promulgated should apply equally regardless of insurance type or method of payment and should consider both of these proposed sections.

## **Impact on other Board statutes and rules**

HB 679 does not directly address existing statutes or rules involving telehealth services. Interestingly, proposed R.C. 4743.09(C) states that the above described list of requirements “all apply to the provision of telehealth services.” It does not state that these requirements are exclusive, but it also does not acknowledge the existence of other telehealth requirements in statutes or rules.

This language does not clear up any existing uncertainty or potential statutory conflict. For instance, R.C. 4743.09(C)(5)(a) states that a physician or a PA “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.” This language makes the ability of physicians and PAs to provide telehealth services to out of state patients dependent on the laws of another state. However, this is more expansive than the current restrictions for physicians that exist in R.C. 4731.36(A) which allows telehealth only in these circumstances:

- (4) A physician or surgeon in another state or territory who is a legal practitioner of medicine or surgery therein and provided services to a patient in that state or territory, when providing, not later than one year after the last date services were provided in another state or territory, follow-up services in person or through the use of any communication, including oral, written, or electronic communication, in this state to the patient for the same condition;
- (5) A physician or surgeon residing on the border of a contiguous state and authorized under the laws thereof to practice medicine and surgery therein, whose practice extends within the limits of this state. Such practitioner shall not either in person or through the use of any communication, including oral, written, or electronic communication, open an office or appoint a place to see patients or receive calls within the limits of this state.

Further, the requirements of R.C. 4743.09 focus on the general logistics of telehealth services without specific requirements for special situations which impact public health such as prescribing, recommending medical marijuana, and officed based opioid treatment. These are situations where the Medical Board has rules regarding the necessity of in person visits with articulated exceptions. This is an area where the Medical Board could seek to amend the legislation to provide more clarity so that particular situations where public health concerns require inpatient visits are not subject to blanket requirements for telehealth.

While HB 679 does not specifically address other existing statutes or rules that involve telehealth, it does address and leave intact statutes regarding supervision, collaboration, or referral agreements or practices. Specifically, proposed section 4743.09(F) states that “[n]othing in this section eliminates or modifies any other provision of the Revised Code that requires a health care professional who is not a physician to practice under the supervision of, in collaboration with, in consultation with, or pursuant to the referral of another health care professional.”

## **Discussion of Legal concerns with Standard of Care and the Ability to Bring a Standard of Care Action**

Proposed section 4743.09 does not set many requirements for the standard of care. However, division (D) of the proposed statute states “When a patient has consented to receiving telehealth services, the health care professional who provides those services is not liable in damages under any claim made on the basis that the services do not meet the same standard of care that would apply if the services were provided in-person.” Thus, for civil liability, this proposed statutory language indicates that the standard of care for telehealth services is lower than that for in person healthcare services provided. This does not directly speak to the standard of care for telehealth services for professional disciplinary action by the Medical Board.

The Medical Board is authorized by proposed section 4743.09(B) to “adopt any rules it considers necessary to implement this section.” This would at the least allow the Medical Board to adopt rules that make it a violation of minimal standards of care for failure to follow the listed requirements in the proposed 4743.09(C). These violations would be for failing to:

- (1) conduct an initial in-person visit with a patient before providing telehealth services to the patient, except that the professional may waive this requirement if the professional determines that a situation is critical and an in-person visit is not practical.
- (2) use technology with secure video capabilities . A health care professional shall ensure that any username or password information and any electronic communications between the professional and a patient are securely transmitted and stored.
- (3) conduct at least one in-person visit each year with each patient who receives telehealth services from the professional, except that the professional may waive this requirement if the professional determines that a situation is critical and an in-person visit is not practical.

These requirements are not as substantive as the standard of care prescribed in Board rules such as OAC 4731-11-09 for prescribing to persons not seen by the physician or OAC 4731-32-03 Standard of Care for recommending treatment with medical marijuana. These rules include the necessity of establishing a diagnosis and treatment plan and specific requirements for documentation in the medical record.

One could make the argument that the phrase “adopt any rules it considers necessary to implement this section” would include rules that prescribe a more detailed the standard of care. A narrower reading of HB 679 would allow the Medical Board to bring a standard of care action, but for the limited requirements in 4743.09(C). One possible amendment to the legislation could be authorizing each health care professional licensing board to establish the standard of care for its licensees by rule. This rule authorization could also enable boards to eliminate any potential conflicts with existing rules on telehealth or rules that require an in-person visit.



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MEMORANDUM

TO: Michael Schottenstein, MD, President, State Medical Board of Ohio  
Members, State Medical Board of Ohio

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

DATE: June 11, 2020

RE: Legal Analysis of Amended Substitute House Bill 679 Telehealth Services as passed by the House and its Impact on Medical Board (Draft protected by Attorney-Client privilege and Attorney Work Product doctrine)

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This memorandum provides a summary of provisions in Am. Sub. HB 679 as passed by the House that affect the Medical Board and its licensees. It should be read in conjunction with the June 3, 2020 legal memo provided to the Board discussing the bill's effect on: (1) jurisdiction of the Board as to telehealth; (2) other Medical Board laws and rules; and (3) legal concerns with standard of care and the ability to bring a standard of care action. This bill, as passed on June 10, 2020, does not alleviate most of those concerns. Only further amending of the bill will address the concerns raised in the initial memo and additional questions and concerns expressed in Policy Committee.

**Standard of Care for Initial and Annual Visits**

Proposed section 4743.09(B) in Am. Sub. HB 679 states that “Each health care professional licensing board shall permit a health care professional under its jurisdiction to provide the professional's services as telehealth services in accordance with this section. The board may adopt any rules it considers necessary to implement this section.”

Section 4743.09(C) states “[w]ith respect to the provision of telehealth services all of the following apply:

- (1) A health care professional may use technology to provide telehealth services to a patient during an initial visit **if the appropriate standard of care for an initial visit is satisfied.**
  - (2) A health care professional may deny a patient telehealth services and, instead, require the patient to undergo an in-person visit.
  - (3) When providing telehealth services in accordance with this section, a health care professional shall comply with all requirements under state and federal law regarding the protection of patient information. A health care professional shall ensure that any username or password information and any electronic communications between the professional and a patient are securely transmitted and stored.
-

(4) A health care professional may use technology to provide telehealth services to a patient during an annual visit **if the appropriate standard of care for an annual visit is satisfied.**

(5) In the case of a health care professional who is a physician, physician assistant, or advanced practice registered nurse, both of the following apply:

(a) The 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.

(b) The professional may provide 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.

With respect to requirements (C)(1) and (C)(4), the as introduced version of the bill required an initial and annual in-person visit “except that the professional may waive this requirement if the professional determines that a situation is critical and an in-person visit is not practical.” The current as passed version is more lenient in allowing initial and annual visits to occur via telehealth, but does require that “the appropriate standard of care” for an initial visit or annual visit be satisfied.

Additionally, the original requirement for providing telehealth services via technology with secure video capabilities was eliminated in (C)(3). There is no differentiation for types of services where video may be more appropriate. This change removes the inconsistency between telehealth services provided by Medicaid and those provided by other payors regarding technology to be used.

Further, the bill eliminated the more restrictive requirement that only specifically enumerated services could be provided via telehealth for Medicaid and for telehealth services provided by community mental health and addiction services providers certified by the Ohio Department of Mental Health and Addiction Services. This change eliminates inconsistency regarding reimbursable telehealth services among different payors.

Proposed section 4743.09 does not define the standard of care, but division (D) states “When a patient has consented to receiving telehealth services, the health care professional who provides those services is not liable in damages under any claim made on the basis that the services do not meet the same standard of care that would apply if the services were provided in-person.” Thus, for civil liability, this proposed statutory language indicates that the standard of care for telehealth services is different than that for in person healthcare services provided.

This does not directly speak to the standard of care for telehealth services for professional disciplinary action by the Medical Board, but does highlight the need to explicitly define the standard care or allow the healthcare professional licensing board to define this standard of care by rule especially since (C)(1) and (C)(4) reference the “appropriate standard of care”.

A standard of care requirement that informed consent be obtained once before billing for telehealth services was added in the as passed version of the bill.

The conflict between division (C)(5)(a) and the more restrictive Medical Board provisions for providing out of state telehealth services in R.C. 4731.36(A) remains in the as passed version of the bill.

### **Addition of Comprehensive Teledentistry Provisions in Floor Amendment**

A House floor amendment was added into the bill that allowed the Dental Board to define the standard of care for teledentistry and treats the specialized practice of dentistry as needing specialized requirements for the providing of teledentistry services. The amendment listed several requirements for the standard of care that all licensed dentists must have in written protocols including a catch all provision for “any other provisions required by the board.” The amendment also included this language specific to the standard of care:

“(3) Dental services delivered through the use of teledentistry shall be consistent with the standard of care, including when the standard of care requires the use of diagnostic testing or the performance of a physical examination, and comply with the requirements of this chapter and rules of the board.”

This same sort of amendment could be an avenue for the Medical Board to pursue to achieve clarity for the standard of care for telehealth services by its licensees and also consistency with the Medical Board’s other statutes and rules that speak to either telehealth or the requirement of an in-person visit in specialized situations such as prescribing drugs, recommending medical marijuana, and office based opioid treatment.

### **Insurance Issues for Medical Board Licensee**

Last, there are changes to insurance and reimbursement requirements. Proposed R.C. 4743.09(E)(2) adds that “A health care professional may negotiate with a health plan issuer to establish a reimbursement rate for fees associated with the administrative costs incurred in providing telehealth services as long as a patient is not responsible for any portion of the fee.”

Also, the bill retains the requirement in R.C. 3902.30 (B)(1) that “a health benefit plan shall provide coverage for telehealth services on the same basis and to the same extent that the plan provides coverage for the provision of in-person services. This has been previously stricken in the as introduced HB 679.

In addition, the bill replaces the original provision that a health benefit plan not impose cost-sharing requirement for telehealth services provided by telephone or email with the following language in R.C. 3902.30(D):

(2)(a) A health benefit plan shall not impose a cost- sharing requirement for a communication when all of the following apply:

(i) The communication was initiated by the health care professional.

- (ii) The patient consented to receive a telehealth service from that provider on any prior occasion.
- (iii) The communication is conducted for the purposes of preventive health care services only.
- (b) If a communication described in division (D)(2)(a) of this section is coded based on time, then only the time the health care professional spends engaged in the communication is billable.

This is a very limited prohibition and would expand the communications for which a cost-sharing requirement could be billed, thus allowing more telehealth services delivered by telephone or email to be billed with a cost-sharing requirement.

Finally, the as passed bill removes the method of reimbursing electronic mail or telephone telehealth services by tallying the minutes spent per patient on a running total and then reimbursing for a block of time spent on the services that is equivalent to the standard amount of time spent on a telehealth service.

To: Members of the Ohio House Insurance Committee

Fr: Joe Rosato, Director of Government Relations, Ohio State Medical Association

Da: June 2, 2020

Re: HB 679

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The Ohio State Medical Association (OSMA) appreciates and commends the Ohio House for taking action on the critical issue of telemedicine. Amidst the ongoing public health emergency presented by COVID-19, many Ohio physicians have taken the opportunity to safely provide care via telehealth during this period. Telemedicine presents a valuable opportunity to better serve certain patient populations, such as those living in rural areas, elderly and disabled patients who cannot easily travel, and people in need of behavioral health care services. OSMA is a longtime advocate for increased access to telemedicine and we are looking forward to continuing to work with elected officials and other interested parties to make access to telehealth easier and more affordable for both physicians and their patients.

Our association would like to offer several technical suggestions regarding the current version of House Bill 679. Please see the specific line numbers from the bill indicated below with our comments.

**Lines 82-84**

These lines would treat telehealth provided by audio only or by email more favorably than telehealth services administered via other means (such as audio/video). Given the vast and changing scope of technology, OSMA suggests that elimination of cost-sharing requirements not be limited to telehealth services delivered by telephone or email, but should encompass all other methods.

**Lines 89-94**

The determination of payment for providers administering telehealth services outlined by these lines in the bill is not consistent with how providers are paid now. We find fundamentally changing the way that providers are reimbursed concerning and believe these provisions require further discussion.

**Lines 200-204, and 214-219**

These requirements currently reside in administrative rule set forth by the state medical board, and therefore, can be lifted as needed, as many have for the duration of the COVID-19 pandemic. As the landscape of telehealth rapidly changes as technology advances, administrative rules can be adjusted or lifted in an easy and timely manner should circumstances prove

necessary. For that reason, OSMA requests that these provisions be removed from the bill.

**Lines 223-225**

It appears these lines intend to address the potential problem of health care providers practicing within the scope of practice laws of the state in which the patient is located. OSMA appreciates the inclusion of this language in the bill; however, as the provider must also practice within the scope of practice laws of Ohio (the state in which they are licensed), we request that additional language be included in HB 679 to reflect that as well.

**Lines 240 – 242**

This language appears to prohibit providers from providing remote patient monitoring services. In addition, OSMA has questions on who would bear the cost of the devices, and how health care providers would be reimbursed.

**Lines 244-246**

This provision would exempt telehealth services from the requirement for patient consent before billing for care delivery. OSMA believes that it is still important for patients to provide informed consent before being billed for telehealth services, so we suggest that for the protection of patients, these lines be changed to instead require a one-time consent for patients exclusively being seen via telehealth similar to how billing consent is received from a patient done for an initial in-person visit.

**Line 267 – 281**

These lines define what services are able to be delivered via telehealth. This seems to be contradictory to earlier lines 112 - 114 in the bill which mention coverage parity. Therefore, we would recommend lines 267 – 281 be removed.

**Lines 324-327**

This language would limit where patients can receive telehealth services, and in effect, exclude their own homes. Currently, many patients are safely receiving care at home through telehealth to help prevent the spread of COVID-19. As these provisions would undermine the intent of the bill by severely restricting delivery of telehealth services and excluding many patients from the ability to receive care through telehealth, OSMA requests that these lines be removed.

**Lines 447 – 479**

These lines define what services are able to be reimbursed via telehealth. This seems to be contradictory to earlier lines 112 - 114 in the bill which refer to coverage parity. Therefore, we would recommend lines 447 – 479 be removed.

We would be remiss not to mention reimbursement parity for telehealth services, which has been one of our highest priorities in the efforts to facilitate telehealth access. OSMA continues to strongly

encourage that health plans be required to reimburse health care professionals for telehealth services at the same rate as in-person services. Provided that such services are clinically appropriate to be delivered via telehealth, these services should be reimbursed at the same level as they would be reimbursed if delivered in-person. This would be a strong tool to empower more widespread utilization of telehealth across the state.

In our efforts to improve access to care, we are dedicated to ensuring that care is just as high-quality as it would be if the provider and patient were in the same room, and that through telehealth we maintain those connections between physician and patient, and the essential human element to the practice of medicine.

Thank you for your consideration of our comments on HB 679. We look forward to discussing this legislation further and encourage you to contact us with any questions.

HB 679	Telehealth				
Issue	Staff Recommendation	IP testimony	Board comments	Next steps as identified in Policy 7/8	
Bill does not account for current SMBO in person requirements	Support bill but with guardrails; lobby senate for guardrails		Dr. Schottenstein: supports existing requirements for in-person; Mr. Giacalone: marijuana, ongoing chronic pain; office based opiate treatment; see additional below comments about in-person requirements and standard of care		
Bill does not require initial in-person visit	Standard of care should dictate initial in-person visits, to include today's requirements and more	<p><b>OSU:</b> Would like patients to be seen in-person by the provider at least once per year or before establishing care</p> <p><b>Buckeye:</b> Such requirements may undermine an obvious benefit of broad-based telehealth: avoiding the time and expense of in-person consultations, especially in rural areas. Annual check-up decisions also should be left to providers and patients to avoid unnecessary care and expense.</p>	Mr. Giacalone: we need some in person requirements (see above); Dr. Feibel: most medical specialties require an initial in-person visit; Dr. Sojin: initial visit is critical for exam, as well as to establish relationship		
Bill is not clear on Board's ability to create standard of care requirements	Advocate for explicit rule making authority (like tele-dentistry); standard of care rules should acknowledge some in-person requirements, including initial visits, where necessary	<p><b>Dental:</b> We are in the process of exploring the next generation of teledentistry, including the use of asynchronous technology to extend dental services in a safe and efficient manner.</p> <p><b>OSMA:</b> Wants lines 200-204, and 214-219 removed from the bill, which relate to administrative SMBO rule</p>	Mr. Giacalone and Dr. Schottenstein support the rule making authority; At 6/10/20 meeting, Dr. Feibel provided examples where standard of care can't be met via telehealth		
Bill creates conflict with current out of state practice reqs	Harmonize approach; support Ohio doctor's ability to support patients out of state; still require licensure for out of state who want to practice here		Dr. Schottenstein: supports ability to practice out of state with patients; Mr. Giacalone: ohio providers should follow ohio and other state's guidelines if practicing out of state		
Bill expands communications for which licensee can bill; changes accounting method of email and telephone	<p><b>Billing:</b> Board should remain neutral on billing; <b>Mode of communication:</b> preference video and allow for discretion for telephone (capability of patient; rural areas); require documentation when video is unavailable</p>	<p><b>OSMA &amp; OSU</b> have various concerns with language in the bill related to billing</p>	<p><b>Billing:</b> Dr. Schottenstein: ok with as passed; Mr. Giacalone question as to whether we've taken a position on billing in the past <b>Mode of communication:</b> Dr. Bechtel and Dr. Johnson (in July meeting): indicated that telephone without video might be useful for more vulnerable populations; Dr. Schottenstein: does not favor restricting ability to conduct visit by telephone; Dr. Sojin: telephone visits should be limited for when there is a lack of video technology; Mr. Giacalone: reminder that the board has seen problematic prescribing practices, reinforcing the need for video</p>		
<p><b>Other areas for discussion at 7/8 meeting:</b></p>					
Further discussion on how telehealth vehicle vary based on different factors (location of patient; disease state; age of patient)					
Ad Hoc Committee or Agenda item in Policy?					
Other items we may want to consider for rules (in addition to in-person requirements)					



**TO:** Stephanie Loucka, Executive Director  
**FROM:** Jill Reardon, Director of External Affairs; Cierra Lynch, Stakeholder Liaison  
**SUBJECT:** State Medical Board of Ohio External Affairs/Legislative Team Overhaul Action Plan  
**DATE:** 6/22/2020

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## Introduction

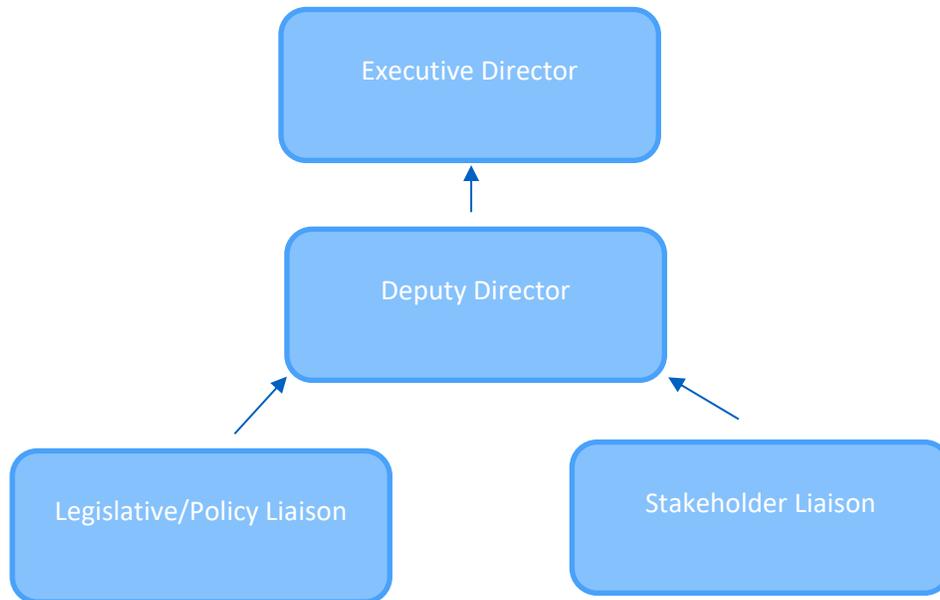
The purpose of this memorandum is to outline the proposed short-term and long-term changes to the State Medical Board's external affairs and legislative team. This memorandum will also showcase several new measures the team will be utilizing to communicate more effectively with board members, policy makers, stakeholders, and other state agencies.

## Content:

1. External Affairs Team Structure
  - a. Current structure
  - b. General role responsibilities
  - c. Short-term objectives
2. Messaging
  - a. Updates to SMBO website
  - b. Weekly legislative newsletter
    - i. Real-time updates
  - c. Communication with agency liaisons and legislative staff
3. Strategy
  - a. Bill tracking
  - b. Activity tracking
  - c. File sharing

## External Affairs Team Structure

### Current Structure:



### General Role Responsibilities:

#### Deputy Director

- Meet with Legislative/Policy (LP) lead and assistant daily to make sure the most relevant legislation is being targeted, and appropriate hearings attended. Discuss messaging and actions needed.
- Get report from LP lead regarding all activity on pertinent legislation in committees and review all testimony given to help determine next steps and keep Exec Director up to date.
- Ensure meetings and communications are taking place with necessary committee members, committee staff and chamber staff and all is appropriately communicated and documented in shared files.
- Work with LP lead to get info together for Exec Director and Board for all bills of interest and determine if board input is needed either at policy committee or sooner if necessary.
- Make sure Exec Director, and board members (if needed) are being used, to weigh in on legislation and to meet with committee chairs, members, and chamber staff.
- Spearhead drafting of testimony given by exec director or other staff.
- Draft and or review all communications to the General Assembly.
- Work with LP on communications to the board and policy committee updates.
- Attend or review all meetings of other state health care boards and update exec director and other exec staff, as necessary.
- Take lead on constituent and legislative inquiry messaging.
- Communicate to, and work with, with stakeholder associations and other state healthcare boards and commissions.
- Coordinate the advisory councils under the Medical Board.
- Coordinate any JCARR or Controlling board messaging to committee members.

## Legislative/Policy Liaison

- Daily check in with DD to talk about legislative strategy/update on bills, committees, and messaging.
- Attend Ohio General Assembly (OGA) committee hearings and coordinate hearing attendance with LP assistant.
- Review all newly introduced legislation that may be of interest to the board. Send newly introduced legislation to Exec Director, Chief legal counsel and DD of External Affairs and any other necessary staff with memo indicating the impact it may have on the Medical Board and its path going forward.
- Monitor status and progress of all legislation of interest to the Medical Board and keep spreadsheet updated in real time of important and of tangential interest. Give brief update daily of legislative actions to Exec Dir, DD and assistant while legislature is in session.
- Keep all legislative and policy info filed in shared documents including meetings held and conversations held.
- Target legislation of the most impact to the board, that has a path to become law, and work with DD for direction on messaging. Any direct messaging to the OGA to be reviewed by the Exec Director and board as appropriate. Send weekly report to the DD of External Affairs and cc Exec Director and assistant.
- Contribute to the weekly legislative update going to the Board, Exec Director and Exec staff.
- Give update at Medical Board Policy Committee meeting of pertinent current legislation and actions taken on that legislation relative to messaging and meetings held.
- Work with DD to determine and then discuss with Medical Board Policy Committee any direction and decisions needed from them on legislation and or policy during the committee meeting or before if necessary.
- Work with any policy committee legislative sub committees.
- Do national and statewide policy research as needed.

## Stakeholder Liaison

- Create and update spreadsheet of all legislation we are following and statuses
- Put all upcoming committee hearings for the senate and house and agenda for the following week on DD's calendar and legislative/policy liaison's calendar.
- Create newsletter update weekly of legislative activity and upcoming week view to send to Board and Exec staff.
- Monitor and spearhead the messaging to all constituent, and other state agencies inquiries.
- Assist with advisory council meetings and communications.
- Coordinate with Medical Board communications to get pertinent information and messaging put on our web site including all testimony given by agency before the OGA.
- Attend OGA committees as assigned.

## Short-term Objectives:

During the summer months, the House and Senate Chambers do not typically meet for session or committees. The external affairs team will use this period of legislative inactivity to accomplish the following tasks:

1. Deputy Director:
  - a. Schedule meetings for Exec. Director to meet with House and Senate leadership, both caucuses and committees.

## 2. Legislative Liaison/Policy Liaison

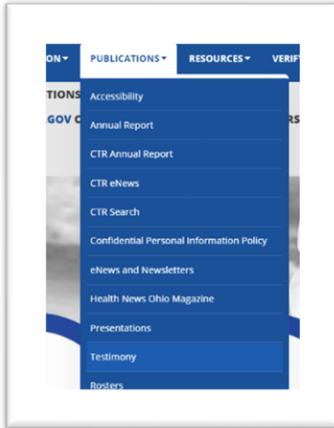
- a. Do introductory meetings with all committee and caucus staff that hear Med bd bills. Introductions to JCARR, Controlling Board, state health care associations and boards and Governor's office legislative staff.
- b. Work with DD and assistant to review all current legislation, impact, board opinions and work with DD and Exec Director to develop strategic plan for fall, any decisions necessary, or opinions needed from the board and next steps that need to be taken.
- c. Work on new legislative status sheet used to update the board
- d. Meet with legislative staff of pertinent health care associations and touch base with them on any positions they have or may be developing on current legislation.
- e. Any policy research needed.

## 3. Stakeholder Liaison

- a. Set up system in Medical Board shared files for all legislative memos, status sheets and bills to be stored. Research and move all documents and emails into that system.
- b. Set up Gongwer and Hannah to perform bill and committee tracking and reports for all pertinent and tangential Medical Board and state government issues.
- c. Work on CoArc reporting for Respiratory Care Advisory Council.
- d. Work on general disciplinary statistic reports that can be presented at each advisory council.

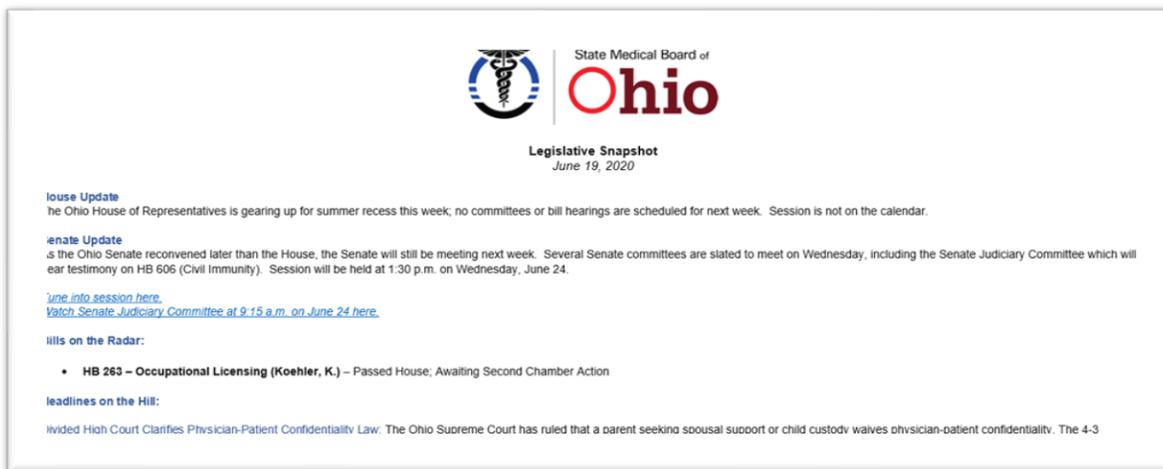
## Messaging

### Website:



**New Testimony Page:** There is currently no legislative section on the State Medical Board Website. We aim to create a dedicated webpage to post all legislative testimony delivered by the State Medical Board. As we move to increase our presence on Capitol Square, having SMBO testimony publicly posted on our website will help stakeholders better understand our position on bills that affect them.

### Weekly Legislative Newsletter:



We will send out a legislative snapshot every Friday at the close of business. The snapshot will provide board members with a comprehensive overview of tracked bill action in the House and Senate, in addition to other developments which affect the Board and its licensees.

- ❖ **Real-time updates:** We will send out memos on important legislative updates to policy committee members in real-time.

### Communication with agency liaisons and legislative staff:

The external affairs team will set up introductory meetings with agency liaisons and legislative staff over the next two months to establish points of contact and improve working relationships.

## Strategy

### Bill tracking:

The external affairs team will create a central bill tracking spreadsheet accessible by all staff members. The spreadsheet will contain all bills the board is currently tracking with their respective sponsor(s), status, position, testimony dates, and links to any relevant documents, such as LSC analysis. The tracker will be updated in real-time. (*Finish date: July 15, 2020*)

### Activity tracking:

As a compliment to the bill tracker, the external affairs team will also create an activity tracker. The activity tracker will record any legislative interactions from the board, such as meeting with legislators or delivering testimony. The tracker will include a date of activity along with a detailed description of the event as well as any relevant documents, such as testimony or meeting hand-outs. (*Finish date: July 15, 2020*)

### File sharing:

The team will create its own external affairs folder in the LAN for all trackers and items to be stored in. This will allow other departments to easily access legislative materials.