AGENDA
POLICY COMMITTEE
DECEMBER 9, 2020

1. Minutes Review
2. Rule Review Update
3. Rules at CSI
   a. Temporary Military Licensure-4731-36-04, OAC
   b. Light-Based Medical Devices-Chapter 4731-18, OAC
   c. Weight-loss rules-4731-11-04, 4731-11-04.1, OAC
   d. Hearing rules-Chapter 4731-13, OAC
   e. Consult Agreement Rules,
4. Legislative Update
5. Pharmacy Board updates
Dr. Soin called the meeting to order at 9:04 a.m.

Minutes Review

Mr. Giacalone moved to approve the draft minutes of the October 14, 2020 meeting of the Policy Committee. Dr. Bechtel seconded the motion. The motion carried.

Rule Review Update

Ms. Anderson stated that the proposed continuing medical education (CME) rules were released from the Common Sense Initiative (CSI) in late October and have been filed with the Joint Committee on Agency Rule Review (JCARR). Three dietetics rules will be filed with CSI this week. Also, the Board has a public rules hearing scheduled for December 4, 2020.

Ms. Anderson continued that CSI received no comments on the proposed radiologist assistant rules, the exposure prone invasive procedure rules, or the hearing rules. Ms. Anderson expected to be able to file these rules with JCARR in January 2021.

Rules with the Common Sense Initiative

Controlled Substance Prescribing Rules:

Ms. Anderson stated that the comment period has ended for two packages of rules at the Common Sense Initiative (CSI). The personal information rules, which relate to internal Board policies, received no comments. One comment was received on the controlled substance prescribing rules from Jennifer Hayhurst of the Ohio State Medical Association (OSMA). Ms. Hayhurst requested that the
Board engage experts to provide advice regarding the Board’s weight-loss rule, 4731-11-04. Ms. Hayhurst noted in her comment that this rule has been virtually unchanged for decades.

Ms. Anderson noted that the Board of Pharmacy is very supportive of the weight-loss rules as they are, while bariatric physicians find the rules antiquated and not helpful for patients. Ms. Anderson also noted that this is one of the only areas in which the Board requires prescribing to be in-line with the labeling.

Ms. Anderson stated that the Committee could possibly have a conference call or video call with experts identified by OSMA so that they can provide input. Ms. Anderson requested that a physician member of the Policy Committee assist in evaluating the experts’ input and tailoring it specifically to the rule.

Dr. Bechtel opined that the Committee should take the same approach as with the light-based medical device rules, in which a Board member spearheaded efforts to form a group of experts to evaluate the rules in a very focused manner and provide recommendations grounded in evidence-based medicine. Ms. Montgomery agreed and asked if there is an association that represents bariatric physicians. Ms. Anderson stated that, based on input provided by Ms. Hayhurst, there is no Ohio association of bariatric physicians, but there are several national groups.

Mr. Giacalone, noting that the Board reviewed these rules five years ago, asked what has changed to warrant another review. Mr. Giacalone further noted that the reason the Board adopted this rule was due to widespread abuse of these medications. Mr. Giacalone agreed that there should be input from associations and clinicians, but added that there should also be input from the Board of Pharmacy, the Drug Enforcement Administration, and the Food and Drug Administration so that there is balance between the potential benefits of changing the rule and the risk of drug abuse in the general population. Dr. Schottenstein agreed, stating that there may be evidenced-based medicine that suggests the rule should be altered, but it must be weighed against the risk of these medications being abused.

Dr. Soin stated that there is no promise or guarantee that the rule will be changed, but there may be new information that the Committee can consider and possibly lead to a change in the rule. Dr. Soin stated that he would be happy to work with Ms. Anderson and meet with experts identified by OSMA, then report back to the Committee in December.

Dr. Bechtel moved to approve the plan outlined by Dr. Soin and Ms. Anderson to meet with identified experts and report back to the Committee. Ms. Montgomery seconded the motion. The motion carried.

**Physician Assistant Consultation Rules, First Draft**

Ms. Anderson stated that House Bill 203 was recently passed by the legislature. This legislation, which becomes effective on December 16, allows physician assistants to enter into consult agreements with pharmacists. Ms. Anderson has produced an initial draft of rules based on the Board’s consult agreement rules for physicians. Ms. Anderson will meet later with Cameron McNamee from the Board of Pharmacy to discuss the rules they are drafting, as well as issues with respect to terminal distributors and other areas in which physicians cannot simply be substituted with physician assistants due to other rules and laws.

Dr. Johnson noted a section of 4730-2-07(E) of the draft rule:
A physician assistant holding prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician shall not prescribe any drug or device to perform or induce an abortion.

Dr. Johnson asked if this was already a rule that is in place for physician assistants. Ms. Anderson answered that this provision is already in statute. Dr. Johnson stated that a patient who has had a miscarriage can be given a medication if they desire, rather than having a procedure done. Dr. Johnson was uncertain if this rule would apply in the case of a miscarriage, which obstetricians term a "missed abortion." Ms. Anderson stated that that topic is somewhat outside the confines of this rule, but she can provide Dr. Johnson with information on that topic.

Ms. Montgomery asked about the provision that allows the "practitioner" to override the decision of a pharmacist. Ms. Anderson stated that that is an area the Committee should discuss; while the Board is comfortable with a physician being able to override when necessary, the Committee should consider the situation involving a physician assistant. Ms. Anderson noted that physician assistants are supervised by a physician who has to approve them entering into a consult agreement with a pharmacist.

Dr. Bechtel moved to circulate the draft rule to the Physician Assistant Policy Committee, the Board of Pharmacy, the Board of Nursing, and other interested parties for comment. Ms. Montgomery seconded the motion. The motion carried.

Updated Sexual Misconduct Draft Legislation

Mr. Smith stated that the Board’s Sexual Misconduct Committee met in October and had an extensive discussion about draft legislation. Other Board members were also given an opportunity for additional input. A memo with an overview of the draft legislation has been provided to Committee members for their review. Mr. Smith commented that this legislation represents the input of many people, most particularly Ms. Anderson and Ms. Canepa. Mr. Smith stated that because the Board is moving forward with a sexual battery statute that criminalizes both sexual conduct and sexual contact, the draft legislation does not include a statutory proposal related to misdemeanor sexual imposition.

Mr. Smith stated that Mr. Giacalone had suggested that the California Medical Board be contacted to see if there had been any unintended consequences from their patient notification law, which was passed last year and is very similar to the patient notification provision in the draft legislation. This provision would require a licensee to provide notification to patients if they are on probation for certain specific violations.

Mr. Smith stated that he had a productive conversation with the California Medical Board’s legal counsel, who stated that there had been some challenges with getting a copy of the signed notification from the provider. Therefore, the draft legislation includes a phrase that states the signed copy shall be kept in the patient’s medical record and be made immediately available to the Board upon request. Mr. Smith stated that although this is not currently tied to a criminal penalty or a fine, it would be enforceable through the Board’s disciplinary statute if it is included as a term of probation.

Dr. Schottenstein asked if there had been any unintended consequences from the California legislation or if it had been counterproductive in some way. Mr. Smith replied that California has not seen adverse consequences and all the feedback has been positive.
Dr. Feibel opined that something regarding any finding of misconduct related to child pornography should be added, as that does not seem to be covered in the definition of sexual misconduct in 4731.991(A). Mr. Smith stated that he can look into that. Mr. Smith stated that the draft legislation is very patient-oriented and involves patient harm and licensee interaction with patients. Therefore, if anything additional is considered it would be tied to the patient. Dr. Soin asked if 2907.01(E) of the draft legislation could relate to child pornography. Mr. Smith replied that the proposal has been tied to the commission of any sexual misconduct with a patient or key third party, so as currently drafted there would have to be a connection to the patient themselves.

Ms. Montgomery asked if the staff is suggesting doing away with the statute on sexual imposition. Mr. Smith responded that there is no suggestion to do away with the statute, but the Medical Board is not putting forth a proposal to change the statute in such a way that would include specific Medical Board licensees. Ms. Montgomery asked if the proposal is just being made applicable to another statute. Mr. Smith replied that that is correct. Mr. Smith stated that the proposal addresses both sexual conduct and sexual contact in one statute, then differentiates the level of offense based on whether it is conduct, intercourse, or contact.

Ms. Montgomery commented that the memo was very well-written. Ms. Montgomery asked if a licensee’s failure to report is considered a minor misdemeanor in this draft. Mr. Smith replied that previous drafts had that that violation as a minor misdemeanor with subsequent violations as fourth-degree misdemeanors. However, the current draft makes all the violations fourth-degree misdemeanors, which is consistent with the criminal reporting statute.

Dr. Soin stated that many of these important topics should be discussed by the Board’s Sexual Misconduct Committee. Regarding the memo for review today, the Policy Committee agrees that the staff did a very good job and the memo is appropriate.

**Telehealth FAQ Updates**

Mr. Smith stated that the proposed new FAQ’s reflect questions that have been received regarding Rule 4731-11-09. If approved, these will be added to the existing FAQ’s. There are no substantive changes to the existing FAQ’s.

**Dr. Bechtel moved to approved the new FAQ's. Dr. Johnson seconded the motion.** The motion carried.

**Legislative Update**

Ms. Wonski stated that the legislative team has been preparing for the legislature’s lame duck session, which begins today with committee hearings. Ms. Wonski anticipated that language proposed by the Board will be officially added to two bills, while several other bills are being monitoring for legislative movement.

**Senate Bill 246, Occupational Licensing Reciprocity:** Ms. Wonski stated that the legislative team has worked with the committee chair and the bill’s sponsor to address concerns about retention of the Board’s ability to make a determination of whether an applicant has adequately met Ohio’s qualifications for licensure. An updated draft of the substitute bill includes most of the Board’s requested changes, but not in their entirety. Ms. Wonski appreciated the willingness of the sponsor to work with the Board and make some compromises. Ms. Wonski expected the substitute bill to be adopted at the next committee meeting, which has not yet been scheduled.
**Senate Bill 364, Interstate Medical Licensing Compact:** Ms. Wonski stated that the legislative team traveled to meet with this bill’s sponsor in her district to express the Board’s concerns. The sponsor seemed to understand the concerns and advised that she would take them into consideration.

**House Bill 263, Occupational Licensing:** Ms. Wonski stated that this bill would require the Board to provide a comprehensive list of criminal offenses that would prevent a person from being licensed in Ohio. Since the last Board meeting, the legislative team has worked with other licensing boards to develop a solution to the concerns about the bill’s language.

**House Bill 492, Physician Assistants:** Ms. Wonski stated that this bill would expand the ability of physician assistants to perform procedural sedation for purposes of rapid intubation. Several stakeholders have expressed opposition to this language. Ms. Wonski commented that this bill is being watched very closely.

**House Bill 679, Telehealth:** Ms. Wonski stated that this bill continues to progress through the legislature. The Board’s requested amendments have been drafted by the Legislative Services Commission and the team is waiting for those amendments to be adopted as part of the bill. Ms. Wonski gave special thanks to Mr. Gonidakis, who was instrumental in facilitating meetings with the committee chair and vice-chair. Ms. Wonski also thanked Dr. Feibel, who has offered to submit testimony, either in person or in writing, in support of the bill.

**House Bill 407, Clinician Integrity and Medical Accuracy Act:** Ms. Wonski stated that this bill would prevent a state or local government entity from requiring a physician to provide a patient with medical service or information that, in the physician’s clinical judgment, is not deemed medically accurate or appropriate for the patient. This bill is being analyzed by the Board’s policy and legal teams. More information will be provided at the next Policy Committee meeting if it appears this bill will move through the legislative process.

**House Bill 598, Emergency Medical Technicians:** Ms. Wonski stated that this bill temporarily authorizes emergency medical technicians (EMT) to perform certain medical services in the hospital during a declared emergency. This bill is being analyzed by the Board’s policy and legal teams. More information will be provided at the next Policy Committee meeting if it appears this bill will move through the legislative process.

**November 3 General Election:** Ms. Wonski stated that a memo summarizing the results of the November 3, 2020 general election has been included in the meeting materials for the members’ reference.

**House Bill 747, Prescribing and Dispensing Drugs for Off-Label Use:** Mr. Giacalone asked if this bill would arguably override the Board’s weight-loss prescribing rules. Mr. Giacalone noted that the bill would basically absolve physicians from any action by state regulatory board if they issue a prescription for a drug to be used in a manner other than the use approved by the U.S. Food and Drug Administration (FDA). Ms. Wonski stated that the same concerns have been brought up by Ms. Anderson and Mr. Smith. The legislative team will continue to monitor the bill.

Mr. Giacalone asked if the Board should be more than just an interested party, noting that if the Board decides to keep the weight-loss prescribing rules unchanged, this legislation will be a problem. Mr. Giacalone also wondered if this bill would affect opioid prescribing. Ms. Loucka stated that the bill is not expected to move, but if there is any movement the Board will strengthen its position.
Letter Regarding ODMHAS Proposed Rules

Ms. Loucka stated that an informational memo has been included in the meeting materials regarding a letter sent to Dr. Schottenstein from a group of physicians at the Ohio Department of Medical Health and Addiction Services (ODMHAS). The letter expresses concerns about a proposed ODMHAS rule that will allow non-physicians to order seclusion and restraints. Ms. Loucka stated that she appreciates the letter from the physicians, but noted that allowing non-physicians such authority is not prohibited under the Board’s current rules and laws.

Dr. Schottenstein commented that when he first read the letter, he was taken aback that consideration was being given to allowing non-physicians to order seclusion and/or restraints at state run hospitals. Dr. Schottenstein stated that ordering seclusion and/or restraints is one of the most consequential medical decisions a physician can make because those actions are potentially emotionally harmful and potentially dangerous to the patient. Dr. Schottenstein added that it is also a civil rights issue. Because it is a decision of last resort, Dr. Schottenstein opined that the decision should only be made by a physician.

However, Dr. Schottenstein stated that the Joint Committee revised its rules on seclusion and restraints to all licensed practitioners, not just physicians. Additionally, physician assistants are already writing these orders in other health systems in Ohio. Dr. Schottenstein further noted that ODMHAS does not currently employ physician assistants. Also, the Board’s ability to regulate physician assistants is derived from the legislature, which has not limited physician assistants from that function. Physician assistants are still obligated to practice within the confines of their supervisory agreement and follow the standard of care. Consequently, Dr. Schottenstein did not think the Board is in a position to push back on this expansion of the physician assistant scope of practice because physician assistants are already doing this in Ohio. To pursue such a limitation now would be a restriction of physician assistants’ scope of practice and could open anti-trust and restraint of trade issues.

Dr. Schottenstein opined that it was right to bring this to the Committee’s attention and that Ms. Loucka’s proposed response is appropriate. Since this issue originated with the Joint Commission, there are potentially national implications. Dr. Schottenstein questioned whether the Federation of State Medical Boards (FSMB) has a position on this issue. Ms. Loucka stated that staff can reach out to the FSMB.

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 9:55 a.m.

bt
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Update

DATE: November 19, 2020

Attached are the updated rule schedule and rule spreadsheet. I have also attached the rule plan for 2021 for rules due for the five-year rule review.

Action Requested: No action requested
2021 Rule Plan

The following is a plan for rules that are due for the five-year rule review in 2021, which are not already in process.

- 4731-1-12 Examination-Due 11.30.21
- 4731-1-16 Massage Therapy Curriculum-Due 11.30.21
- 4731-11-08 Utilizing controlled substances for self and family members-Due 8.17.21
- 4731-14-01 Pronouncement of Death-Due 6.30.21
- 4731-23-01 Delegation of Medical Tasks-Definitions-Due 11.30.21
- 4731-23-02 Delegation of Medical Tasks-Due 11.30.21
- 4731-23-03 Delegation of medical Tasks-Prohibitions-Due 8.17.21
- 4731-23-04 Violations-Due 8.17.21
- 4731-26-01 Sexual Misconduct Definitions-Due 6.30.21
- 4731-26-02 Prohibitions-Due 6.14.21
- 4731-26-03 Violations; Miscellaneous-Due 6.30.21

Plan for Filing:

November 2020: Research and draft technical updates, such as inclusion of dietetics and respiratory care chapters if needed.

December 2020: Circulate drafts to internal staff and AAGs; for certain rules that reference statutes of other agencies, circulate to that agency, such as Board of Nursing, Board of Pharmacy, Chiropractic Board, EMT Board, and Department of Developmental Disabilities.

January 2021: Present draft rules to Policy Committee for approval for initial circulation.

February 2021: Bring comments received to Policy Committee for approval to file with CSI.

March 1, 2021: File rules with CSI

Will have to build out schedule for JCARR after rules are released from CSI.
New rules for consideration in 2021:

PA consult agreement rules
## Legal Dept. Rules Schedule
### As of 11/19/20

### To December Board Meeting for Adoption
Military Rules for all license types:
- 4730-1-06.1
- 4731-1-25
- 4731-6-35
- 4731-24-05
- 4731-36-01
- 4731-36-02
- 4731-36-03
- 4759-4-12
- 4759-4-13
- 4761-4-03
- 4761-8-01
- 4761-9-02
- 4761-12-01
- 4762-1-01
- 4774-1-02.1
- JCARR refile: 4730-1-06

### RULES AT CSI

**Comment Deadline 5/27/20**
- 4731-18 – Light Based Medical Device Rules

**Comment Deadline 10/19/20**
- 4731-11-02
- 4731-11-03
- 4731-11-04
- 4731-11-04.1
- 4731-11-07
- 4731-11-11

**Comment Deadline 11/6/20**
- 4774-1-01
- 4774-1-02
- 4774-1-03
- 4774-1-04
- 4731-17-01
- 4731-17-02
- 4731-17-03
- 4731-17-04
- 4731-17-05
- 4731-17-06
- 4731-17-07
- 4731 Chapter 13 – 36 rules

**Comment Deadline 11/23/20**
- 4759-4-04
- 4759-4-08
- 4759-6-02

### RULES AT JCARR

**Ready to be filed with JCARR**
- 4731-8-01
- 4731-8-02
- 4731-8-03
- 4731-8-04
- 4731-8-05
- 4731-8-06
- 4731-36-04

**Rules Hearing – 12/4/20**
- 4731-10 CME rules
- JCARR jurisdiction ends 1/3/2021

### RULES SENT FOR INITIAL CIRCULATION

**Comment Deadline – September 25, 2020**
- 4731-6-14
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MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Temporary Military Licensure Rule-4731-36-04, OAC

DATE: November 25, 2020

On November 13, 2020, I received the CSI recommendation for proposed rule 4731-36-04, OAC. The rule authorized by Am. Sub. Senate Bill (133rd General Assembly) establishes the process for the Board to grant a temporary license to members of the military and their spouses who are licensed in another jurisdiction.

CSI recommends that the rule is amended to address two areas: (1) provide more detail as to how the Board will obtain documentation to determine military status, how the Board will record, track and monitor applications from military members and spouses, and how the Board will prioritize and expedite licensing for military members and spouses; and (2) clarify that the Board will waive all fees associated with the issuance of the temporary license or certificate. A copy of the CSI recommendation is attached for your review.

I have provided a draft which adds paragraphs (G) and (H) to the proposed rule. Paragraph (G) states that the Board shall process the application for the temporary license or certificate in accordance with Rule 4731-36-03, OAC. Rule 4731-36-03, which is on the agenda for adoption today, sets forth the Board’s requirements in processing applications for members of the military and spouses.

Paragraph (H) states that the Board shall waive all fees associated with the issuance of the temporary license or certificate. This language is also included in the authorizing statute, 4743.041(G), Ohio Revised Code.

Action Requested: Review the proposed amendments, determine whether to adopt them, and make recommendation to the Board. If the Board approves amendments, authorize notification to CSI and file rule with JCARR.
MEMORANDUM

TO: Kim Anderson, Ohio State Medical Board

FROM: Jacob Ritzenthaler, Regulatory Policy Advocate

DATE: November 13, 2020

RE: CSI Review – Temporary Licensure for Members of the Military and Spouses (OAC 4731-36-04)

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office’s comments to the Board as provided for in ORC 107.54.

Analysis

This rule package consists of one new rule proposed by the State Medical Board of Ohio (Board). This rule package was submitted to the CSI Office on February 14, 2020, and the public comment period was held open through February 28, 2020. Unless otherwise noted below, this recommendation reflects the version of the proposed rule filed with the CSI Office on February 14, 2020.

Ohio Administrative Code (OAC) 4731-36-04 establishes the process for the Board to grant a temporary license to members of the military and their spouses who are licensed in another jurisdiction, in response to Am. Sub. Senate Bill 7 (133rd General Assembly). The rule requires an applicant for temporary licensure to have a valid license or certification to practice in another jurisdiction for one of the licenses under the purview of the Board, which includes physicians, podiatrists, physician assistants, massage therapists, cosmetic therapists, dietitians, anesthesiologist assistants, respiratory care professionals, radiologist assistants, acupuncturists, Oriental medicine practitioners, and genetic counselors. The rule also sets timeframes for the application process, Board response, and application for full licensure.
During early stakeholder outreach, the Board sent the rule to interested parties for review via email and included the rule in discussion with the Board’s Policy Committee. The Board did not receive any stakeholder comments. During the CSI public comment period, the Board received comments from 20 stakeholders. These comments included support for the proposed rule, as well as suggestions that would expand temporary licensure outside the scope of the authorizing statute. The Board did not make changes based on these comments.

The business community impacted by the rule includes applicants for a temporary license who are military members or a spouse. The adverse impact created by the rule includes the time and effort spent by individuals to apply and the cost to complete a background check. The Board states in the BIA that a background check costs $47.25. The Board states that any adverse impacts created by the rule are necessary to provide guidelines for the granting of licenses.

**Recommendations**

Amended Substitute Senate Bill 7 (133rd General Assembly) provides military members and their spouses with better employment opportunities by simplifying the process to transfer their occupational licenses to Ohio. The bill mandates that state licensing agencies issue licenses or certificates to military members and spouses who already hold a valid license to practice a trade or profession in another state, in a timely manner and at no cost.

The bill ensures that the State of Ohio has procedures in place to provide exceptional customer service and support to our military members and their families. Therefore, CSI makes the following recommendations to the Board.

1. **Track, Prioritize, and Expedite**

   ORC 5903.04, as amended by Am. Sub. S.B. 7, requires boards to establish and implement processes by rule for 1) obtaining documentation to determine military status, 2) recording, tracking, and monitoring applications from military members and their spouses, and 3) prioritizing and expediting licensing for military members and their spouses, including any appropriate special accommodations.

   The proposed rule does not provide any more information than what is already required in statute, and does not address how the Board will obtain documentation, record, track, monitor, prioritize, and expedite licensing.

   Therefore, CSI recommends that the Board more clearly define how it will meet its statutory obligations regarding these processes.
2. Fees

ORC 4743.041(G) requires a licensing office to waive all fees associated with the issuance of a temporary license or certificate. It is unclear from the current draft of the rule if the Board is offering the license at no cost. Therefore, CSI recommends the Board consider clarifying the fee language.

Conclusion

The CSI Office concludes that the Ohio State Medical Board should review its proposed rule based on the recommendations above prior to filing it with the Joint Committee on Agency Rule Review.
4731-36-04 Temporary licensure for members of the military and spouses who are licensed in another jurisdiction

(A) “Military duty” has the same meaning as in section 4743.041 of the Revised Code.

(B) Pursuant to section 4743.041 of the Revised Code, the state medical board of Ohio shall issue a temporary license or certificate to practice the professions governed by Chapters 4730., 4731., 4759., 4761., 4762., 4774., and 4778. if the individual demonstrates to the satisfaction of the board all the following:

1. The individual holds a valid license or certificate to practice the profession issued by any other state or jurisdiction
2. The individual is in good standing in the state or jurisdiction of licensure or certification
3. The individual or the individual’s spouse is on military duty in this state.

(C) An applicant for a temporary license or certificate must certify that, to the best of the applicant’s knowledge, the applicant is not under investigation by the licensing agency of any state or jurisdiction.

(D) No application submitted to the board shall be considered complete until the applicant has complied with the requirements of paragraph (A) of rule 4731-4-02 of the Administrative Code and the board has received the results of the criminal records checks.

(E) If an applicant for a temporary license or certificate fails to complete the application process within six months of initial application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.

(F) The board shall issue a temporary license or certificate within fourteen days of having received the results of a criminal records check, provided that the application is otherwise complete, and the applicant is not under investigation by the licensing agency of any state or jurisdiction.

(G) The board shall process the application for a temporary license or certificate in accordance with rule 4731-36-03 of the administrative code.

(H) The board shall waive all fees associated with the issuance of the temporary license or certificate.

(I) A temporary license or certificate issued under this section shall be valid for a two-year period unless revoked or suspended. A temporary license or certificate may not be renewed and a new temporary license may not be issued.

(J) A holder of a temporary license or certificate may apply for licensure under Chapters 4730., 4731., 4759., 4761., 4762., 4774., and 4778 of the Revised Code at any time before or after
expiration of the temporary license. A holder or previous holder of a temporary license or certificate must meet all requirements for licensure under the applicable chapter of the Revised Code and rules adopted thereunder.
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: November 30, 2020

The proposed amended rules regarding light-based medical devices (Rules 4731-18-01 through 4731-18-04) were filed with the Common Sense Initiative and circulated to interested parties for comment. The Board received comments from fourteen different individuals and entities. The comments are attached for your review. The summary groups the comments by their general content.

Relax delegation requirements in the proposed amended rules:

1. Tammy Hands of Janssen Lasers commented that Ohio should allow delegation of lasers and light-based medical devices to non-medical personnel citing safety improvements in the devices.
2. Jason Lichten, MD of Central Ohio Plastic Surgery, Inc. states that Ohio should follow other states and delegate lasers for tattoo removal or IPL applications and that he would like to see the rule allow delegation of hair removal and vascular lasers to licensed aesthetiticians.
3. Amanda Nelson, CT of the Cosmetic Therapy Association of Ohio would like to see the elimination of the requirement physician delegation for laser hair removal for cosmetic therapists.
4. Kelly Ott-Statzer, CT opposes the rules indicating that they will have a detrimental impact on cosmetic therapists and raises antitrust concerns.
5. Antoinette Sepsi, CT opposes any practice restrictions for cosmetic therapists and raises antitrust concerns.
6. Alex Thiersch, CEO, American Med Spa Association stated that requiring a physician to perform patient examinations is too restrictive and a nurse practitioner or physician assistant should be able to perform the patient examinations. Mr. Thiersch comments that requiring on-site supervision is excessive for low risk procedures. Mr. Thiersch states that the restriction of ablative procedures to physicians does not comport to the practice environment elsewhere in the country and he recommends a tiered approach where procedures are grouped by risk and the chance of complication or injury. Mr.
Thiersch indicates that the rule should be modified to require the supervising physician to review each delegate’s training, education and skill and assess their competency rather than setting minimum training requirements.

Restrict delegation requirements in the proposed amended rules:

1. Martha Hickmann, M.D., FAAD opposes the delegation of light-based medical devices for non-ablative procedures, phototherapy, and photodynamic therapy as it could lead to serious patient complications.
2. Rishi Gandhi, M.D., FAAD opposes the delegation of non-ablative lasers to physician assistants, nurse practitioners and registered nurses.
3. Jeffrey Wargo, M.D, a dermatology resident at Wright State opposes the delegation of non-ablative laser procedures to physician assistants, nurse practitioners, registered nurses and medical assistants due to concerns of harm to patients, including burns, hyperpigmentation and scarring.
4. Frank Papay, MD, FACS, FAAP, Chair, Dermatology & Plastic Surgery Institute; Allison Vidimos, M.D., Shilpi Khetarpal, M.D, and James Zins, M.D. of the Cleveland Clinic are opposed to physician delegation of vascular and non-ablative lasers, indicating that 8 hours of training is insufficient. Their letter provided de-identified examples of adverse results to patients, including burns and scarring and two journal articles were attached.
5. Matt Molenda, M.D., FAAD, MBA, FACMS, FASDS indicates that he is not in support of expanding laser use to RNs, LPNs, or CTs due to safety issues and that he is not supportive of ablative lasers being delegated to non-physicians due to increased concerns for scarring and infection.

Physician Assistant Comments:

1. Matt Molenda, M.D., FAAD, MBA, FACMS, FASDS states that he is supportive of the delegation of all non-ablative lasers (not just non-ablative vascular lasers) to physician assistants.
2. Elizabeth Adamson, Executive Director, Ohio Association of Physician Assistants expressed concerns that the Physician Assistant Policy Committee was not properly consulted and that the delegation requirements for physician assistants conflict with Sections 47310.19(B)(1) and (2), 4730.20(A)(8), and 4730.21, Ohio Revised Code.
3. Mona S. Foad, M.D., MHS, FAAD, Jessica P. Watkins, PA-C, Megan Niese, PA-C and Anna Donovan, C-NP of MONA Dermatology stated that the physician pre and post procedure evaluation is not necessary for physician assistants due to their current supervisory agreements and the training requirements in the rules. On-site physician supervision should not be required 100% of the time for physician assistants. It is recommended that the physician must be available by phone and within an appropriate
distance in case complications arise. Finally, it is recommended that vascular laser
delegation should be expanded to include other laser types for dermatologic uses.

Definitional Concerns:

1. Eric Plinke of Dinsmore indicates that the definition of vascular laser in Rule 4731-18-
01(J) is confusing. It is not clear if vascular laser is a subcategory of light-based medical
device.
2. Alex Thiersch, CEO of American Med Spa Association indicates that the definition of
phototherapy in 4731-18-01(B) does not include red and blue LED light treatment to treat
acne or reduce redness. The definitions of ablative and non-ablative procedures in Rule
4731-18-01(C) and (D) leave a gap and does not address “intra-epidermal ablative
procedures” which may excise a portion of the epidermis but is not expected to excise to
the dermo-epidermal junction.

In addition, the Physician Assistant Policy Committee reviewed the proposed amended rules and
provided feedback at its meeting on August 21, 2020. The minutes are included for your review.
The PAPC expressed concerns that the proposed rules conflict with current practices and the
added restrictions could delay care. There was concern with the requirements for direct
supervision.

The concerns raised regarding the treatment of physician assistants need to be addressed. The
rules as drafted appear to be different than the statutory requirements for supervisory agreements
between physician assistants and their supervising physicians, most specifically Section 4730.21,
Ohio Revised Code. This statutory section sets forth the requirements that the supervising
physician must address in the supervisory agreement, and address the requirements regarding
training, on-site supervision and the limit on the number of physician assistants that may be
supervised at one time. Under the statute, the supervising physician may only authorize a
physician assistant to perform services if the physician is satisfied that the physician assistant is
capable of competently performing the service. The supervising physician shall be continuously
available for direct communication by being on-site or available through telecommunications
and location that allows the physician to assure proper care of patients. Finally, this statutory
section also states that the supervising physician may not supervise more than five physician
assistants at one time. Attached please find a draft that addresses this issue.

I would appreciate input on the definitional concerns. Are there amendments that could clarify
the definitions?

Action Requested: Discuss proposed amendments for filing with CSI.
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<td><a href="mailto:doctor@Ohioplastic.com">doctor@Ohioplastic.com</a></td>
<td>Central Ohio Plastic Surgery</td>
<td>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? (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.</td>
</tr>
<tr>
<td>Alex Thiersch</td>
<td><a href="mailto:Alex@americanmedspa.org">Alex@americanmedspa.org</a></td>
<td>American Medspa Association</td>
<td>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? (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.</td>
</tr>
<tr>
<td>Martha Hickmann, M.D.</td>
<td><a href="mailto:mhickmann50@gmail.com">mhickmann50@gmail.com</a></td>
<td>Central Ohio Plastic Surgery</td>
<td>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.</td>
</tr>
<tr>
<td>Eric Plinke</td>
<td><a href="mailto:Eric.Plinke@dinsmore.com">Eric.Plinke@dinsmore.com</a></td>
<td>Dinsmore</td>
<td>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(U) and 4731-18-03(A).</td>
</tr>
<tr>
<td>Amanda Nelson, CT</td>
<td><a href="mailto:cosmetictherapyohio@gmail.com">cosmetictherapyohio@gmail.com</a></td>
<td>Cosmetic Therapy Association</td>
<td>Include laser hair removal as part of the scope of practice for cosmetic therapists and do not require delegation and supervision by a physician.</td>
</tr>
<tr>
<td>Mona Foad, M.D.; Jessica Watkins, PA; Megan Niese , PA; Anna Donovan, CNP</td>
<td></td>
<td>Mona Dermatology</td>
<td>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.</td>
</tr>
<tr>
<td>Rishi Gandhi, M.D.</td>
<td><a href="mailto:rishi.gandhi@gmail.com">rishi.gandhi@gmail.com</a></td>
<td>Central Ohio Plastic Surgery</td>
<td>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.</td>
</tr>
<tr>
<td>Jeff Wargo, M.D.</td>
<td><a href="mailto:jwargo75@gmail.com">jwargo75@gmail.com</a></td>
<td>Central Ohio Plastic Surgery</td>
<td>Concerned with non-physicians performing nonablative laser procedures. Same as Dr. Gandhi.</td>
</tr>
<tr>
<td>Matthew Molenda M.D.</td>
<td><a href="mailto:molenda@braviaderm.com">molenda@braviaderm.com</a></td>
<td>Bravia Dermatology</td>
<td>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.</td>
</tr>
<tr>
<td>Frank Papay MD; Allison Vidimos, MD, Shilpi</td>
<td><a href="mailto:Barnhab@ccf.org">Barnhab@ccf.org</a></td>
<td>Cleveland Clinic</td>
<td>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.</td>
</tr>
<tr>
<td>Elizabeth Adamson, Executive Director</td>
<td>OAPA</td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Kelly Ott-Statzer, CT</td>
<td><a href="mailto:inot1980@icloud.com">inot1980@icloud.com</a></td>
<td></td>
<td>Rule changes will be harmful to CTs. Will raise anti-trust issues. Delay rule change until occupational licensing issues are addressed in HB 452.</td>
</tr>
<tr>
<td>Antoinette Sepsi, CT</td>
<td><a href="mailto:not1980@icloud.com">not1980@icloud.com</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
May 26, 2020

Kimberly Anderson
OHIO MEDICAL BOARD
via email Kimberly.Anderson@med.ohio.gov
cc Common Sense Initiative CSIPublicComments@governor.ohio.gov

Re: Proposed Rules 4731-18-01 through 4731-18-04

Dear Ms. Anderson,

On behalf of the American Med Spa Association (AmSpa), allow me to submit the following comments in relation to the current proposed rules for Light Based Procedures under Ohio Administrative Code Chapter 4731-18. We applaud the efforts to address the concerns surrounding unsupervised laser and light-based procedures in medical spas, an increasingly troublesome issue with which our industry is grappling across the country. While the proposal is well-intentioned and has some favorable components, we feel that because of the complexity and breadth of issues involved, the current proposal will ultimately not provide an adequate solution to the problem at hand and will unduly burden compliant practitioners. Therefore, we must oppose the proposed changes in their current form. AmSpa has been working on comprehensive medical spa standards and certification that we believe will fully address the underlying issues, and we request that we work together on creating a more focused solution.

AmSpa is the largest trade group in the medical spa industry. Consisting of more than 3,000 members, with close to 500 in Ohio alone, AmSpa is dedicated to ensuring the non-invasive aesthetic industry is safe and that its practitioners are trained, qualified and compliant. AmSpa’s goal since its founding in 2013 is to ensure the aesthetic industry understands and complies with the myriad health care regulations put in place to ensure the public is protected and, ultimately, rid the industry of unqualified practitioners and unsupervised medical spas. AmSpa has endeavored to develop and disseminate comprehensive practice standards that will not only address the circumstances contemplated in your current proposed rules, but also ensure that medical spas
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.
The regulations to structure a compliant medical spa industry, quickly followed Ohio’s guidance. We look forward to hearing from you on how we can help shape multi-multiple procedures from different manufacturers. Skills and knowledge in a certain procedure can translate to others. Knowledge and skill in one device can translate to its use in a number of different 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 supervises the procedures being performed, we ensure that the procedures are performed properly and that all medical centers and their practitioners are held to the same standard of care. This, in turn, will help to prevent the spread of misinformation and ensure that the public is well-informed about the procedures being performed. We commend your efforts in this regard and look forward to working with you to establish a clear standard for the industry.

Conclusion

AmSpa welcomes the opportunity to work with all stakeholders in this process. We are glad that the State of Ohio has recognized the need for greater regulation of laser and light procedures. We cannot support your proposed rules in their current form. We have been researching, training and educating the industry for several years, and we have access to advisors and professionals who have been in the field for more than 20 years. We believe that by working together, Ohio can be a leader in the field of medical spa industry. It is our hope that we can help shape the regulations to ensure that the procedures being performed are safe and effective. We look forward to hearing from you on how we can help shape the regulations to structure a compliant medical spa industry.
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

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

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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 revisited 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.
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

AND

Common Sense Initiative Office at: 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

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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?

Jason Lichten, MD
Central Ohio Plastic Surgery, Inc.
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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
  AND
  Common Sense Initiative Office at: 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

Ohio
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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
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 light and laser devices.

These devices require extensive knowledge of laser physics and laser tissue interaction. These topics are typically taught in dermatology residency or advanced procedural fellowships. Without proper education and supervised training, there is a high risk of harm to patients, including burns, hyperpigmentation, and scarring.

I have treated several of these complications from offices where the patient believed they were seeing a skilled laser expert. In many cases, these complications result in extensive costs and patient distress.

In order to protect the public and our patients, I strongly encourage the 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

Rishi K. Gandhi, MD FAAD

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Rishi K. Gandhi, MD FAAD
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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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

Bravia Dermatology
2000 Regency Ct, Suite 201
Toledo, OH 43623

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braviaderm.com

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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

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May 26, 2020

Kimberly Anderson
State Medical Board of Ohio
30 E. Broad Street, 3rd 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(8)(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.

OAPA
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. All that for warning 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 articulate 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
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 27th 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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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  
Med.ohio.gov

-----Original Message-----  
From: Antoinette Sepsi <inot1980@icloud.com>  
Sent: Thursday, May 28, 2020 8:33 AM  
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>  
Cc: vickie aboutface-ctc.com <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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Minutes of the Physician Assistant Policy Committee  
August 21, 2020

Members present:  Scott Cackler, PA; Kindra Engle; Kit Kuklos; Jonathan Feibel, M.D.

Also present:  Jill Reardon, Deputy Director of External Affairs; Kimberly Anderson, Chief Legal Counsel; Cierra Lynch, Stakeholder Liaison; Chelsea Wonski, Legislative Director.

The meeting was called to order at 2:02 p.m.

I. Approval of minutes

The Draft minutes of the Committee’s January 3, 2020 meeting was approved.

II. Introduction of External Affairs Staff

Ms. Reardon introduced the Medical Board’s new External Affairs staff, which will also provide support to the PAPC. Cierra Lynch serves as Stakeholder Liaison, Chelsea Wonski serves as Legislative Director, and Ms. Reardon is the Deputy Director of External Affairs.

III. Introduction of Jonathan Feibel, M.D.

Ms. Reardon introduced Dr. Feibel as the newest member of the PAPC, recently appointed by Medical Board President Dr. Schottenstein. Dr. Feibel is an orthopedic surgeon and has served on the State Medical Board of Ohio since 2019.

IV. Legislative Update

**House Bill 679, Telehealth:** Ms. Wonski stated that this legislation has passed the House, but has not yet been assigned to a Senate committee. The Board’s *ad hoc* Telehealth Committee, which is chaired by Dr. Feibel, continues to track the bill’s progress and work on proposed amendments to address the Board’s concerns.

**Senate Bill 246, Occupational Licensing Reciprocity:** Ms. Wonski stated that work the Board continues to work on amendments to this bill that would allow the Board to vet out-of-state applicants to the same standard as in-state applicants.

**House Bill 747, Off-Label Prescribing:** Ms. Wonski stated that this bill would restrict the Board from taking action against a licensing based solely on off-label prescribing.

V. Rule Review Update

Ms. Anderson stated that the rules that the Committee had worked on following the most recent physician assistant legislation are nearly final. These proposed rules would remove the physician assistant formulary. The proposed rules will be brought to the Medical Board for final adoption on September 9, with an anticipated effective date of September 30.
Ms. Anderson stated that the Committee had reviewed proposed rules on light-based medical devices in 2018. In the initial circulation of those proposed rules, some groups expressed concerns about possible anti-trust issues. The proposed rules were sent to the Common Sense Initiative (CSI) for anti-trust review, which was concluded in December 2019.

A number of public comments were received from the regular CSI rule review process, which have been provided to the Committee for review. Several comments, including from the Ohio Association of Physician Assistants, are about how physician assistants are treated in these rules. This matter was discussed by the Medical Board’s Policy Committee, which recommended bringing the matter to PAPC for feedback.

Mr. Cackler stated that he had the same concerns as were expressed in the comments. Mr. Cackler stated that the proposed rules conflict with many practices and the added restrictions could delay care. Mr. Cackler stated that the rules are confusing with regard to delegation. Mr. Cackler further stated that the requirements for direct supervision can lead to a delay in therapy if the ordering physician is not the physician assistant’s supervising physician.

Ms. Anderson stated that amendments can be drafted to address the concerns about supervision. Other Committee members were invited to provide comments to Ms. Anderson by email by September 4.

VI. PAPC Vacancies

Ms. Reardon stated that there is currently a vacancy on PAPC for a consumer member who is not affiliated with the medical profession. Committee members who know of any possible candidates for that vacancy were asked to inform Ms. Reardon or Ms. Lynch.

IV. Adjournment

Ms. Kindra moved to adjourn. Mr. Cackler seconded the motion. The motion carried.

The meeting adjourned at 2:19 p.m.
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” means any device that can be made to produce or amplify electromagnetic radiation at wavelengths equal to or greater than one hundred eighty nm but less than or equal to 1.0 X 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.
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.

Delegation” means the assignment of the performance of a service to a person who is not a physician.

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.

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.

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

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.

A physician shall not delegate the application of light based medical devices for ablative procedures.

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.

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.

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.

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.

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

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

(a) Eight (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;

(8) For delegation to a registered nurse or licensed practical nurse, the physician provides on-site supervision at all times that the person to whom the delegation is made is applying the vascular laser; and,

(9) For delegation to a registered nurse or licensed practical nurse, the physician supervises no more than two persons pursuant to this rule at the same time.

(B) A physician may delegate the application of light based medical devices 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) For a physician assistant, the authorization must meet the requirements of Chapter 4730.21 of the Revised Code;

(7) For cosmetic therapists, registered nurses and licensed practical nurses, the physician shall ensure the person to whom the delegation is made has received adequate education and training to provide the level of skill and care required including:
(a) Eight (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.

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

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

(C) Notwithstanding paragraph (B)(8) of this rule, the physician may provide off-site supervision when the light based medical device is applied for the purpose of hair removal to an established patient if the person to whom the delegation is made pursuant to paragraph (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 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) For physician assistants, the authorization shall meet the requirements of Section 4730.21 of the Revised Code;

(5) For registered nurses, licensed practical nurses, and certified medical assistants, 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) For physician assistants, the authorization shall meet the requirements of Section 4730.21 of the Revised Code;

(5) For registered nurses and licensed practical nurses, 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 and the completion of this training is documented by the person to whom the delegation is made; and

(6) For registered nurses and licensed practical nurses, the physician provides on-site supervision at all times that the person to whom the delegation is made is applying the 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.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Update

DATE: November 19, 2020

The Board’s hearing rules are currently pending at CSI. The Board’s hearing examiners have asked to add some language allowing for virtual hearings on the motion of the hearing examiners or the parties. Currently, the hearing examiners are able to hold virtual hearings under the temporary language extending the Open Meetings Act provisions. This language would allow hearing examiners to utilize virtual hearings in other situations, where appropriate.

Please see the attached amendment to Rule 4731-13-03, Ohio Administrative Code.

Action Requested: Approve rule amendment for filing amended rule with CSI.
4731-13-03. Authority and duties of hearing examiners

(A) Hearings shall be conducted before hearing examiner pursuant to section 4731.23 of the Revised Code.

(B) All hearings shall be open to the public, but the hearing examiner conducting a hearing may close the hearing to the extent necessary to protect compelling interests and rights or to comply with statutory requirements. In the event the hearing examiner determines to close the hearing, the hearing examiner shall state the reasons in the public record.

(C) The hearing examiner shall conduct hearings in such a manner as to prevent unnecessary delay, maintain order and ensure the development of a clear and adequate record.

(D) The authority of the hearing examiner shall include, but not be limited to, authority to:

   (1) Administer oaths and affirmations;

   (2) Order issuance of subpoenas and subpoenas duces tecum to require the attendance of witnesses at hearings and depositions in lieu of live testimony and to require the production of evidence for hearings and depositions in lieu of live testimony;

   (3) Examine witnesses and direct witnesses to testify;

   (4) Make rulings on the admissibility of evidence;

   (5) Make rulings on procedural motions, whether such motions are oral or written;

   (6) Hold prehearing conferences;

   (7) Request briefs before, during or following the hearing;

   (8) Prepare entries, proposed findings, proposed orders or reports and recommendations pursuant to rule 4731-13-15 of the Administrative Code;

   (9) Make rulings on requests to broadcast, record, televise or photograph the hearing;

   (10) Take such other actions as may be necessary to accomplish the purposes of paragraph (C) of this rule; and

       (11) Determine the order in which any hearing shall proceed.

(E) The authority of the hearing examiner shall not include authority to grant motions for dismissal of charges, or modify, compromise or settle charges or allegations.

(F) The hearing examiner shall have such other powers, duties, and authority as are granted by statutes or rules.

(G) All rulings on evidence and motions and on any other procedural matters shall be subject to review by the board upon presentation of the proposed findings of facts and conclusions of
law of the hearing examiner. When such rulings warrant, the board may remand the matter to the attorney hearing examiner.

(H) The hearing examiner may assist the board by reviewing the evidence in matters that have been subject to a notice of opportunity for hearing but for which no timely hearing request has been filed. In such matters the hearing examiner may prepare proposed findings and a proposed order for the board's consideration.

(I) Briefs provided under paragraph (D)(7) of this rule shall comply with the requirements set forth in rule 4731-13-07.1 of the Administrative Code.

(J) Upon the motion of a party, or upon the hearing examiner’s own motion, the hearing examiner shall have the authority to conduct hearings by use of a live, real-time video-conferencing system. Such a system must provide a means, through the use of software that is widely accessible to the general public without charge, for the hearing examiner, attorneys, the respondent, witnesses, and a court reporter, along with any other necessary participants, to see and converse with each other and to display documentary and physical evidence. Further, the video-conferencing system must also provide a means by which members of the public may view and listen to the hearing.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Consult Rules Update

DATE: December 3, 2020

Section 4729.39(E)(1), ORC, states that the Board of Pharmacy shall adopt rules to be followed by pharmacists in consult agreements, *in consultation with the State Medical Board and Board of Nursing*.

Section 4729.39(E)(2), ORC, states that the State Medical Board shall adopt rules to be followed by physicians and physician assistants, *in consultation with the Board of Pharmacy*.

Attached for your consideration, please find a copy of the Pharmacy Board’s proposed rules related to consult agreements, as updated by the recent statutory changes which will become effective 12/16/20.

Also attached are the proposed rules for the Medical Board which reflect changes in Section 4729.39 and adds physician assistants.

**Action Requested:**

1. Review proposed rules from Board of Pharmacy and communicate any comments or concerns.
2. Review proposed rules for the State Medical Board and approve submission to the Board of Pharmacy for consultation as required in Section 4729.39(E)(2), Ohio Revised Code.
PROPOSED RULES FOR STAKEHOLDER COMMENT

Issued 11/20/2020

Acting under the authority of the Ohio Revised Code Chapter 4729, the State of Ohio Board of Pharmacy proposes the amendment/adoptions of rules regarding consult agreements and standards for managing drug therapy.

The intent of the rules is to ensure compliance with recent legislation, HB 203 and ORC 4729.39, that authorized pharmacists to enter consult agreements with certain physician assistants and advanced practice registered nurses.

Comments on the proposed rules will be accepted until close of business on December 11, 2020. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov.
4729:1-6-01 Definitions - consult agreements.

(A) "Certified nurse practitioner," "certified nurse-midwife," "clinical nurse specialist," and "standard care arrangement" have the same meanings as in section 4723.01 of the Revised Code.

(B) "Collaborating physician" means a physician who has entered into a standard care arrangement with a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

(AC) "Communication between a pharmacist and practitioner acting under a consult agreement, physician acting under a consult agreement," as used in division (BD)(6) of section 4729.39 of the Revised Code, means any of the following:

1. Electronic mail that confirms delivery;
2. Interoperable electronic medical records system;
3. Facsimile that confirms delivery;
4. Electronic prescribing system;
5. Electronic pharmacy record system;
6. Documented verbal communication; or
7. Any other method of documented notification as outlined in the consult agreement between the pharmacist and physician/practitioner.

(BD) "Comorbid disease," as used in division (BD)(3)(a) of section 4729.39 of the Revised Code, means an additional disease that co-occurs with a primary disease. A comorbid disease may be related to or occur independently of the primary disease.

(CE) "Communicated" as used in division (BD)(4) of section 4729.39 of the Revised Code, means consent shall be obtained from each individual patient participating in a consult agreement. With the exception of inpatient management of patient care at an institutional facility, consent shall be obtained prior to a pharmacist managing a patient's drug therapy and shall communicate all of the following:

1. A pharmacist may be utilized in the management of the patient's care; and
2. The patient's or an individual authorized to act on behalf of a patient's right to elect to participate in and withdraw from the consult agreement.

(2) Consent as required in paragraph (CE)(1) of this rule may be obtained as a part of the patient's initial consent to treatment.

(D) "Consult agreement" means an agreement that has been entered into pursuant to section 4729.39 of the Revised Code.

(E) "Institutional facility" has the same meaning as defined in agency 4729 of the Administrative Code.

(F) "Managing pharmacist" means a pharmacist managing a patient's drug therapy pursuant to a consult agreement.

(G) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.
"Physician assistant" means an individual who is licensed to practice as a physician assistant under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority.

Positive identification means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(a) A manual signature on a hard copy record;
(b) A magnetic card reader;
(c) A bar code reader;
(d) A biometric method;
(e) A proximity badge reader;
(f) A board approved system of randomly generated personal questions;
(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or
(h) Other effective methods for identifying individuals that have been approved by the board.

A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

"Practitioner" means any of the following:

(1) Physician;
(2) Physician assistant;
(3) Clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

"Primary disease," as used in division (BD)(3)(a) of section 4729.39 of the Revised Code, means a disease that arises spontaneously and is not associated with or caused by a previous disease, injury, or event, but that may lead to a comorbid disease.

"OARRS report" means a report of information related to a specific person generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

"Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

"Supervising physician" means a physician who has entered into a supervision agreement with a physician assistant under section 4730.19 of the Revised Code.

"Training and experience related to the particular diagnosis for which drug therapy is prescribed," as used in division (AC)(3) of section 4729.39 of the Revised Code, means an Ohio licensed pharmacist whose license is in good standing and who meets the training and experience criteria specified in paragraph (A)(1)(k) of rule 4729:1-6-02 of the Administrative Code.
“Written notice,” as used in division (8D)(2)(b) of section 4729.39 of the Revised Code, means one of the following methods that is capable of confirming delivery of the required written notice:

1. Electronic mail;
2. Interoperable electronic medical records system;
3. Facsimile;
4. Electronic prescribing system;
5. Electronic pharmacy record system;
6. Any other method in writing that provides notice in a timely manner; or
7. Any other method of notification as outlined in the consult agreement that might reasonably be expected to allow for the confirmed transmission of the written notification required.
4729:1-6-02 Consult agreements.

(A) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

(a) Identification of the physician practitioner(s) and pharmacist(s) authorized to enter into the agreement. This may include:

(i) Individual names of physician practitioners and pharmacists;

(ii) Practitioner Physician or pharmacist practice groups; or

(iii) Identification based on institutional credentialing or privileging.

(b) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.

(c) A description of the drugs or drug categories managed as part of the agreement.

(d) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement.

(e) A description of the types of blood, urine or other tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the managing pharmacist as long as the tests relate to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement.

(f) A description of how the managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification.

(g) A description of how communication between a managing pharmacist and physician practitioner acting under a consult agreement shall take place at regular intervals specified by the practitioner physician who authorized the agreement. The agreement may include a requirement that a managing pharmacist send a consult report to each consulting practitioner physician.

(h) A provision that allows a physician practitioner to override a decision made by the managing pharmacist when appropriate.

(i) A quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.

(j) A description of a continuous quality improvement (CQI) program used to evaluate the effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.

(k) The training and experience criteria for managing pharmacists. The criteria may include privileging or credentialing, board certification, continuing education or any other training requirements. The agreement shall include a process to verify that the managing pharmacists meet the specified criteria.

(l) An effective date and expiration date.

(2) Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(b) to (A)(1)(e) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and made readily retrievable.
(3) The agreement shall be signed by the primary physician, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(4) All amendments to a consult agreement shall be signed and dated by the primary physician, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(5) A consult agreement shall be valid for a period not to exceed two years.

(6) Only Ohio licensed physicians and Ohio licensed pharmacists may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(B) Record keeping. As required by section 4729.39 of the Revised Code, a managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records and are subject to the confidentiality requirements of rule 4729:5-3-05 of the Administrative Code.

(C) Managing drug therapy.

(1) For the purpose of implementing any actions related to the management of drug therapy listed in division (B)(1) of section 4729.39 of the Revised Code, the managing pharmacist may be authorized as one or both of the following, as specified in the consult agreement:

(a) A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement.

(i) For all outpatient prescriptions issued, the pharmacist shall comply with rules 4729:5-5-15 and 4729:5-5-05 of the Administrative Code.

(ii) For all inpatient prescriptions or orders issued at an institutional facility, the pharmacist shall comply with the requirements of agency 4729 of the Administrative Code.

(b) With respect to non-controlled dangerous drugs only, an agent of the consulting physician. As an agent of the consulting physician, a pharmacist is authorized to issue a drug order, on behalf of the consulting physician, in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. A pharmacist issuing a prescription as an agent of a physician shall comply with all the following:

(i) For all outpatient prescriptions, the pharmacist shall comply with rules 4729:5-5-15 and 4729:5-5-05 of the Administrative Code.
(ii) For all inpatient prescriptions or orders issued at an institutional facility, the pharmacist shall comply with the prescription requirements of agency 4729 of the Administrative Code.

(iii) Except as provided in paragraphs (C)(1)(b)(v) and (C)(1)(b)(vi) of this rule, the prescription shall include the required information of the consulting practitioner(s).

(iv) The prescription shall also include the name of the managing pharmacist acting as the agent of the consulting practitioner(s).

(v) The telephone number where the managing pharmacist can be personally contacted during normal business hours. The telephone number may be in addition to or in place of the telephone number required by rule 4729:5-5-15 of the Administrative Code.

(vi) Pursuant to the consult agreement, all required positive identification (including a manual signature) on a prescription shall be of the managing pharmacist on behalf of the consulting practitioner(s).

(2) If the managing pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, a copy of the consult agreement or privileging documentation shall be made available to the dispensing pharmacist or the person administering the dosage ordered if it is requested in order to prove the right of the managing pharmacist to act in this manner.

(3) A managing pharmacist shall request and review an OARRS report covering at least a one-year time period prior to any of the following:

(a) Adding a controlled substance drug to a patient's drug therapy; or

(b) Adjusting a controlled substance drug's strength, dosage form, frequency of administration or route of administration.

(4) Except as provided in paragraph (C)(5) of this rule, a managing pharmacist shall not delegate drug therapy management to anyone other than another authorized pharmacist practicing under the consult agreement.

(5) A managing pharmacist may delegate the administration of a drug to a licensed healthcare professional in accordance with their applicable scope of practice pursuant to the managing pharmacist's order.

(6) A managing pharmacist authorized to prescribe controlled substances pursuant to paragraph (C)(1)(a) of this rule shall comply with all the following:

(a) Maintain a valid controlled substance prescriber registration issued by the state board of pharmacy by submitting an application and a valid consult agreement, in a manner determined by the board, authorizing the pharmacist to prescribe controlled substances.

(i) A pharmacist shall be required to renew their controlled substance prescriber registration in accordance with a renewal schedule adopted by the board. A controlled substance prescriber registration shall be deemed void if the pharmacist no longer holds a valid consult agreement authorizing the prescribing of a controlled substance. Failure to obtain or maintain a valid controlled substance prescriber registration prohibits a pharmacist from prescribing controlled substances.

(2) A pharmacist shall be required to notify the board, in a manner determined by the board, if they are no longer authorized to prescribe controlled substances pursuant to a consult agreement. Notification shall occur within five business days. A controlled substance prescriber registration shall be deemed void if the pharmacist no longer has a valid consult agreement authorizing the prescribing of a controlled substance. Failure to obtain or maintain a valid controlled substance prescriber registration prohibits a pharmacist from prescribing controlled substances.

(3) A pharmacist applying for a controlled substance registration shall be an Ohio licensed pharmacist in good standing. The pharmacist shall not be the subject of any current board disciplinary action or have a restricted license. In determining whether to grant a registration, the board may consider any previous disciplinary action.

(iv) The board may deny a registration if the applicant fails to meet any of the required qualifications or if the board finds that issuing a controlled substance registration presents a danger to public safety.
(b) Subject to approval by the United States drug enforcement administration (D.E.A.), prescribe utilizing a valid D.E.A. registration, which includes, shall include, unless otherwise authorized by the board.

(i) Obtaining and maintaining a valid registration with the D.E.A.; or,

(ii) If permitted by D.E.A., a pharmacist who is employed as a staff prescriber of a hospital pursuant to a consult agreement who is not individually registered under the provisions of the controlled substances act and, therefore, does not possess a D.E.A. registration, may administer, dispense, and prescribe controlled substances, as specified in a consult agreement, under the registration of the hospital. A hospital that authorizes a pharmacist to dispense or prescribe under its registration shall assign a specific internal code number for each managing pharmacist so authorized.

(c) Unless a pharmacist utilizes a hospital’s D.E.A. registration, failure to obtain or maintain a valid D.E.A. registration shall prohibit a managing pharmacist from prescribing controlled substances.

(d) A pharmacist that obtains a valid registration with the D.E.A. pursuant to paragraph (C)(6)(b)(i) of this rule shall:

(i) Submit the pharmacist’s registration information, in a manner determined by the board, within thirty days of issuance.

(ii) Submit any changes to a pharmacist’s registration, in a manner determined by the board, within thirty days of any change to the registration.

(7) A prescription, to be valid, must be issued for a legitimate medical purpose by a pharmacist authorized pursuant to a consult agreement. The responsibility for the proper prescribing is upon the managing pharmacist, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be considered a violation of this rule and may be subject to disciplinary action in accordance with Chapter 4729. of the Revised Code or any rule promulgated thereunder.

(D) Therapy management by formulary. The requirements of this chapter and section 4729.39 of the Revised Code do not apply within an institutional facility when the pharmacists are following the requirements of a formulary system that was developed pursuant to section 4729.381 of the Revised Code.

(E) Review of consult agreements. Upon the request of the state board of pharmacy, a pharmacist shall immediately provide a consult agreement and any relating policies or documentation pursuant to this rule and division (B)(3) of section 4729.39 of the Revised Code. The state board of pharmacy may prohibit the execution of a consult agreement if the board finds any of the following:

(1) The agreement does not meet the requirements set forth in section 4729.39 of the Revised Code or this chapter of the Administrative Code; or

(2) The agreement, if executed, would present a danger to patient safety.
4729:1-6-03 Standards for managing drug therapy.

(A) A managing pharmacist shall prescribe in accordance with a valid prescriber-patient relationship. This includes, but is not limited to, the following:

(1) Reviewing a thorough history of the patient;

(2) Except as provided in paragraphs (F) and (G)(2) of this rule, conducting an initial consultation with the patient via in-person meeting, video conference, or by telephone;

(3) Ordering tests and evaluation of test results in accordance with section 4729.39 of the Revised Code;

(4) Prescribing medication in accordance with this division of the Administrative Code, ruling out the existence of any recognized contraindications;

(5) Consulting with the authorizing practitioner physician on the consult agreement when necessary; and

(6) Documenting these steps in the patient's medical record.

(B) The pharmacist's prescriptive authority shall not exceed what is specified in the consult agreement and shall not exceed the prescriptive authority of the consulting practitioner.

(C) A managing pharmacist shall comply with the same requirements for the prescribing dangerous drugs of a physician pursuant to Chapter 4731-11 of the Administrative Code.

(D) A pharmacist, as part of an opioid treatment program licensed by the state, may administer, but not prescriber, controlled substance narcotics pursuant to a consult agreement in accordance with this division of the Administrative Code for the maintenance or detoxification treatment of opioid addiction.

(E) Except as provided in paragraphs (F) and (G)(1) of this rule, a managing pharmacist shall, at a minimum, conduct a follow-up consultation with the patient on an annual basis. The review shall be conducted via in-person meeting, video conference or by telephone and shall be documented in the patient's medical record.

(F) Paragraphs (A)(2) and (E) of this rule do not apply to the inpatient management a patient's drug therapy pursuant to a consult agreement in an institutional facility.

(G) A hospital, clinic or other healthcare facility that utilizes managing pharmacists for the purposes of authorizing prescriptions that were originally issued by a consulting practitioner shall comply with the following:

(1) A managing pharmacist, consulting practitioner, or agent of the consulting practitioner, shall, at a minimum, conduct a follow-up consultation with the patient on an annual basis. The review shall be conducted via in-person meeting, video conference or by telephone and shall be documented in the patient’s medical record.

(b) The required follow-up consultation with patients pursuant to paragraph (G)(1)(a) of this rule does not apply if the patient, or an individual authorized to act on behalf of a patient, elects to opt-out of the follow-up consultation.

(2) The initial consultation requirement by a managing pharmacist is not required if the managing pharmacist is only engaged in the authorization of prescriptions.

(3) In addition to the communication requirements in paragraph (C) of rule 4729:1-6-01 of the Administrative Code, the hospital, clinic or healthcare facility shall:
(a) Obtain patient consent specifically authorizing the use of managing pharmacists to authorize prescriptions pursuant to a consult agreement.

(b) Provide contact information, either electronically or in writing, of the person or persons at the hospital, clinic or other healthcare facility who are responsible for answering questions regarding the patient’s drug therapy.

(4) Notwithstanding any other provision of the Administrative Code, all prescriptions authorized pursuant to this paragraph shall include the name of the managing pharmacist authorizing the prescription and the telephone number where the managing pharmacist can be personally contacted during normal business hours.

(5) Managing pharmacists authorizing prescription refills in accordance with this paragraph shall utilize an electronic health records system that complies with the following:

(a) The system shall provide managing pharmacists and consulting physicians-practitioners with real-time access to the patient’s complete medical record maintained by the consulting practitioner, including patient lab results and prescriber and pharmacist notes.

(b) The electronic health records system shall have the capability to allow communication between managing pharmacists and consulting practitioners.

(6) The consult agreement shall include an algorithm that is specific to refill authorizations. The algorithm must include, but is not limited to, the following decision criteria for managing pharmacists to follow when conducting prescription refill authorizations:

(a) Required lab results;

(b) Any restrictions or limitations; and

(c) The maximum amount of time between prescriber visits a refill may be authorized based upon prevailing standards of care.
Consult agreements.

(A) For purposes of this chapter, practitioner includes the following:

1. Physician authorized to practice medicine and surgery or osteopathic medicine and surgery under chapter 4731 of the revised code.

2. Physician assistant who is licensed to practice as a physician assistant under chapter 4730 of the revised code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority.

(B) Requirements of a consult agreement.

1. A consult agreement shall include all of the following:

   a. Identification of the physician practitioner(s) and pharmacist(s) authorized to enter into the agreement. They may include:

      i. Individual names of physician practitioners and pharmacists;

      ii. Physician Practitioner or pharmacist practice groups; or

      iii. Identification based on institutional credentialing or privileging.

   b. A description of the patient’s consent to drug therapy management pursuant to the consult agreement as set forth in paragraphs (H) and (I) of rule 4729:1-06-01 of the Administrative Code.

   c. The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.

   d. A description of the drugs or drug categories managed as part of the agreement.

   e. A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement.

   f. A description of the types of blood, urine or other tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and
evaluated by the managing pharmacist as long as the tests relate directly to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated.

(g) A description of how the managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code.

(h) A description of how communication between a managing pharmacist and physician practitioner acting under a consult agreement shall take place at regular intervals specified by the physician practitioner who authorized the agreement. The agreement may include a requirement that the managing pharmacist send a consult report to each consulting physician practitioner.

(i) A provision that allows a physician practitioner to override a decision made by the managing pharmacist when appropriate.

(j) An appropriate quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.

(k) A description of a continuous quality improvement (CQI) program used to evaluate effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.

(l) The training and experience criteria for managing pharmacists. The criteria may include privileging or credentialing, board certification, continuing education or any other training requirements. The agreement shall include a process to verify that the managing pharmacists meet the specified criteria.

(m) A statement that the physician practitioners and pharmacists shall meet minimal and prevailing standards of care at all times.

(n) An effective date and expiration date.

(o) Any other requirements contained in rules 4729:1-6-01, 4729:1-6-02 and
4729:1-6-03 of the Administrative Code.

(2) Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(c) to (A)(1)(f) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and available to an agent of the board upon request.

(3) The agreement shall be signed by the primary physician-practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

   (a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or

   (b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(4) All amendments to a consult agreement shall be signed and dated by the primary physician-practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

   (a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or

   (b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

   (c) Amendments to the consult agreement are required when the scope of the managing pharmacist's permitted procedures expands past what was contemplated within the agreement.

(5) A consult agreement shall be valid for a period not to exceed two years.
(6) Only the following Ohio licensed physicians or practitioners practicing in Ohio and Ohio licensed pharmacists may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(a) Physicians

(b) Physician assistants if entering into a consult agreement is authorized by one or more supervising physicians under a supervision agreement under section 4730.19 of the Revised Code.

(C)(D) Recordkeeping. The primary physician or practitioner, physician-practitioner group or institution as defined in agency 4729 of the Administrative Code shall maintain a copy of the original consult agreement, and all amendments made thereafter, and a record of actions made in consultation with the managing pharmacist regarding each patient’s drug therapy. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records.

(D)(E) Managing drug therapy.

(1) For the purpose of implementing the management of a patient’s drug therapy by an authorized managing pharmacist acting pursuant to a consult agreement, the primary physician or practitioner must:

(a) Provide the managing pharmacist with access to the patient’s medical record; and

(b) Establish the managing pharmacist’s prescriptive authority as one or both of the following:

(i) A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. For all prescriptions issued by a pharmacist pursuant to this paragraph, the pharmacist shall comply with rules 4729-5-30 and 4729-5-13 of the Administrative Code; and or

(ii) With respect to non-controlled dangerous drugs only, an agent of the consulting physician or practitioner(s). As an agent of the consulting physician or practitioner(s), a pharmacist is authorized to
issue a drug order, on behalf of the consulting practitioner(s), in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement, and

(c) Specifically authorize the managing pharmacist’s ability to:

(i) Change the duration of treatment for the current drug therapy; adjust a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinue a drug, or to prescribe new drugs; and or

(ii) Order blood, urine and other tests related to the drug therapy being managed and to evaluate those results, and

(d) Identify the extent to which, and to whom, the managing pharmacist may delegate drug therapy management to other authorized pharmacists under the agreement.

(E) Review of consult agreements. Upon the request of the state medical board, the primary practitioner shall immediately provide a copy of the consult agreement, amendments, and any relating policies or documentation pursuant to this rule and section 4729.39 of the Revised Code. The state medical board may prohibit the execution of a consult agreement, or subsequently void a consult agreement, if the board finds any of the following:

(1) The agreement does not meet the requirements set forth in section 4729.39 of the Revised Code or this division of the administrative code; or

(2) The consult agreement, if executed, would present a danger to patient safety.
Standards for managing drug therapy.

(A) A physician practitioner may elect to manage the drug therapy of an established patient by entering into a consult agreement with a pharmacist. The agreement is subject, but not limited to, the following standards:

(1) The primary physician practitioner must ensure that the managing pharmacist has access to the patient’s medical record, the medical record is accurate, and that while transferring the medical record, the primary physician practitioner ensures the confidentiality of the medical record.

(2) The physician practitioner must have an ongoing physician practitioner-patient relationship with the patient whose drug therapy is being managed, including an initial assessment and diagnosis by the physician practitioner prior to the commencement of the consult agreement.

(3) With the exception of inpatient management of patient care at an institutional facility as defined in agency 4729 of the Administrative Code, the physician practitioner, prior to a pharmacist managing the patient’s drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement, in such a manner that the patient or the patient’s representative understands scope and role of the managing pharmacist, which includes the following:

(a) That a pharmacist may be utilized in the management of the patient's care;

(b) That the patient or an individual authorized to act on behalf of a patient has the right to elect to participate in and to withdraw from the consult agreement.

(c) Consent may be obtained as part of the patient's initial consent to treatment.

(4) The diagnosis by the physician practitioner must be within the physician practitioner’s scope of practice.

(5) The physician practitioner shall meet the minimal and prevailing standards of care.

(6) The physician practitioner must ensure that the pharmacist managing the patient’s drug therapy has the requisite training, and experience related to the particular diagnosis for which the drug therapy is prescribed. Physicians practicing at institutional or ambulatory outpatient
facilities may meet this requirement through institutional credentialing standards or policies.

(7) The physician practitioner shall review the records of all services provided to the patient under the consult agreement.

(B) Quality assurance mechanisms. The following quality assurance mechanisms shall be implemented to verify information contained within the consult agreement, and ensure the managing pharmacist’s actions are authorized and meet the standards listed in paragraphs (A) and (B) of this rule:

(1) Verification of ongoing physician practitioner-patient relationship. A physician practitioner-patient relationship can be established by detailing criteria set forth in paragraph (A)(2) of this rule, within the consult agreement.

(2) Verification that physician practitioner diagnosis is within the physician practitioner’s scope of practice. Establishing that a diagnosis is within the physician practitioner’s scope of practice may be established by detailing the criteria set forth in paragraph (A)(4) of this rule, within the consult agreement.

(3) Verification that pharmacist’s training and experience is related to the drug therapy. Establishing that a pharmacist’s requisite training and experience with a particular drug therapy is related to the diagnosis for which the drug therapy is prescribed, may be established by detailing the criteria set forth in paragraph (A)(6) of this rule, within the consult agreement.

(C) Continuous quality improvement program. The following should be included in the development of a continuous quality improvement program in order to evaluate the effectiveness of patient care and ensure positive patient outcomes:

(1) Notifications to primary physician practitioner. The managing pharmacist must notify the primary physician practitioner of the following situations regarding any pharmacist authorized to manage drug therapy under the agreement:

(a) A pharmacist has had their pharmacist license revoked, suspended, or denied by the state board of pharmacy;

(b) If prescribing controlled substances, a pharmacist has failed to renew their controlled substance prescriber registration;
(c) If prescribing controlled substances, a pharmacist fails to obtain or maintain a valid D.E.A. registration;

(D) Overriding decisions of managing pharmacist. Any authorized [physician, practitioner] identified under the consult agreement may override any decision, change, modification, evaluation or other action by any pharmacist acting pursuant to consult agreement or under the direction of the managing pharmacist, that was made with respect to the management of the patient’s drug therapy under the consult agreement.
Legislative Update: December 9, 2020

Bills of high interest or with significant activity since the last board meeting:

**SB 246 – Occupational Licensing (Sen. Roegner, McColley)**

*To require an occupational licensing authority to issue a license or government certification to an applicant who holds a license, government certification, or private certification or has satisfactory work experience in another state under certain circumstances.*

**Areas of Interest:**

- The policy team worked with the bill sponsor and the Legislative Service Commission to draft amendments to the bill which were adopted on 12/1/2020
- The requested amendments would allow the board to retain current standards of review but if the bill passes, license reciprocity would still be granted to out of state license holders.
- The sub bill would retain a lookback limitation from criminal convictions of five years. The original bill only allowed a two-year lookback.
- The policy team will advocate an extension of the 5-year period to 10 years or more.

**Board Position:** Neutral

**Status:** Eight hearing was held 12/1/2020 in Senate General Government and Agency Review.

**SB 364 – Join Interstate Medical Licensure Compact (Sen. Roegner)**

*To enter into the Interstate Medical Licensure Compact.*

**Areas of Interest:**

- Requires entrance into the interstate medical licensing compact
- Model compact language must be adopted as written and cannot be amended
- The policy team met with OSMA and we’re advised that they will likely support this language
- The policy, legal and licensing team are currently researching this issue. Several other states with introduced legislation and passed legislation have been contacted as well as the IMLC Executive Director Marschall Smith.
- The policy team will be attending an interested party meeting hosted by the bill sponsor.
- The policy team also held a meeting with the bill sponsor to discuss concerns.

**Board Position:** Opposed

**Status:** 9/16/2020 Introduced in the Senate. Referred to Senate Health, Human Services and Medicaid - There are no currently scheduled hearings.

To revise the initial occupational licensing restrictions applicable to individuals convicted of criminal offenses

Areas of interest: Limited look back period for criminal convictions check of five years. Removal of references to good moral character and "moral turpitude"

- Requires state licensing authorities to provide a list of disqualifying offenses that would bar an individual from licensure.
- The licensing authority may only consider the listed disqualifying offenses when deciding whether to license an individual and for no more than five years preceding the application for licensure.
- The five-year lookback limitation does not apply to offenses that are violent or sexual in nature.
- Prohibits a state licensing authority from refusing to issue an initial license to an individual based solely on being charged with or convicted of a criminal offense or a nonspecific qualification such as "moral turpitude" or lack of "moral character."
- If an individual is denied licensure, the licensing authority must provide a reason for the refusal along with the earliest date that the individual may reapply and the individual’s ability to offer evidence of rehabilitation upon reapplication.
- In conjunction with the boards of pharmacy, nursing, chiropractic and dental, amendments have been requested to the language to create a new ORC section to apply to healthcare licensing agencies. Those requested amendments were included in the House passed version of the bill.
- The addition of the amendments specify that licensing authorities can consider disciplinary actions taken against an individual who has already been licensed with no lookback limitation.
- Testimony was submitted at the third committee to outline the concerns of the Board and offer suggested changes.

Board Position: Opposed

Status: Third hearing held in Senate Transportation, Commerce and Workforce held 12/2/2020


To modify the laws regarding physician assistants.

Areas of Interest: Decouples national accreditation from licensure. Renames the PA/physician “supervision agreement” to “collaborative agreement” to more accurately represent the relationship between practitioners. Eliminates physician liability for the actions of a physician assistant. Allows a physician assistant to “pink-slip” a patient. Allows physician assistants to perform fluoroscopy. Permits a physician assistant to perform rapid intubation and procedural sedation, order fluoroscopy. Permits a physician assistant to perform rapid intubation and procedural sedation, order rapid intubation and procedural sedation, and order drugs needed to perform rapid intubation and procedural sedation in a health care facility

- Met with the lobbyist representing the PAs. This bill is unlikely to proceed through the entire legislative process. Alternatively, an amendment around procedural sedation is likely to be pursued.

Board Position: Opposed
**Status:** Awaiting first hearing in House Health

**HB 679 – Telehealth (Rep Fraizer, Holmes)**

*To establish and modify requirements regarding the provision of telehealth services and to declare an emergency.*

- The ad-hoc committee continues to discuss the bill provisions. Changes around initial visits, consistency in standard of care, Medical Board rulemaking authority and synchronous technology are proposed based on the last discussions with the committee.
- The legal team has drafted changes based on those discussions
- The policy team has presented the amendments to the bill sponsor, the committee chair and the vice chair to be added to the bill.

**Board Position:** Support- closely monitoring- awaiting the addition of Board requested amendments

**Status:** Third hearing in Senate Insurance and Financial Institutions was held 11/18/2020

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**Bills that continue to be monitored but have not seen significant activity since the last board meeting:**

**SB 1 – Reduce the number of regulatory restrictions**

*To require certain agencies to reduce the number of regulatory restrictions in their administrative rules, to require the approval of the Joint Committee on Agency Rule Review for Department of Health orders to be effective for more than fourteen days, and to modify the Department's rulemaking authority.*

**Areas of interest:** Requires state agencies to reduce regulatory restrictions in rules by 30% by 2022. Prohibits agencies from adopting rules that would increase the percentage of regulatory restrictions contained in its rules. Requires an agency to produce a base inventory of rules by 12/31/2019.

**Board Position:** Interested Party - the rule reductions only apply to cabinet level agencies

**Status:** Senate did not agree to House Amendments 5/28/2020 – Conference committee was held 12/1/2020

**SB 31 – Exempt EMS telecommunicator from public records law (Sen.Roegner)**

*To include emergency service telecommunicators, certain Ohio National Guard members, federal judges, regional physician advisory board members, and first responders as individuals whose residential and familial information is exempt from disclosure under the Public Records Law, to address matters related to contact tracing, and to require the Bureau of Workers’ Compensation or Industrial Commission to disclose a claimant's name to a journalist upon written request.*

**Areas of interest:** Exempts emergency medical service workers’ personal records such as addresses from being made public, the House added an amendment requiring a signed consent before someone undergoes contact tracing, an important way to stem the spread of the coronavirus.
Board Position: Interested Party
Status: Senate did not agree to House Amendments 5/28/2020 – Awaiting Conference Committee

SB 105 – Massage Therapy Licensing (companion HB 374) (Sen.Brenner)
To make changes to the massage therapy licensing law.
Areas of interest: Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.
Board Position: Interested Party
Status: Awaiting third hearing in Senate Health and Human Services – Second hearing was held 9/18/2019

SB 156 – Prohibits Defrauding an Alcohol, Drug and Urine Screening Test (Sen.Gavarone)
To enact section 2925.15 of the Revised Code to prohibit defrauding an alcohol, drug, or urine screening test.
Areas of interest: Prohibits defrauding a drug or urine screening test, and bans the sale and use of fake urine for that purpose. Fake urine could be synthetic, the urine of another person, or the person’s own urine if it was collected before the screening.
Board Position: Interested Party
Status: Awaiting third hearing in House Criminal Justice Committee. Second hearing was held 5/28/2020

SB 178- Podiatrists authority to administer the flu vaccine (Sen.Schuring)
To provide the authority of podiatrists to administer influenza vaccinations.
Areas of interest: Allows a podiatrist to administer a flu vaccine.
Board Position: Interested Party
Status: Signed by Governor DeWine 11/27/2020. This language becomes effective on 2/25/2021

SB 236- Regards radiation control and radiation technology professionals (Sen. Stephen Huffman)
To amend the Revised Code regarding the Ohio Department of Health’s Radiation Control Program and the regulation of radiation technology professionals.
Areas of interest:
- Authorizes the Director of Health, when adopting rules governing Ohio’s Radiation Control Program, to deviate from the Suggested State Regulations for Control of Radiation if doing so is warranted and does not pose a health, environmental, or safety risk.
• Specifies that one of the activities radiographers and nuclear medicine technologists are licensed to perform is to document orders for contrast and radio-pharmaceuticals, respectively, in patient medical records.
• An amendment was added in the House Health committee that would allow anesthesiologist assistants the ability to order and direct others to administer drugs under a supervision agreement.
• OSMA and The Ohio Society of Anesthesiologists have expressed a neutral position on the amendments language as it harmonizes the language to similar passed to allow CRNA

**Board Position:** Neutral

**Status:** Passed out of the House Health Committee. The bill now awaits a floor vote and a subsequent vote for Senate concurrence.

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**SB 238- License and regulate art and music therapists (Sen. Yuko)**

*To license and regulate art therapists and music therapist*

**Areas of interest:** Places music therapists under the purview of the Medical Board. Art therapists would be regulated by the Counselor, Social Worker and Marriage and Family Therapist Board

**Board Position:** Interested Party

**Status:** 2nd hearing held in Senate Transportation, Commerce and Workforce 9/23/2020

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**SB 293 - Create Court of Claims Procedure for Open Meeting Violations (Sen. Manning)**

*To create a procedure within the Court of Claims to hear complaints alleging a violation of the Open Meetings Law.*

**Areas of interest:** Creates a procedure within the Court of Claims to hear complaints alleging a violation of the Open Meetings Law

**Board Position:** Interested Party

**Status:** Awaiting a first hearing in House Civil Justice. First House hearing was held 11/10/2020

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**SB 305 Telemedicine (Sen. Craig)**

*To require health plan issuers to cover telemedicine services during a state of emergency and to declare an emergency.*

**Areas of interest:** Requires health insurers to cover telemedicine during a state of emergency. The bill includes an emergency clause that would make the bill effective upon signing by the Governor if the bill is passed by both chambers of the legislature.

**Board Position:** Interested Party

**Status:** Second hearing was held in Senate Insurance and Financial Institutions 12/1/2020.
SB 308 Civil Liability - Emergency Services (Sen. Matt Huffman) (Companion HB 606)

To revise the law governing immunity from civil liability for health care providers during disasters, to provide qualified civil immunity to service providers providing services during and after a government-declared disaster or emergency due to COVID-19, and to declare an emergency.

Areas of interest: The requirement of proving gross negligence will make these minimal standard of care professional disciplinary violations, which are intended to protect public health and safety, very difficult to pursue

Board Position: Interested Party

Status: HB 606 passed out of both chambers 9/1/2020.

SB 341 – Nursing Licensure Compact (Sen. Roegner)

To enact sections 4723.11 and 4723.111 of the Revised Code to enter into the Nurse Licensure Compact.

Areas of interest: No current concerns – monitoring due to potential for physician interstate compact language

Board Position: Interested Party

Status: First hearing held in Senate Health and Human Services 9/22/2020

SB 348 – Regards boards of health (Sen. Schaffer, Roegner)

To prohibit local boards of health from using certain threatening words in notifications to the public, to allow local boards of health to reject Department of Health orders during an emergency, to allow health care professionals who serve on a board of health to receive continuing education credit, and to change the makeup of local boards of health.

Areas of interest: Allows up to five hours of CME credit for serving on a local board of health.

Board Position: Interested Party

Status: First hearing held in Senate Health, Human Services and Medicaid 9/1/2020

SB 365– Extend authority to hold meetings by electronic technology (Sen. Fedor)

To extend the authorization for members of a public body to hold and attend meetings or hearings via electronic technology, during the period of the emergency declared by Executive Order 2020-01D on March 9, 2020, until the declared emergency is terminated.

Areas of interest: Extends the authorization to hold virtual meetings

Board Position: Support


To include forensic mental health providers, mental health evaluation providers, regional psychiatric hospital employees, emergency service telecommunicators, and certain Ohio National Guard members as individuals whose residential and familial information is exempt from disclosure under the Public Records Law and to address matters related to contact tracing.

Areas of interest: Allows exemption to certain healthcare providers from public records law.

Board Position: Support


HB 177 – Standard care arrangements and prescribing requirements (Rep. Brinkman)

Regarding standard care arrangements entered into by advanced practice registered nurses and collaborating physicians or podiatrists; physician prescribing of schedule II controlled substances from convenience care clinics; and clearances by licensed health professionals of concussed student athletes.

Areas of interest: Allows an advanced practice registered nurse who is a certified nurse practitioner, clinical nurse specialist, or certified nurse-midwife to practice without a collaborating physician or podiatrist.

Board Position: Opposed

Status: First hearing in House Health was held 4/9/2019

HB 203 – Specifies requirements for mobile dental facility operations (Rep. Lipps)

To specify requirements for the operation of mobile dental facilities and to authorize pharmacists to enter consult agreements with certain physician assistants and advanced practice registered nurses.

Areas of interest:

- Establishes a greater framework for a statewide mobile dental facility database
- Allow the medical records of a mobile dental facility patient to transfer to a dental office so that those patients can receive more effective and efficient follow up services.
- The as passed version of the bill was amended to include language from SB 303 (Pharmacy Consult Agreements).
- Authorizes pharmacists to enter into consult agreements with certain advanced practice registered nurses and physician assistants for the management of patient drug therapies.
- Maintains existing law provisions allowing pharmacists to enter into consult agreements with physicians.
- Authorizes a pharmacist, when managing a patient’s drug therapy under a consult agreement, to order and evaluate laboratory and diagnostic tests for the patient, rather than limiting it to blood and urine tests as under current law.
- Requires the board of pharmacy to consult with the medical board to develop rules to be followed by pharmacists.
- Requires the medical board to consult with the board of pharmacy to develop rules to be followed by physicians.
• Requires the board of nursing to consult with both the medical board and the board of pharmacy to develop rules to be followed by clinical nurse specialist, certified nurse-midwives and certified nurse practitioners.

**Board Position:** Interested Party

**Status:** Passed and signed. Effective 12/15/2020

**HB 323 - Authorize psychologists to prescribe drugs/therapeutic devices (Rep. Don Manning)**

*To authorize certain psychologists to prescribe drugs and therapeutic devices as part of the practice of psychology*

**Areas of interest:**

**Board Position:** Strongly Oppose

**Status:** Awaiting third hearing in House Health. Second hearing was held 1/28/2020

**HB 341- Addiction Treatment Drugs (Rep. Ginter)**

*Regarding the administration of addiction treatment drugs, federal agency access to the Ohio Automated Rx Reporting System, the Board of Pharmacy’s exemption from open meetings requirements, the occasional sale of certain drugs at wholesale, and naloxone access and education.*

**Areas of interest:**

• Authorizes a pharmacist to administer by injection any long-acting or extended-release drug prescribed by a physician to treat drug addiction, instead of limiting the pharmacist’s authority to the administration of opioid antagonists as under current law.

• Also permits the state’s prescription drug monitoring program, The Ohio Automated RX Reporting System (OARRS), to share data with the Defense Health Agencies (DHA) prescription drug monitoring program.

• An amendment was added to authorize certain advanced practice registered nurses and physician assistants to develop protocols to permit individuals and employees of service entities to personally furnish or administer naloxone.

**Board Position:** Interested Party

**Status:** Passed and signed. Effective 12/15/2020

**HB 374 – Massage Therapy License (Rep. Plummer, Manchester) (companion SB 105)**

*To make changes to the massage therapy licensing law.*

**Areas of interest:** Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board. SB 105 is more likely to move in the legislative process.

**Board Position:** Interested Party

**Status:** Fourth hearing held in House Commerce and Labor 12/2/2020

To enact sections 3902.50, 3902.51, 3902.52, 3902.53, and 3902.54 of the Revised Code regarding out-of-network care.

**Areas of interest:** Requires hospitals to provide upfront costs for basic items and services

**Board Position:** Interested Party

**Status:** Third hearing was held in Senate Insurance and Financial Institutions on 12/1/2020

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HB 407 – Enact Clinician Integrity and Medical Accuracy Act (Rep. Liston and Rep. Russo)

To establish provisions to be known as the "Clinician Integrity and Medical Accuracy Act.

**Areas of interest:** Prohibits a state or local government entity from requiring a physician to provide a patient with a medical service or information that is not, in the physician's clinical judgment, medically accurate and appropriate for the patient. Specifies that a state or local government entity cannot prohibit a physician from providing a patient with a medical service or information that is, in the physician's clinical judgment, appropriate for the patient and evidence-based or medically accurate

**Board Position:** Interested Party

**Status:** Awaiting first hearing in House Health.

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To regulate the practice of surgical assistants.

**Areas of interest:** Requires that all surgical assistants be registered with the State Medical Board - allows for the application of a waiver in areas where there are shortages - grants authority to the Board to create rules.

**Board Position:** Interested Party

**Status:** Awaiting second hearing in House Health. First hearing held 5/19/2020

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HB 484 – Athletic Training (Rep. Abrams, Carfagna)

To amend sections 4755.60 and 4755.62 and to enact section 4755.621 of the Revised Code regarding the practice of athletic training.

**Areas of interest:** Eliminate language in current law that restricts ATs by only allowing administering of “topical” care”.

**Board Position:** Interested Party


To create the crime of fraudulent assisted reproduction and civil actions for an assisted reproduction procedure without consent.

Areas of Interest: "Prohibits a health care professional from purposely or knowingly using human reproductive material from a donor while performing an assisted reproduction procedure if the person receiving the procedure has not expressly consented to the use of that donor’s material"

Board Position: Interested Party

Status: Awaiting first hearing in House criminal justice. Referred 2/4/2020

HB 547- Restrict Cost Sharing- Occupational Licensing/ Physical Therapists (Rep.LaRe)

To enact sections 3902.50 and 3902.51 of the Revised Code to restrict cost sharing requirements with regard to occupational and physical therapists.

Areas of Interest: Caps cost-sharing for occupational and physical therapy

Board Position: Interested Party

Status: Third hearing held in House Insurance 12/1/2020


To amend section 3902.30 of the Revised Code to require health plan issuers to cover telemedicine services during a state of emergency, and to declare an emergency.

Areas of Interest: Requires health plan insurers to cover telemedicine during a state of emergency

Board Position: Support

Status: Awaiting first hearing in House Insurance. Referred 5/5/2020


To temporarily authorize emergency medical technicians to perform certain medical services in hospitals and to declare an emergency.

Areas of Interest: Allows EMTs to continue care inside any area of a hospital and perform medical services under the supervision of a physician, physician assistant designated by a physician or a registered nurse designated by a physician during the COVID-19 emergency.

Board Position: Interested Party

Status: Awaiting first hearing in House Health
HB 606- Grant Immunity to essential workers who transmit COVID-19 (Rep. Grendell)

To make temporary changes related to qualified civil immunity for health care and emergency services provided during a government-declared disaster or emergency and for exposure to or transmission or contraction of certain coronaviruses.

Areas of Interest:

- Grants temporary qualified immunity to specified health care providers who provide health care services or emergency services during a declared disaster or emergency;
- Grants immunity from tort liability and professional discipline for such services provided as a result of, and in response to, a disaster or emergency that results in injury, death, or loss allegedly resulting from (1) actions or omissions in the provision, withholding, or withdrawal of those services, (2) decisions related to the provision, withholding, or withdrawal of those services, and (3) compliance with an executive order or director’s order;
- Grants immunity from tort liability and professional discipline for injury, death, or loss that allegedly resulted because a health care provider was unable to treat a person, including the inability to perform any elective procedure, due to an executive or director’s order or a local health order issued in relation to an epidemic or pandemic disease or other public health emergency;
- Excludes from immunity in tort actions conduct that constitutes a reckless disregard of the consequences or intentional or willful or wanton misconduct on the part of the person against whom the action is brought.
- The legislation does not grant an immunity from tort or other civil liability or a professional disciplinary action to a health care provider for actions that are outside the skills, education, and training of the health care provider, unless the health care provider undertakes the action in good faith and in response to a lack of resources caused by a disaster or emergency.
- The legislation does not affect any legal responsibility of a health care provider to comply with any applicable law of this state or rule of an agency of this state.

Board Position: Support

Status: Passed and signed. Effective 12/16/2020


To amend sections 3727.50, 3727.51, 3727.52, and 3727.53 and to enact sections 3727.80 to 3727.88 of the Revised Code regarding staffing ratios and other employment conditions for registered nurses employed by hospitals.

Areas of Interest: Addresses the staffing ratios of registered nurses in hospitals

Board Position: Interested Party

Status: Awaiting first hearing in House Commerce and Labor. Referred 5/19/2020


To amend section 3796.01 of the Revised Code to authorize the use of medical marijuana for autism spectrum disorder.

Areas of Interest: Authorize medical marijuana for autism spectrum disorder
**Board Position:** Oppose - the Board has already declared positions on these allowed conditions

**Status:** Awaiting first hearing in House Health. Referred 5/27/2020

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**HB 650 – Medical Marijuana – Anxiety, Opioid Use Disorder (Rep. Upchurch)**

To amend section 3796.01 of the Revised Code to authorize the use of medical marijuana for anxiety, autism spectrum disorder, and opioid use disorder.

**Areas of Interest:** Authorize medical marijuana for anxiety, opioid use disorder

**Board Position:** Oppose - the Board has already declared positions on these allowed conditions

**Status:** Awaiting first hearing in House Health. Referred 5/27/2020

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Regarding the operation of businesses, practice of certain professions, and completion of education as it relates to COVID-19.

**Areas of Interest:** Authorizes pharmacists to administer Covid-19 vaccines and order COVID-19 diagnostic tests.

**Board Position:** Interested Party

**Status:** Second hearing in Senate General Government and Agency Review was held 12/1/2020

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**HB 747 – Prescribing and Dispensing Drugs for off-label use (Rep. Grendell, Cutrona)**

To enact sections 4723.283, 4729.261, 4730.253, and 4731.201 of the Revised Code regarding the prescribing and dispensing of drugs for off-label uses.

**Areas of Interest:** Prohibits the Board of Nursing and State Medical Board from taking actions on a license solely for issuing a prescription for a drug to be used in a manner other than the use approved by the U.S. FDA, except when the issuance of such a prescription conflicts with acceptable and prevailing standards of safe care.

- Applies to the following license types: Certified Nurse Practitioner, Clinical Nurse Specialist, Physician Assistant, Licensees practicing medicine in accordance with chapter 4731 of the Ohio revised code
- Feedback from the board is needed

**Board Position:** Interested Party

**Status:** Awaiting first hearing in House Health. Referred 8/31/2020
Federal Legislation:

S. 3993 - Equal Access to Care Act (Sen. Cruz, Sen. Blackburn)

Areas of Interest: Allows healthcare professionals to provide telehealth services across state lines during a pandemic

Board Position: Interested Party


S. 4421 - TREAT Act - temporary licensing reciprocity for telehealth and interstate health care treatment (Sen. Christopher Murphy)

Areas of Interest: Temporary authorization of telehealth and interstate treatment

Board Position: Interested Party


Areas of Interest: To provide immunity from liability under section 4 of the Clayton Act for damages in cases against occupational licensing boards that meet appropriate standards, to provide for the establishment of those standards, and for other purposes.

Board Position: Interested Party


H.R. 8723 - Adoption by the State of the Interstate Medical Licensure Compact,

Areas of Interest: In the case of a State that has not, by the date that is 3 years after the date of the enactment of this Act, joined, through enactment of a State law, the Interstate Medical Licensure Compact facilitating physician interstate licensure, as of the day after such 3-year period, the State shall not be eligible for any funds or assistance administered by the Bureau of Health Workforce of the Health Resources and Services Administration of the Department of Health and Human Services. In the case of a State that becomes ineligible for such funds or assistance pursuant to the previous sentence, if such State after such 3-year date joins, through enactment of a State law, the Interstate Medical Licensure Compact, the Secretary of Health and Human Services may determine such State is no longer ineligible for such funds or assistance pursuant to the previous sentence.

Board Position: Interested Party

Status: Introduced 10/30/2020. Read twice and referred to the House Committee on Energy and Commerce.
<table>
<thead>
<tr>
<th>Bill Number/Link</th>
<th>Name</th>
<th>Current Bill Status</th>
<th>Committee Assignment</th>
<th>Board Position</th>
<th>Bill Sponsor(s)</th>
<th>Date Introduced</th>
<th>Areas of Interest</th>
<th>Action Taken</th>
<th>Action Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB 1</td>
<td>Reduce Regulatory Restrictions</td>
<td>Passed Senate and House with amendments</td>
<td>Conference Committee for concurrence of House amendment</td>
<td>Neutral - the rule reductions only apply to cabinet level agencies</td>
<td>Sen. Rob McColley (R-1)</td>
<td>5/6/2020 - Conference committee held 12/2/2020</td>
<td>Requires state agencies to reduce regulatory restrictions in rules by 30% by 2022. Prohibits agencies from adopting rules that would increase the percentage of regulatory restrictions contained in its rules. Requires an agency to produce a base inventory of rules by 1/31/2016.</td>
<td>2/12/2019</td>
<td>The policy team will continue to monitor this bill throughout the legislative process</td>
</tr>
<tr>
<td>SB 31</td>
<td>Exempt EMS telecommunicator info from Public Records Law</td>
<td>Passed Senate and House with amendments</td>
<td>Conference Committee for concurrence of House amendment</td>
<td>Interested party</td>
<td>Sen. Kristina Roegner (R-27)</td>
<td>5/28/2020 - awaiting conference committee</td>
<td>Exempts emergency medical service workers' personal records such as addresses from being made public, the House added an amendment requiring a signed consent before someone undergoes contact tracing, an important way to stem the spread of the coronavirus.</td>
<td>2/12/2019</td>
<td>The policy team will continue to monitor this bill throughout the legislative process</td>
</tr>
<tr>
<td>SB 105</td>
<td>Massage Therapy Licensing (companion HB 374)</td>
<td>Awaiting third hearing</td>
<td>Senate Health and Human Services 3/21/2019</td>
<td>Interested Party</td>
<td>Sen. Andrew Brenner (R-19)</td>
<td>3/13/2019</td>
<td>Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.</td>
<td>None</td>
<td>The policy team will continue to monitor this bill throughout the legislative process</td>
</tr>
<tr>
<td>SB 156</td>
<td>Prohibits Defrauding an Alcohol, Drug or Urine Screening Test</td>
<td>Passed Senate 2/12/2020 Referred to House Committee</td>
<td>House Criminal Justice - 3rd Hearing 12/3/2020</td>
<td>Interested Party</td>
<td>Sen. Theresa Gavarone (R-2)</td>
<td>5/28/2020</td>
<td>Prohibits defrauding a drug or urine screening test, and bans the sale and use of fake urine for that purpose. Fake urine could be synthetic, the urine of another person, or the person's own urine if it was collected before the screening.</td>
<td>None</td>
<td>The policy team will continue to monitor this bill throughout the legislative process</td>
</tr>
<tr>
<td>SB 178</td>
<td>Podiatrists authority to administer the flu vaccine</td>
<td>Passed both chambers 11/19/2020 Signed 11/27/2020. Becomes effective 2/25/2021</td>
<td>House Health 5/12/2020</td>
<td>Support</td>
<td>Sen. Kirk Schuring (R-29)</td>
<td>7/17/2020</td>
<td>Allows a podiatrist to administer a flu vaccine</td>
<td>None</td>
<td>The policy team will continue to monitor this bill throughout the legislative process</td>
</tr>
<tr>
<td>SB 236</td>
<td>Regards radiation control and radiation technology professionals</td>
<td>Passed the House Committee with amendments 12/1/2020 - Awaiting House floor vote and awaiting vote for concurrence</td>
<td>House Health - 3rd hearing held 12/1/2020</td>
<td>Interested Party</td>
<td>Sen. Stephen Huffman (R-5)</td>
<td>11/12/2019</td>
<td>Authorizes the Director of Health, when adopting rules governing Ohio’s Radiation Control Program, to deviate from the Suggested State Regulations for Control of Radiation if doing so is warranted and does not pose a health, environmental, or safety risk. Specifies that one of the activities radiographers and nuclear medicine technologists are licensed to perform is to document orders for contrast and radio-pharmaceuticals, respectively, in patient medical records. * An amendment was added in the House Health committee that would allow anesthesiologist assistants the ability to order and direct others to administer drugs under a supervision agreement</td>
<td>Discussions with stakeholders. OSMA and The Ohio Society of Anesthesiologists are neutral on this language.</td>
<td>The policy team will continue to monitor this bill throughout the legislative process</td>
</tr>
</tbody>
</table>
SB 238  License and regulate art and music therapists  
Introduced 11/13/2019  Referred to House Transportation, Commerce and Workforce 12/4/2019  
Interested party - concerns  Sen. Yuko (D-25)  11/13/2019  
Requires music therapists to be licensed under the medical board. Creates an advisory committee. Art therapists would be regulated by the Counselor, Social Worker and Marriage and Family Therapist Board. Ability of the Board to adequately assess applicants would be greatly reduced as written. The proposed amendments would remedy this issue.

Attempts have been made to contact the Association of Ohio Music Therapists. No response. Met with CSWM&F Board. They advised that this legislation has been seen before.

Policy team has met with bill sponsors and committee chair to discuss concerns -

- A sub bill will be introduced which includes the requested amendments -the amendments would allow the board to retain current standards of review but if the bill passes, reciprocity would still be granted to out of state license holders -the Policy team will continue to advocate for an unlimited lookback period when considering criminal convictions - currently there is a five year limitation - The policy team has re-submitted amendment requests to the sponsors and committee chair -

Amendments were adopted in the bill on 12/1/2020

The policy team will continue to monitor this bill throughout the legislative process.

SB 246  Occupational licensing - reciprocity  
8th Senate hearing held 12/1/2020 - Awaiting 9th hearing  
Senate General Government and Agency Review  
Interested Party  Sen. Kristina Roegner (R-27); Senator Rob McCauley (R-1)  11/26/2019  
Ability of the Board to adequately assess applicants would be greatly reduced as written. The proposed amendments would remedy this issue.

Policy team has met with bill sponsors and committee chair to discuss concerns -

- A sub bill will be introduced which includes the requested amendments -the amendments would allow the board to retain current standards of review but if the bill passes, reciprocity would still be granted to out of state license holders -the Policy team will continue to advocate for an unlimited lookback period when considering criminal convictions - currently there is a five year limitation -

The policy team has re-submitted amendment requests to the sponsors and committee chair -

- Amendments were adopted in the bill on 12/1/2020

The policy team will continue to monitor this bill throughout the legislative process.

SB 293  Create Court of Claims Procedure for Open Meeting Violations  
Passed Senate 6/10/2020  First House Civil Justice Committee hearing was held 11/10/2020  
Second hearing in Senate Insurance & Financial Institutions 5/8/2020  
Creates a procedure within the Court of Claims to hear complaints alleging a violation of the Open Meetings Law.

None

The policy team will continue to monitor this bill throughout the legislative process.

SB 305  Telemedicine  
Passed the Senate 6/3/2020  Awaiting first House committee hearing  
House Civil Justice 6/10/2020  
Interested Party  Sen. Hearcel Craig (D-15)  4/29/2020  
Requires health insurers to cover telemedicine during a state of emergency.

None

The policy team will continue to monitor this bill throughout the legislative process.

SB 308  Civil Liability - Emergency Services  
Passed the Senate 6/3/2020  Awaiting first House committee hearing  
Interested Party  Sen. Matt Huffman (R-12)  5/5/2020  
Revise the law governing immunity from civil liability for health care providers during disasters, to provide qualified civil immunity to service providers providing services during and after a government-declared disaster or emergency due to COVID-19.

None

The policy team will continue to monitor this bill throughout the legislative process.

SB 341  Nursing Licensure Compact  
Third hearing held 12/1/2020  
Senate Health and Human Services 9/1/2020  
Neutral  Sen. Kristina Roegner (R-27)  7/21/2020  
No current concerns – monitoring due to potential for physician interstate compact language

-Policy analysis complete

The policy team will continue to monitor this bill as it progresses through the legislative process.

SB 344  Local Boards of Health  
First hearing 9/1/2020  
Senate Health, Human Services and Medicaid  
Requires licensing boards of health care providers to allow up to five CME credits for serving on a local board of health

-Policy analysis complete

-Licensing has determined that implementation is not a problem -

-determination on whether allowing CME credit for hours served on a local board of health is appropriate

The policy team will continue to monitor this bill as it progresses through the legislative process.
<table>
<thead>
<tr>
<th>Bill No.</th>
<th>Title</th>
<th>Introduced in</th>
<th>Committee</th>
<th>Status</th>
<th>Sponsor</th>
<th>Vote</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB 364</td>
<td>Join Interstate Medical Licensure Compact</td>
<td>9/16/2020</td>
<td>Health, Human Services and Medicaid</td>
<td>Opposed</td>
<td>Sen. Kristina Roegner (R-27)</td>
<td>9/16/2020</td>
<td>Requires entrance into the interstate medical licensing compact. Requires likely support after review. Original language came from the AMA. Met with Commission Executive Director, several states and will be attending an IP meeting. Policy team met with the sponsor and were advised that the bill will not likely see movement this GA. The policy team will continue to monitor this bill throughout the legislative process.</td>
</tr>
<tr>
<td>SB 365</td>
<td>Extend authority to hold meetings by electronic technology</td>
<td>9/16/2020</td>
<td>General Government and Agency Review</td>
<td>Support</td>
<td>Sen. Teresa Fedor (D-11)</td>
<td>9/16/2020</td>
<td>Extends the authority to hold meetings electronically through the end of the declared emergency. Policy and legal review is in progress. The policy team is currently reviewing the passed language for impact on the board.</td>
</tr>
<tr>
<td>HB 61</td>
<td>Health Provider Residential Info</td>
<td>Passed the Senate with amendments 6/10/2020 - concurrence of Senate House refused to concur 6/11/2020</td>
<td>Conference Committee for Amendment - Conferres names 9/22/2020</td>
<td>Support</td>
<td>Rep. Laura Lanese (R-23)</td>
<td>2/12/2019</td>
<td>To include forensic mental health providers, mental health evaluation providers, and regional psychiatric hospital employees as individuals whose residential and familial information is exempt from disclosure under the Public Records Law. None. The policy team will continue to monitor this bill throughout the legislative process.</td>
</tr>
<tr>
<td>HB 177</td>
<td>standard care arrangements and prescribing requirements</td>
<td>Sixth hearing in House Health 1/28/2020</td>
<td>House Health</td>
<td>Opposed</td>
<td>Rep. Brinkman (R-27)</td>
<td>3/28/2019</td>
<td>Allows an advanced practice registered nurse (APRN) who is a certified nurse practitioner, clinical nurse specialist, or certified nurse-midwife to practice without a collaborating physician or podiatrist. Eliminates the requirement that the APRN enter into a standard care arrangement with one or more collaborating physicians or podiatrists and practice in accordance with the agreement. Makes conforming changes to the laws governing APRNs and other health professionals. Prohibits a physician from issuing a schedule II controlled substance prescription from a convenience care clinic. Allows a school district or youth sports organization to authorize any licensed health professional to assess an athlete for a concussion and to clear the athlete to play. Met with OSMA - They have expressed strong opposition to this language. The policy team will continue to monitor this bill throughout the legislative process.</td>
</tr>
<tr>
<td>HB 203</td>
<td>Requirements for mobile dental facility operations</td>
<td>Concurrence with Senate Amendments passed 9/1/2020</td>
<td>N/A</td>
<td>Opposed to the amendments regarding pharmacy consult agreements</td>
<td>Rep. Scott Lipps (R-62)</td>
<td>4/16/2019</td>
<td>Allows the services provided by Mobile Dental Facilities more effective in order to allow greater access to proper oral health care. AMENDED to included SB 303 language regarding pharmacy consult agreements. None. The policy team will continue to monitor this bill throughout the legislative process.</td>
</tr>
<tr>
<td>Bill</td>
<td>Summary</td>
<td>Status/Action</td>
<td>Interested Party</td>
<td>Vote</td>
<td>Opponent</td>
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<tr>
<td>HB 263</td>
<td>Occupational Licensing - criminal convictions</td>
<td>Passed out of the House 6/9/2020 - Introduced in the Senate 6/10/20</td>
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<td>House Transportation, Commerce and Workforce 6/24/20 3rd hearing was held 12/2/20</td>
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<td>Limited look back period for criminal convictions check of five years. Removal of references to good moral character and “moral turpitude”</td>
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<td>In conjunction with the boards of pharmacy, nursing, chiropractic and dental, amendments have been requested to the language to create a new ORC section to apply to healthcare licensing agencies. The sponsor seems to be unresponsive to the amendment requests. Testimony was submitted outlining the Board's concerns and suggestions for changes.</td>
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<td>The policy team will continue to monitor this bill as it progresses through the legislative process</td>
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<tr>
<td>HB 323</td>
<td>Authorize psychologists to prescribe drugs/therapeutic devices</td>
<td>Awaiting third hearing - Second hearing was held 1/28/2019</td>
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<td>Allows psychologists to prescribe drugs/therapeutic devices as part of the practice of psychology</td>
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<td>Currently under review The policy team will continue to monitor this bill throughout the legislative process</td>
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<tr>
<td>HB 341</td>
<td>Addiction Treatment Drugs</td>
<td>Enacted 9/16/2020 Effective in 90 days - 12/15/2020</td>
<td>Interested Party</td>
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<td>Authorizes a pharmacist to administer by injection any long-acting or extended-release drug prescribed by a physician to treat drug addiction, instead of limiting the pharmacist's authority to the administration of opioid antagonists as under current law. Also permits the state's prescription drug monitoring program, The Ohio Automated RX Reporting System (OARRS), to share data with the Defense Health Agencies (DHA) prescription drug monitoring program. AMENDED - Authorizes certain advanced practice registered nurses and physician assistants to develop protocols to permit individuals and employees of service entities to personally furnish or administer naloxone.</td>
<td>Rep. Tim Ginter (R-5) 9/23/2019</td>
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<td></td>
<td>None The policy team will continue to monitor this bill as it progresses through the legislative process</td>
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<tr>
<td>HB 374</td>
<td>Massage Therapy License (companion SB 105)</td>
<td>4th hearing in House committee was held 12/2/2020</td>
<td>Interested Party</td>
<td></td>
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<td>Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board. * An amendment was added to exclude reflexology from the definition of massage therapy.</td>
<td>Rep. Susan Manchester (R-84)</td>
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<td></td>
<td></td>
<td>None The policy team will continue to monitor this bill as it progresses through the legislative process</td>
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<td>Senate Insurance &amp; Financial Institutions 11/10/2020 Third hearing was held 12/1/2020</td>
<td>Rep. Adam Holmes (R-97) 11/5/2019</td>
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<td>Requires hospitals to provide upfront costs for basic items and services</td>
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<td>None The policy team will continue to monitor this bill as it progresses through the legislative process</td>
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<tr>
<td>Bill</td>
<td>Description</td>
<td>Status</td>
<td>Interested Party</td>
<td>Proponent</td>
<td>Opponent</td>
<td>Notes</td>
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<td>HB 407</td>
<td>Enact Clinician Integrity and Medical Accuracy Act</td>
<td>Awaiting first hearing in House Health 11/18/2019</td>
<td>Rep. Beth Liston (D-21)</td>
<td>11/12/2019</td>
<td>None</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process</td>
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<td>HB 455</td>
<td>Surgical Assistants</td>
<td>First Hearing 5/19/2020</td>
<td>Rep. Todd Smith (R-43)</td>
<td>12/17/2020</td>
<td>Lobbyist representing the surgical assistants asked to discuss this legislation - this bill is not likely to move this GA but will be reintroduced early next year</td>
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<td>HB 484</td>
<td>Athletic Training</td>
<td>Passed the House 6/10/2020</td>
<td>Rep. Cindy Abrams (R-29)</td>
<td>1/28/2020</td>
<td>None</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process</td>
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<tr>
<td>HB 486</td>
<td>Define Crime/ Civil Action - Assisted Reproduction</td>
<td>Awaiting first hearing 2/4/2020</td>
<td>Rep. Jena Powell (R-80)</td>
<td>1/29/2020</td>
<td>None</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process</td>
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<tr>
<td>HB 492</td>
<td>Physician Assistants</td>
<td>Awaiting first hearing in House Health 2/12/2020</td>
<td>Rep. Scott Wiggam (R-1)</td>
<td>2/4/2020</td>
<td>Sent letter of opposition to the PA association lobbyist, the bill sponsor, the committee chair, Association of Anesthesiologists and OSMA</td>
<td>The policy team will continue to monitor this bill as it progresses through the legislative process</td>
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</table>

Prohibits a state or local government entity from requiring a physician to provide a patient with a medical service or information that is not, in the physician's clinical judgment, medically accurate and appropriate for the patient. Specifies that a state or local government entity cannot prohibit a physician from providing a patient with a medical service or information that is, in the physician's clinical judgment, appropriate for the patient and evidence-based or medically accurate.

ReQUIRES that all surgical assistants be registered with the State Medical Board - allows for the application of a waiver in areas where there are shortages - grants authority to the Board to create rules.

Allows ATs to work under a collaboration agreement with physicians. Eliminate language in current law that restricts ATs by only allowing administering of "topical" care.

Prohibits a health care professional from purposely or knowingly using human reproductive material from a donor while performing an assisted reproduction procedure if the person receiving the procedure has not expressly consented to the use of that donor's material.

Decouples national accreditation from licensure. Renames the PA/physician "supervision agreement" to "collaborative agreement" to more accurately represent the relationship between practitioners. Eliminates physician liability for the actions of a physician assistant. Allows a physician assistant to "pink-slip" a patient. Allows physician assistant to perform fluoroscopy. Permits a physician assistant to perform rapid intubation and procedural sedation, order rapid intubation and procedural sedation, and order drugs needed to perform rapid intubation and procedural sedation in a health care facility. Other technical corrections.
**HB 547**: Restrict Cost Sharing - Occupational/Physical Therapists  
- Third hearing held 12/1/2020  
- House Insurance  
- Interested Party: Rep. Jeff LaRe (R-77)  
- 3/10/2020  
- Caps cost-sharing for occupational and physical therapy  
- None  
- The policy team will continue to monitor this bill as it progresses through the legislative process

**HB 580**: Telemedicine  
- First hearing 9/23/2020  
- House Insurance  
- 3/23/2020  
- Require health plan issuers cover telemedicine in emergency  
- None  
- The policy team will continue to monitor this bill as it progresses through the legislative process

**HB 598**: Authorize EMTs to perform medical services in hospitals  
- Awaiting first hearing in House Health  
- House Health 5/5/2020  
- 4/6/2020  
- Temporarily authorizes emergency medical technicians to perform certain medical services in hospitals and to declare an emergency  
- None  
- The policy team will continue to monitor this bill as it progresses through the legislative process

**HB 606**: Grant immunity to essential workers who transmit COVID-19  
- Enacted 9/14/2020  
- Effective in 90 days 12/13/2020  
- N/A  
- Interested Party: Rep. Diane Grendell (R-76)  
- 4/10/2020  
- Grants immunity from tort liability and professional discipline for injury, death, or loss that allegedly resulted because a health care provider was unable to treat a person, including the inability to perform any elective procedure, due to an executive or director’s order or a local health order issued in relation to an epidemic or pandemic disease or other public health emergency; Excludes from immunity in tort actions conduct that constitutes a reckless disregard of the consequences or intentional or willful or wanton misconduct on the part of the person against whom the action is brought  
- Memo drafted with concerns and sent to the bill sponsor

**HB 629**: Staffing/Employment Conditions for Registered Nurses  
- Awaiting first hearing in House Commerce and Labor  
- 5/19/2020  
- 5/12/2020  
- Addresses the staffing ratios of registered nurses in hospitals  
- None  
- The policy team will continue to monitor this bill as it progresses through the legislative process

**HB 641**: Medical Marijuana - Autism Spectrum Disordered  
- Awaiting first hearing in House Health  
- 5/27/2020  
- Oppose: the Board has already declared positions on these allowed conditions: Rep. Juanita Brent (D-12)  
- 5/19/2020  
- Authorize medical marijuana for autism spectrum disorder  
- None  
- The policy team will continue to monitor this bill as it progresses through the legislative process
### HB 650: Medical Marijuana - Anxiety, Opioid Use Disorder
- **Awaiting first hearing**
- **Oppose** - the Board has already declared positions on these allowed conditions
- **Authorize the use of medical marijuana for anxiety, autism spectrum disorder, and opioid use disorder**
- **None**
- **The policy team will continue to monitor this bill as it progresses through the legislative process**

**HB 673: Regarding business, professions, education during COVID-19**
- 2nd Senate hearing was held 12/1/2020
- **Referred to Senate General Government and Agency Review 6/24/2020**
- **Interested Party**
- **Authorize the use of medical marijuana for anxiety, autism spectrum disorder, and opioid use disorder**
- **None**
- **The policy team will continue to monitor this bill as it progresses through the legislative process**

**Sub. HB 679: Telehealth**
- Passed out of the House 6/10/2020
- **Second Senate Hearing held 11/18/2020**
- **Support - following closely**
- **Legal is drafting amendments based on discussion with the Ad-hoc telehealth committee**
- **Amendments from the ad hoc committee have been drafted. Awaiting adoption in next committee meeting**

**HB 747: Prescribing and Dispensing Drugs for Off-label Use**
- **Introduced**
- **Passed out of the House 6/10/2020**
- **Second Senate Hearing held 11/18/2020**
- **Support - following closely**
- **Prohibits the Board of Nursing and State Medical Board from taking actions on a license solely for issuing a prescription for a drug to be used in a manner other than the use approved by the U.S. FDA, except when the issuance of such a prescription conflicts with acceptable and prevailing standards of safe care.**
- **Applies to the following license types: Certified Nurse Practitioner, Clinical Nurse Specialist, Physician Assistant, Licensees practicing medicine in accordance with chapter**

### Federal Legislation
**S. 3993: Equal Access to Care Act**
- **Referred to Senate Committee on Health, Education, Labor and Pensions 6/17/2020**
- **Neutral**
- **Sen. Ted Cruz (R-TX) and Sen. Marsha Blackburn (R-TN) 6/17/2020**
- **Allows healthcare professionals to provide telehealth services across state lines during a pandemic**
- **None**
- **The policy team will continue to monitor this bill as it progresses through the legislative process**
<table>
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<tr>
<th>Bill Number</th>
<th>Description</th>
<th>Committee/Reference</th>
<th>Sponsor</th>
<th>Date Referred</th>
<th>Action</th>
<th>Notes</th>
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<tr>
<td>S. 4421</td>
<td>TREAT Act - temporary licensing reciprocity for telehealth and interstate health care treatment</td>
<td>Read twice and referred to the Committee on Health, Education, Labor, and Pensions</td>
<td>Sen. Christopher Murphy (D-CT)</td>
<td>8/4/2020</td>
<td>Temporary authorization of telehealth and interstate treatment</td>
<td>None</td>
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<td>H.R. 8680</td>
<td>Occupational Licensing Board Antitrust Damages Relief Act of 2020</td>
<td>Referred to the House Committee on the Judiciary</td>
<td>Rep. Jamie Raskin (D-MD)</td>
<td>10/23/2020</td>
<td>To provide immunity from liability under section 4 of the Clayton Act for damages in cases against occupational licensing boards that meet appropriate standards, to provide for the establishment of those standards, and for other purposes.</td>
<td>None</td>
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<tr>
<td>H.R. 8723</td>
<td>Adoption by the State of the Interstate Medical Licensure Compact</td>
<td>Referred to House Committee on Energy and Commerce</td>
<td>Rep. Ted Yoho (R-FL 3rd)</td>
<td>10/30/2020</td>
<td>In the case of a State that has not, by the date that is 3 years after the date of the enactment of this Act, joined, through enactment of a State law, the Interstate Medical Licensure Compact facilitating physician interstate licensure, as of the day after such 3-year period, the State shall not be eligible for any funds or assistance administered by the Bureau of Health Workforce of the Health Resources and Services Administration of the Department of Health and Human Services. In the case of a State that becomes ineligible for such funds or assistance pursuant to the previous sentence, if such State after such 3-year date joins, through enactment of a State law, the Interstate Medical Licensure Compact, the Secretary of Health and Human Services may determine such State is no longer ineligible for such funds or assistance pursuant to the previous sentence.</td>
<td>None</td>
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**Key**
- **Monitoring - currently no impact on the Board**
- **Monitoring - potential impact on the Board**
- **Requires immediate action**
- **Enacted**
- **No Longer Active**

The policy team will continue to monitor this bill as it progresses through the legislative process.