MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Progress

DATE: May 28, 2020

Attached please find the Rule Review Spreadsheet and status of the rules under review.

Action Requested: No Action Requested
## Legal Dept. Rules Schedule
### As of 5/20/20

### RULES AT CSI

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### RULES SENT FOR INITIAL CIRCULATION

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DRAFT Misbranded Drugs

NOTE RE: 4731-12.03 for next review

what had been known as NBPME Parts I, II, and III will now be designated as the American Podiatric Medical Licensing Examination (APMLE) Parts I, II, and III
MEMORANDUM

TO: Dr. Soin, Chair, Policy Committee
    Members, Policy Committee

FROM: Jonithon LaCross, Legislative Liaison

RE Legislative Discussion Topics for Policy Committee

DATE: June 10, 2020

Legislation

1. Reciprocity
2. HB679 Telehealth Service
3. HB641 Medical Marijuana – Autism Spectrum Disorder
4. HB650 Medical Marijuana – Anxiety, Opioid Use Disorder
5. SB178 Podiatrists
6. HB455 Surgical Assistants
7. SB303 Pharmacist Consult Agreements
8. HB484 Athletic Trainers/Collaborative Agreements
9. SB156 Prohibits Defrauding an Alcohol, Drug or Urine Screening Test
10. HB606 Grant Immunity to Essential Workers who Transmit COVID-19
11. SB1 Reduce Regulatory Restrictions/JCARR
12. SB308 Civil Liability-Emergency Services
Legislation Status Report

HB263 Occupational Licensing – Criminal Convictions (Rep. Koehler)

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

Bill Summary

- Requires, within 180 days after the bill’s effective date, a state licensing authority to adopt a list of specific criminal offenses for which a conviction, judicial finding of guilt, or plea of guilty may disqualify an individual from obtaining a license.
- Allows a state licensing authority to consider a listed offense when deciding whether an individual is disqualified from receiving an initial license, provided the state licensing authority considers the offense in light of specific factors supported by clear and convincing evidence.
- Prohibits a state licensing authority from considering a listed disqualifying offense when the offense occurred outside of time periods specified in the bill.
- 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.”

Status: 02/05/2020 REPORTED OUT AS AMENDED

Amendment: An Legislative Service Commission (LSC) staffer explained the amendment which includes some reporting requirements for the licensing boards to the Department of Administrative Services (DAS) regarding, among other data, information about the number of licenses granted and denied; a list of criminal offenses reported by individuals who were granted a license and a list for those denied. The amendment also gives the licensing boards the authority to consider past disciplinary action against the individual by them or by boards in other states.

- The amendment also reduces the "look back" period from 10 to five years.
- Policy Matters Ohio, the ACLU gave proponent testimony and the Buckeye Institute gave interested party testimony.
- Medical Board staff collaborated with the Ohio Board of Pharmacy, Nursing Board, Chiropractic Board, Dental Board, and the Veterinary Medical Licensing Board to draft an amendment to Representative Koehler’s office to address joint concerns.
- The bill sponsor rejected the multi-board recommendations.

See separate briefing memo to board.
HB341 Addiction Treatment Drugs (Rep. Ginter)

Regarding the administration of drugs for addiction treatment.

**ORC Sections:** 4723.52, 4729.45, 4729.553, 4730.56, 4731.83

**BILL SUMMARY**

- 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.
- Exempts places in which addiction treatment drugs are directly administered by prescribers, rather than self-administered by patients, from the State Board of Pharmacy’s office-based opioid treatment licensure.
- Provides that a patient whose addiction treatment drugs are directly administered by a prescriber is not to be counted when determining whether an office-based opioid treatment provider is required to be licensed by the Board.
- Authorizes the Board to provide information from its Ohio Automated Rx Reporting System (OARRS) to a prescriber or pharmacist participating in a prescription monitoring program operated by a federal agency if certain conditions are met.

**Status:** 05/20/2020 Second Hearing, Proponent & Opponent Testimony

**Medical Board position:** None taken

**Medical Board staff communications to legislature:** None


To make changes to the massage therapy licensing law.

**ORC Sections:** 2927.17, 4731.04, 4731.15, 4731.41, 503.40, 503.41, 503.411, 503.42, 503.43, 503.44, 503.45, 503.46, 503.47, 503.48, 503.49, 503.50, 715.61

**Bill Summary**

- Standardizes, for purposes of regulation by the State Medical Board, townships, and municipal corporations, terminology regarding massage therapy and individuals authorized to perform massage therapy.
- As part of that standardization:
  - Eliminates a township’s authority to issue licenses to individuals who perform massage therapy;
  - Requires that if a township opts to regulate massage establishments, the regulations must require all massage therapy to be performed only by specified state-licensed professionals or massage therapy students;
• Purports to require a municipal corporation that opts to regulate massage establishments
to require all massage therapy to be performed by a state-licensed professional or a
student, similar to township regulation.
• Regarding a township’s authority to regulate massage establishments, eliminates a permit
requirement and otherwise modifies permit application procedures.

Status: 12/11/2019 House Commerce and Labor, (First Hearing, Sponsor testimony given)

Medical Board position: None taken

Medical Board staff communications to legislature: None

HB388 Regarding Out-Of-Network Care (Rep. Holmes)

Regarding out-of-network care.

ORC Sections: 3902.50, 3902.51, 3902.52

Bill Summary

• Requires an insurer to reimburse an out-of-network provider for unanticipated out-of-
network care provided at an in-network facility.
• Requires an insurer to reimburse an out-of-network provider or emergency facility for
emergency services provided at an out-of-network emergency facility.
• Prohibits a provider from balance billing a patient for unanticipated or emergency care as
described above when that care is provided in Ohio. Establishes negotiation and arbitration
procedures for disputes between providers and insurers regarding unanticipated or emergency
out-of-network care.
• Requires a provider to disclose certain information to patients regarding the cost of other out-
of-network services.

Amendment:

• The provider will send the bill to the insurance plan, and the plan will propose a
reimbursement that represents the highest among these three options: their in-network rate,
their out-of-network rate or the Medicare rate. The provider could then accept or decline that
proposed reimbursement. If they accept it, it’s over. If they reject it, a period of negotiation
starts where the plan and the provider discuss what the rate should be, and that is between
them. If that doesn’t work out, it goes to arbitration.
• During arbitration, a provider or a practice of providers can bundle up to 15
claims in the
same coding set and the same provider license type. Arbitrators can consider documents on
four factors, Butler said, comparing it to a house appraisal. “You’re trying to get a fair
market value. A lot of people are familiar with that process.”
• First, the provider can provide documents showing what other insurance plans are
reimbursing for the same service.
The plans can submit documents showing payments other providers have agreed to in the network for the same service.
Each side can present whether the provider or plan was in network before, up to six years in the past.
The arbitrator can also consider the results of previous arbitration between the parties conducted under the bill, if relevant.

**Status:** 5/20/2020 - PASSED BY HOUSE; Vote 95-0

**Medical Board position:** None taken

**Medical Board staff communications to legislature:** None


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.

**Status:** 1/29/2020 - House State and Local Government, (Second Hearing)

See separate briefing memo to board.


To regulate the practice of surgical assistants.

**ORC Sections:** 4731.07, 4731.071, 4731.10, 4785.01, 4785.02, 4785.03, 4785.04, 4785.05, 4785.06, 4785.07

**Bill Summary**

- Creates a registration with the State Medical Board of Ohio for surgical assistants
- A surgical assistant must meet the following requirements:
  - Is at least eighteen years of age;
  - Has attained a high school degree or equivalent;
  - Is credentialed as a surgical assistant by the national board of surgical technology and surgical assisting or national commission for certification of surgical assistants.
- An applicant is eligible for a registration if:
  - The applicant practiced as a surgical assistant at a hospital or ambulatory surgical facility located in this state during any part of the six months that preceded the effective date of the bill;
• The applicant successfully completed a training program for surgical assistants operated by a branch of the United States armed forces.
• If the state medical board determines that an applicant meets the requirements for a registration to practice as a surgical assistant, the secretary board shall issue the registration to the applicant.
• The registration shall be valid for a two-year period unless revoked or suspended, shall expire on the date that is two years after the date of issuance, and may be renewed for additional two-year periods.
• An individual who holds a current, valid registration to practice as a surgical assistant may assist a physician in the performance of surgical procedures by engaging in one or more of the following activities:
  • Providing exposure; Maintaining hemostasis; Performing one or more of the following tasks: Making incisions; Closing or suturing surgical sites; Manipulating or removing tissue; Implanting surgical devices or drains; Suctioning surgical sites; Placing catheters; Clamping or cauterizing vessels or tissues; Applying dressings to surgical sites; Injecting or administering anesthetics; Any other tasks as directed by the physician.
• An individual may practice as a surgical assistant without holding a current, valid registration if all of the following apply:
  • The hospital or ambulatory surgical facility at which the individual practices or intends to practice has submitted to the state medical board, on behalf of its current and prospective employees, an application for a waiver from the requirement that surgical assistants be registered with the board;
  • As part of the application, the hospital or facility submits evidence that it is located in an area of the state that experiences special health problems and physician practice patterns that limit access to surgical care;
  • After receiving and reviewing the application, the board grants to the hospital's or facility's employees a waiver from the registration requirements;
  • If the individual practices only at a hospital or ambulatory surgical facility that has been granted a waiver.
• The state medical board shall adopt rules establishing standards and procedures for the regulation of surgical assistants and shall do all of the following:
  • Establish application procedures and fees for the registration of surgical assistants; Establish registration renewal procedures and fees; Specify the reasons for which the board may refuse to issue or renew, suspend, or revoke a registration; Establish procedures for waiver applications submitted.
• The board may adopt any other rules it considers necessary.

Status: 05/19/2020 House Health, (First Hearing)

Medical Board position: None taken

Medical Board staff communications to legislature: None

Regarding the practice of athletic training.

**ORC Sections:** 4755.60, 4755.621

**Bill Summary**

- Makes changes to the law governing the practice of athletic training, including by requiring an athletic trainer to practice under a collaboration agreement with a physician or podiatrist.

**Amendment:**

- Narrows the definition of "athletic trainer" by removing references to "daily living activities."
- Tightens the ability of athletic trainers to refer to other athletic trainers;
- Removes of the definition of "athletic injury."

**Status:** 06/02/2020 BILL AMENDED, House Health, (Third Hearing)

**Medical Board position:** None taken

**Medical Board staff communications to legislature:** None

HB486 Define Crime/Civil Action – Assisted Reproduction (Rep. Powell)

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

**ORC Sections:** 2901.13, 2305.117, 2907.13, 4731.86, 4731.87, 4731.871, 4731.88, 4731.881, 4731.89, 4731.90

**Bill Summary**

- An action for an assisted reproduction procedure performed without consent shall be brought within ten years after the procedure was performed.
- An action that would otherwise be barred may be brought not later than five years after the earliest date that any of the following occurs:
  1) The discovery of evidence based on deoxyribonucleic acid analysis sufficient to bring the action against the health care professional.
  2) The discovery of a recording providing evidence sufficient to bring the action against the health care professional.
  3) The health care professional confesses.
- Adds that a prosecution shall be barred unless it is commenced within the following periods after an offense is committed when a prosecution of a violation of section 2907.13 of the
Revised Code shall be barred unless it is commenced within ten years after the offense is committed.

- No health care professional shall purposely or knowingly use 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 the material from that donor.
- Whoever violates is guilty of fraudulent assisted reproduction, a felony of the third degree.

**Status: 02/04/2020 Referred to Criminal Justice Committee**

**Medical Board position:** None taken


To Modify the laws regarding physician assistants.

**ORC Sections:** 1.64, 2108.61, 2133.211, 3701.351, 3727.06, 4730.02, 4730.03, 4730.04, 4730.05, 4730.06, 4730.07, 4730.08, 4730.11, 4730.14, 4730.19, 4730.20, 4730.201, 4730.203, 4730.21, 4730.22, 4730.25, 4730.26, 4730.32, 4730.41, 4730.411, 4730.42, 4731.22, 4761.17, 4773.02, 5122.01, 5122.10; 4730.204; and to repeal sections 4730.111 and 4730.44

**Bill Summary:**

- 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’s 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.

**Status: 02/11/2020 Referred to Health Committee**

**Medical Board position:** None taken.

**Medical Board staff communications to legislature:** None taken at this time.
HB547 Restrict cost sharing-occupational/physical therapists (Rep. LaRe)

To restrict cost sharing requirements with regard to occupational and physical therapists.

**ORC Sections:** 3902.50, 3902.51

**Bill Summary**

- Prohibits a health benefit plan from imposing cost sharing for occupational or physical therapy services that is greater than the cost sharing for an office visit to a primary care physician or primary care osteopath physician.
- Requires a health plan issuer to clearly state on its website and on all relevant literature that coverage for occupational and physical therapy is available along with any limitations.
- Makes a violation of the bill’s provisions an unfair and deceptive practice in the business of insurance.

**Status:** 05/19/2020 House Insurance, (Second Hearing)

**Medical Board position:** None taken

HB606 Grant Immunity to Essential Workers Who Transmit COVID-19 (Rep. Grendell)

Grant immunity to essential workers who transmit COVID-19.

**ORC Sections:** 9.87, 2743.02, 2744.01, 4123.68

**Bill Summary**

- Grants temporary qualified immunity to specified health care providers who provide health care services or emergency services during a declared disaster or emergency as described below.
- 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.
- Declares an emergency.

**Status:** 06/03/2020 Referred to Senate Judiciary Committee

**Medical Board position:** None taken
HB629 Regards Staffing/Employment Conditions for Registered Nurses (Rep. Skindell)

Regarding staffing ratios and other employment conditions for registered nurses employed by hospitals.

**ORC Sections:** 3727.50, 3727.51, 3727.52, 3727.53, 3727.80, 3727.88

**Bill Summary:** Being Completed

**Status:** 05/19/2020 Referred to Commerce and Labor Committee

**Medical Board position:** None taken

HB641 Medical Marijuana – Autism Spectrum Disorder (Rep. Brent)

To authorize the use of medical marijuana for autism spectrum disorder.

**ORC Sections:** 3796.01

**Bill Summary**

- Adds “Autism spectrum disorder” to the qualifying conditions for Medical Marijuana.

**Status:** 05/27/2020 - Referred to Health Committee

**Medical Board Position:** TBD

HB650 Medical Marijuana – Anxiety, Opioid Use Disorder (Rep. Upchurch)

To authorize the use of medical marijuana for anxiety, autism spectrum disorder, and opioid use disorder.

**ORC Sections:** 3796.01

**Bill Summary**

- Adds “Anxiety, Autism Spectrum Disorder, and Opioid use Disorder” to the qualifying conditions for Medical Marijuana.

**Status:** 05/27/2020 - Referred to Health Committee

**Medical Board Position:** TBD

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

**ORC Sections:** 3902.30, 4723.94, 4732.33, 5123.60, 5164.95, 4731.2910 (4743.09), 3721.60, 4730.60, 4753.20, 4755.90, 4757.50, 4758.80, 4759.20, 5119.368, 5123.603

**Bill Summary**

Insurance coverage of telehealth services

- Prohibits a health benefit plan from imposing cost sharing for telehealth services provided via telephone or email.
- Requires telehealth services provided via telephone or email to be tallied using minutes spent per patient on a running total and reimbursed for a block of time in a manner equivalent to the standard amount of time spent on a telehealth service.
- Allows the Superintendent of Insurance to adopt rules as necessary to carry out the bill’s provisions governing insurance coverage of telehealth services.

Medicaid coverage of telehealth services

- Provides that specified health care practitioners may provide telehealth services to a patient participating in the Medicaid program and that specified providers are eligible to submit claims to the Ohio Department of Medicaid for payment for telehealth services rendered.
- Establishes requirements that must be satisfied when providing telehealth services to an individual in the Medicaid program.
- Specifies certain telehealth services that are eligible for payment by the Medicaid program.
- Requires the Department to adopt rules authorizing the directors of other state agencies that administer portions of the Medicaid program to adopt rules regarding the provision of telehealth services.

Provision of telehealth services by health care professionals

- Permits specified health care professionals to provide telehealth services.
- Requires telehealth services provided by health care professionals to be done so according to specified conditions and standards.
- Permits certain health care licensing boards to adopt rules as necessary to carry out the bill’s provisions regarding the provision of telehealth services.
- Provides that a health care professional is not liable in damages under a claim that
telehealth services provided do not meet the standard of care that would apply if services were provided in-person.

- Prohibits a health care professional from charging a fee associated with the administrative costs of providing telehealth services.

Certified community mental health, addiction service providers

- Permits community mental health service providers and community addiction service providers certified by the Ohio Department of Mental Health and Addiction Services (OhioMHAS) to provide specified services through telehealth.

- Specifies requirements and standards that must be satisfied when telehealth services are provided.

- Permits OhioMHAS to adopt rules necessary to carry out the bill’s provisions.

Video-conference visitation in long-term care facilities

- Specifies that during a declared disaster, epidemic, pandemic, public health emergency, or public safety emergency, long-term care facilities must provide residents and their families with video-conference visitation options.

Assistance at health care appointments

- Provides that during a declared disaster, epidemic, pandemic, public health emergency, or public safety emergency, an individual who with a developmental disability or other permanent disability may have a parent or guardian present during a health care procedure, test, or other care visit.

Emergency

- Declares an emergency.

Status: 06/03/2020 House Insurance, (Second Hearing)

**SB1 Reduce Regulatory Restrictions (Sen. McColley, Sen. Roegner)**

Reduce number of regulatory restrictions. Limit ODH orders and create JCARR review.

**ORC Sections:** 101.35, 106.021, 106.03, 106.031, 121.95, 3701.13, 101.354, 101.355, 101.36, 107.57, 121.031, 121.951, 121.952, and 121.953

**Bill Summary**

- Limit ODH orders under Ohio Revised Code (ORC) 3701.13 to 14 days and require approval from three of the five members of each chamber on the Joint Committee on Agency Rule Review (JCARR) to extend such orders.

- Any Ohioan has standing to seek a court order requiring the governor or state health
director to comply with the JCARR oversight requirement without having to prove they will be “irreparably harmed” if the court does not intervene.

- Any public health order under ORC 3701.13 issued on or after April 29, 2020 would cease to be effective 14 days after the bill’s effective date.
- Requires each state agency to reduce the regulatory restrictions contained in its rules by 30% by 2022, according to a schedule set forth in the bill.
- Prohibits an agency from adopting new regulatory restrictions that would increase the percentage of restrictions in the agency's rules.
- Requires an agency that does not achieve a reduction in regulatory restrictions according to the required schedule to eliminate two restrictions before enacting a new rule containing a restriction.
- Effective January 1, 2023, limits the total number of regulatory restrictions that may be in effect in Ohio to a number that is 70% of the current total number of regulatory restrictions.
- Specifies which entities are considered state agencies under the bill and how rules adopted by an otherwise independent official or agency organized under a state agency are counted for the purposes of the bill.
- Provides guidelines for determining which rules contain regulatory restrictions.
- Requires an agency to produce a base inventory of rules containing regulatory restrictions before December 31, 2019.
- Requires an agency to produce a revised inventory and historical progress report before March 15, 2021, and annually thereafter until the agency has reduced the regulatory restrictions identified in its rules by 30%.
- Requires an agency, as part of a rule's five year review, to review the rule for regulatory restrictions and consider whether the rule should be amended or rescinded to eliminate the restrictions.
- Allows an administrative department head to direct otherwise independent officials or state agencies organized under the department to reduce regulatory restrictions.
- Allows an agency that does not achieve a required percentage reduction in regulatory restrictions by a deadline to appear before the Joint Committee on Agency Rule Review (JCARR) to show cause why the agency could not achieve the required reduction.

**Status: 06/03/2020 Senate Appoints Managers; K. Schuring, K. Roegner & N. Antonio Named as Senate Conferees**

**Medical Board position:** The rule reductions in this bill apply only to cabinet level agencies, or a state agency organized under an administrative department, an administrative department head. It also includes the Attorney General, the Secretary of State, the Auditor of State, and the Treasurer of State, as well as the Department of Education, the State Lottery Commission, the Ohio Casino Control Commission, the State Racing Commission, and the Public Utilities Commission of Ohio.
SB105 Massage Therapy Licensing (Sen. Brenner)

To make changes to the massage therapy licensing law.

**ORC Sections:** 2927.17, 4731.04, 4731.15, 4731.41, 503.40, 503.41, 503.411, 503.42, 503.43, 503.44, 503.45, 503.46, 503.47, 503.48, 503.49, 503.50, 715.61

**BILL SUMMARY**

- Standardizes, for purposes of regulation by the State Medical Board, townships, and municipal corporations, terminology regarding massage therapy and individuals authorized to perform massage therapy.
- As part of that standardization:
  - Eliminates a township’s authority to issue licenses to individuals who perform massage therapy;
  - Requires that if a township opts to regulate massage establishments, the regulations must require all massage therapy to be performed only by specified state-licensed professionals or massage therapy students;
  - Purports to require a municipal corporation that opts to regulate massage establishments to require all massage therapy to be performed by a state-licensed professional or a student, similar to township regulation;
- Regarding a township’s authority to regulate massage establishments, eliminates a permit requirement and otherwise modifies permit application procedures.

**Status:** 09/18/2019 Senate Health, Human Services and Medicaid, (Second Hearing)

**Medical Board position:** None taken.

**Medical Board staff communications to legislature:**

- Reviewed legislative drafts.
- Advised Senator Brenner on the effects of the legislation on Massage Therapy regulation and licensure.

SB156 Prohibits Defrauding an Alcohol, Drug, or Urine Screening Test (Sen. Gavarone)

To prohibit defrauding an alcohol, drug, or urine screening test.

**ORC Sections:** 2925.15

**Bill Summary:**

- Enacts six prohibitions, under the new offense of “defrauding an alcohol, drug, or urine screening test,” that pertain to specified conduct related to the use or likelihood of use of synthetic urine, a urine additive, or another person’s urine to defraud such a test.
- Specifies that the offense and a related reporting requirement do not apply if the conduct involved urine or a urine additive and it was solely for a bona fide medical, scientific,
educational, or law enforcement purpose.

**Status:** 05/28/2020 House Criminal Justice, (Second Hearing)

**Medical Board position:** None taken

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**SB178 Podiatrists (Sen. Schuring)**

Regarding the authority of podiatrists to administer influenza vaccinations

**ORC Sections:** 4731.512

**Bill Summary**

- Authorizes podiatrists to administer influenza vaccinations to individuals seven or older.

**Status:** 06/02/2020 House Health, (First Hearing)

**Medical Board position:** None taken

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**SB246 Occupational License Reciprocity (Sen. Roegner, McColley) Companion HB432**

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.

**Status:** 02/19/2020 Senate General Government and Agency Review, (Fifth Hearing)

See separate briefing memo to Board on companion bill HB 432.

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**SB293 Create Court of Claims Procedure for Open Meetings Violations (Sen. Manning, Sen. Blessing)**

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

**ORC Sections:** 121.22, 2323.52, 2743.03, 2746.04, 2743.76

**Status:** 06/03/2020 Senate General Government and Agency Review, (Third Hearing)

**Medical Board position:** None taken
SB303 Regards Pharmacist Consult Agreements (Sen. Stephen Huffman, Sen. Manning)

Regarding the authority of certified registered nurse anesthestists to select, order, and administer certain drugs.

**ORC Sections:** 1751.91, 3923.89, 4723.28, 4729.01, 4729.39, 4730.25, and 5164.14

**Bill Summary**

- 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.

**Status:** 05/20/2020 Portions of SB303 (Huffman, Manning) were amended on the Senate Floor into HB203 (Lipps) on May 20, 2020.

SB308 Civil Liability-Emergency Services (Sen. Matt Huffman)

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

**ORC Sections:** 2305.2311 and 2305.2312

**Bill Summary**

- Authorizes Expands the tort action immunity granted to certain health care providers and emergency medical technicians who provide health care or emergency services during a declared disaster as described below.
- Grants immunity for:
  1. actions taken during a declared emergency,
  2. actions by additional health care providers, such as licensed practical nurses; respiratory care professionals; medical assistants and technicians; dental assistants; nurse aides; orderlies; home health agencies; hospice programs; and facilities, including their agents, employees, officers, board members, and volunteers,
  3. decisions to withhold or withdraw health care services, and
  4. compliance with an executive order or director’s order.
- Extends the immunity to professional discipline and other civil actions.
- Modifies an exception to immunity for actions taken in reckless disregard of the consequences to instead exclude actions that constitute willful or wanton misconduct.
- Removes the current law exception for wrongful death actions.
Amendment

- Removes the requirement that plaintiffs provide claims by clear and convincing evidence in both health care and general business matters.

- Removes the serious physical injury requirement in both sections.

- Provides immunity for health care services that were prohibited during an emergency or disaster.

- Includes a number of health care facilities and providers that were not listed in the original.

- Specifies that, in addition to agents or employees of health care providers, the legislation also covers volunteers, board members and others.

- Specifies that immunity does not apply for intentional or reckless conduct or willful or wanton misconduct.

- Returns the proposed bill to current statutory language excluding EMT civil immunity for wrongful death in a disaster.

Status: PASSED BY SENATE; Vote 24-9 Emergency Clause 25-8
Representatives; appearances.

(A) As used in this chapter of the Administrative Code:

(1) "Respondent" means a person who is requesting or has requested a hearing as provided in Chapter 119. of the Revised Code.

(2) "Representative of record" means one person designated by each party to be the party's agent for purposes of receipt of service pursuant to this chapter of the Administrative Code.

(3) "Hearing" means the adjudication hearing held pursuant to Chapter 119. of the Revised Code when a hearing is requested by an applicant or licensee for whom the Board has proposed formal action under section 4730.25, 4731.22, 4759.07, 4760.13, 4762.13, 4774.13, or 4778.14 of the Revised Code.

(4) "Summary Suspension" means the pre-hearing suspension of the license under division (G) of section 4730.25, 4731.22, 4759.07, 4760.13, 4762.13, 4774.13, or 4778.14 of the Revised Code.

(B) The respondent may represent himself or herself or may be represented by an attorney or attorneys who shall be admitted to the practice of law in Ohio. Each attorney representing the respondent shall enter his or her appearance in writing. The respondent may authorize his or her attorney or attorneys to represent the respondent in all facets of a hearing before the board.

(C) If the respondent is self represented, he or she shall be deemed the representative of record for purposes of service pursuant to this chapter of the Administrative Code. If the respondent is represented by one attorney, that attorney shall be deemed the representative of record for purposes of service pursuant to this chapter of the Administrative Code. If the respondent is represented by more than one attorney, the respondent shall designate one of those attorneys as the representative of record for purposes of service pursuant to this chapter of the Administrative Code.

(D) Each representative from the office of the attorney general shall enter his or her appearance in writing. The office of the attorney general shall identify one attorney from that office as the representative of record for purposes of service pursuant to this chapter of the Administrative Code.

(E) The respondent shall not be required to appear personally at any hearing provided he or she has not been subpoenaed. If a respondent has not been subpoenaed to appear at hearing, a respondent may present his or her position, arguments or contentions
in writing.

(F) An attorney who has filed notice of appearance with the board shall withdraw his or her representation of a respondent by filing a written notice of withdrawal with the board. A written notice of withdrawal should include (i) current address and telephone number of respondent, and (ii) an attestation from the attorney that the respondent has been provided copies of all filings and has been specifically notified of all dates and deadlines.

(G) An attorney who has been designated as a respondent's representative of record for purposes of service pursuant to this chapter of the Administrative Code shall remain the representative of record for that party until a representative of that party files a written notice designating another attorney or the respondent as the representative of record.

(H) Except as otherwise provided under Chapter 119. of the Revised Code, communications from the board or its hearing examiner shall be sent to the representative of record for each party.
4731-13-02  Filing request for hearing.

(A) In order to request a hearing pursuant to Chapter 119. of the Revised Code, the respondent or the respondent's attorney or attorneys shall file a written request for a hearing in accordance with rule 4731-13-08 of the Administrative Code. The request shall be filed within thirty days of the date of mailing of the board's notice of opportunity for hearing upon which service is perfected, of the date of personal service of the board's notice of opportunity for hearing or of the date of publication of the board's notice of opportunity for hearing in accordance with Chapter 119. of the Revised Code, whichever occurs first. The date of mailing of the board's notice of opportunity for hearing shall be the date postmarked on the certified mail receipt.

(B) A respondent properly filing a request for a hearing, whether personally or by attorney or attorneys, shall be entitled to such hearing within fifteen days but not sooner than seven days after such request has been filed unless both parties agree otherwise or a continuance is granted pursuant to section 119.09 of the Revised Code and rule 4731-13-06 of the Administrative Code.
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.
Upon motion by either party, or upon the initiative of the hearing examiner, the hearing examiner may consolidate two or more hearings into a single hearing, unless either party objects for good cause.
Petitions to intervene shall not be permitted.
Continuance of hearing.

(A) Except in matters of summary suspension, the board or the board through its hearing examiner, shall continue the initially scheduled hearing upon its own motion in order to more efficiently and effectively conduct its business unless the circumstances establish that a continuance would not serve the interest of justice. The new hearing date shall be set according to the case management schedule approved by the board for the type of violation alleged and available from the board's website at http://med.ohio.gov/. In setting the new hearing date, the hearing examiner shall make a reasonable attempt to obtain input from the parties. Upon motion of at least one of the parties demonstrating extraordinary circumstances, the hearing examiner may approve a special case management schedule.

(B) A hearing shall be continued only with the approval of the board or its hearing examiner based upon a written motion of a party or upon the initiative of the hearing examiner.

(C) A motion for a continuance shall not be granted unless good cause and proper diligence is demonstrated.

(1) Before granting any continuance, consideration shall be given to harm to the public which may result from delay in proceedings.

(2) In no event will a motion for a continuance requested less than fourteen days prior to the scheduled date of the hearing be granted unless it is demonstrated that good cause exists which would justify the granting of a continuance.

(D) No continuance of a hearing for a summary suspension shall be granted without the written agreement of the respondent or the respondent's attorney or attorneys and of the board through its secretary and supervising member.

(E) If a continuance is granted, the entry granting the continuance shall specify the dates to which the hearing is continued and shall be set in accordance with the case management schedule. Upon motion of at least one of the parties demonstrating extraordinary circumstances, the hearing examiner may approve a special case management schedule.

(F) Hearings shall not be continued due to the unavailability of a subpoenaed witness without approval of the hearing examiner.

(1) The hearing examiner may hold the record open to accept a deposition in lieu of live testimony of a subpoenaed witness.
(2) The procedures set forth in rules 4731-13-20 and 4731-13-20.1 of the Administrative Code shall apply to any deposition in lieu of live testimony taken pursuant to this rule.
Form and page limitations for briefs and memoranda.

(A) All hearing briefs provided under paragraph (D)(7) of rule 4731-13-03 of the Administrative Code and memoranda filed under rule 4731-13-07 of the Administrative Code shall be provided or filed subject to the following requirements:

1. The body text of a brief or memorandum shall be set in a legible typeface of at least twelve points, either single-spaced or double-spaced.

2. A brief or memorandum shall not exceed fifteen pages exclusive of the certificate of service and the appendix unless an exception is granted in advance pursuant to paragraph (A)(3) of this rule.

3. Upon motion by either party, or upon the initiative of the hearing examiner, the hearing examiner may authorize briefs or memoranda that exceed fifteen pages, up to a maximum of thirty pages exclusive of the certificate of service and the appendix, in matters that involve complex legal issues. Unless made upon the record at hearing, a motion for such a determination shall be filed no later than seven days prior to the deadline for filing the brief or memorandum.

4. If a reply memorandum is authorized pursuant to paragraph (C) of rule 4731-13-07 of the Administrative Code, that memorandum shall not exceed seven pages exclusive of the certificate of service and the appendix.

(B) Briefs and memoranda provided in contravention of the requirements set forth in paragraph (A) of this rule will be accepted for filing, however, pages beyond the fifteen page limit shall not be considered. Memoranda filed in contravention of the requirements set forth in paragraph (A) of this rule will be accepted for filing.
4731-13-07  Motions.

(A) Except as otherwise provided under Chapter 4731-13 of the Administrative Code or Chapter 119. of the Revised Code, all motions, unless made upon the record at hearing, shall be made in writing. A written motion shall state with particularity the relief or order sought, shall be accompanied by a memorandum setting forth the grounds therefore, and shall be filed in compliance with rule 4731-13-08 of the Administrative Code. Except in cases of summary suspensions pursuant to division (G) of section 4731.22 of the Revised Code, all prehearing motions except motions for continuance pursuant to rule 4731-13-06 of the Administrative Code and motions to quash pursuant to paragraph (F) of rule 4731-13-13 of the Administrative Code, shall be made no later than fourteen days before the date of hearing unless express exception is granted by the hearing examiner or by this chapter.

(1) If filed by email, motions and supporting or opposing memoranda shall be filed as pdf attachments to emails, and not be incorporated into the body of the email itself.

(2) All supporting or opposing memoranda shall comply with rule 4731-13-07.1 of the Administrative Code.

(B) All motions, together with any supporting documentation, shall be served as provided in rule 4731-13-09 of the Administrative Code.

(C) Any response to a prehearing motion shall be filed within ten days after service of that motion, or at such other time as is fixed by the hearing examiner. A movant may reply to a response only with the permission of the hearing examiner.

(D) Before ruling upon a written motion, the hearing examiner shall consider all memoranda and supporting documents filed. The hearing examiner shall enter a written ruling and shall issue copies to each representative of record. The ruling on all motions made at hearing shall be included in the hearing transcript except where the hearing examiner elects to take the motion under advisement and issue a written ruling at a later time. The hearing examiner shall include in each written ruling on a motion a statement of the reasons therefore.

(E) Except as otherwise provided in this chapter or Chapter 119. of the Revised Code, rulings on all motions filed subsequent to the issuance of the report and recommendation shall be rendered by the board or, if the board is not in session, by its president or the vice president if the president is unavailable acting on its behalf.

(1) Responses to motions shall be filed no later than three days after service of the motion as set forth in the certificate of service attached to the served copy of
the motion. A movant may reply to a response only with the permission of the board through its president or vice president if the president is unavailable, and only under extraordinary circumstances, such as an assertion that a material inaccuracy of fact or law was provided in the response.

(2) Motions for extension of time for filing objections shall be filed on or prior to the deadline for filing the objections. A motion for extension of time for filing objections filed after the deadline will not be considered absent extraordinary circumstances, as determined by the board through its president or vice president if the president is unavailable.
(A) A document is "filed" when it is received and time stamped in the offices of the board. For documents received via e-mail or through any electronic filing system implemented by the board, the time stamp provided by the board's computer shall be the time of receipt. Documents received after five p.m. eastern standard time shall not be considered for filing until the next business day.

(B) An original of any document required to be served by Chapter 4731-13 of the Administrative Code shall be filed with the board not more than three days after service.

(C) All filings shall be addressed to the board to the attention of its hearing unit.
To be considered by the board and its hearing examiner, any document required by Chapter 4731-13 of the Administrative Code to be served shall:

(A) Be served either personally, by regular mail, by facsimile, or by e-mail, or through any electronic filing system which provides automatic notice to parties utilized by the board. Service is complete on the date of mailing, e-mailing, facsimile or personal service of the document.

(B) Contain the name, address, and telephone number of the person submitting the document and shall be appropriately captioned to indicate the name of the respondent.

(C) Have a certificate of service on it. A certificate of service shall be signed and contain the following:

1. The date of service;

2. The method by which service was made;

3. The address where service was made; and

4. The name of the person or authority who was served.
Computation and extension of time.

(A) The date of occurrence of the event causing time to run is not counted in the computation of any time limit under Chapter 4731-13 of the Administrative Code. The last day of the period is included in the computation of the time limit. If the last day of a period is not a regular business day, the time period runs through the end of the next regularly scheduled business day.

(B) The board or its hearing examiner may extend the time for filing or responding to motions and briefs.

(1) Requests for extension of time shall be made in writing and filed as provided in rule 4731-13-08 of the Administrative Code prior to the expiration of any applicable time limit.

(2) Requests for extension of time shall be addressed to the attention of the board's hearing unit.

(3) Requests for extension of time shall be served as provided in rule 4731-13-09 of the Administrative Code.
Notice specifying the date, time and place set for hearing shall be mailed by certified mail to the representatives of record, except that notice of changes to the date, time or place set for hearing shall be mailed by regular mail, e-mail or facsimile if a representative of each party participated in the selection of the new date, time or place.
4731-13-12  

Transcripts.

(A) Duplicate transcripts of the stenographic record taken of hearings may be obtained directly from the court reporter at the requestor's expense prior to receipt of the original transcript by the board, except as otherwise restricted by 4731-13-31 of the Administrative Code.

(B) Upon request made to the board's hearing unit, a copy of the original hearing transcripts may be reviewed at the board offices. Additional copies may be prepared at the requestor's expense and shall be provided by the board within a reasonable period of time.

(C) Original transcripts shall not be removed from the board offices.

(D) Any portion of a hearing transcript which contains information that is required to be kept confidential pursuant to any state or federal law shall be sealed and made part of the hearing record. Confidential portions of hearing transcripts shall be provided only to agents of the parties for purposes of the administrative hearing and shall not be disseminated to any other persons.
4731-13-13    Subpoenas for purposes of hearing.

(A) Upon written request, the board shall issue subpoenas for purposes of hearing to compel the attendance and testimony of witnesses and production of books, records and papers. Each subpoena shall indicate on whose behalf the witness is required to testify. Copies of such subpoenas shall be issued to each representative of record.

(B) For purposes of a hearing conducted pursuant to Chapter 119. of the Revised Code, subpoena requests shall specify the name and address of the individual to be served and the date and time at which the individual is to appear. With respect to the production of books, records and papers, such request shall set a compliance date in accordance with the exchange deadlines established by the hearing examiner in rule 4731-13-18, may not specify a date of compliance less than fourteen days prior to hearing.

(C) Except upon leave of the board or its hearing examiner, subpoena requests are to be filed with the board as provided in rule 4731-13-08 of the Administrative Code at least twenty-one days in advance of the requested date of compliance in order to allow sufficient time for preparation and service of the subpoenas.

(D) In the event that the number of subpoenas requested appears to be unreasonable, the board or its hearing examiner may require a showing of necessity therefore and, in the absence of such showing, may limit the number of subpoenas. Absent such a limitation, subpoenas shall be issued within seven days of request. Failure to issue subpoenas within this time may constitute sufficient grounds for the granting of a continuance.

(E) After the hearing has commenced the hearing examiner may order the issuance of subpoenas for purposes of hearing to compel the attendance and testimony of witnesses and production of books, records and papers. Copies of such subpoenas shall be issued to each representative of record.

(F) Upon motion and for good cause, the hearing examiner may order any subpoena be quashed. Motions to quash shall be made in the manner provided in rules 4731-13-07 and 4731-13-08 of the Administrative Code, except that motions to quash shall be filed at least seven days prior to the date of compliance. The non-moving party may file a response no later than five days after service of the motion to quash or at least one day prior to the date of compliance whichever is earlier. Unless a motion to quash has been granted, a witness shall attend the hearing to which he or she was subpoenaed. The board shall make a reasonable attempt to contact any witness whose subpoena has been quashed.

(G) Witnesses shall not be subpoenaed to prehearing conferences.
4731-13-14

Mileage reimbursement and witness fees.

(A) Mileage shall be paid in the same manner as that allowed in the court of common pleas in criminal cases in the county of hearing.

(B) The respondent shall not subpoena him or her self.

(C) Mileage and witness fees shall be returned by anyone who fails to appear at the hearing for which he or she was subpoenaed.
Reports and recommendations.

(A) Within thirty days following the close of a hearing conducted under Chapter 119. of the Revised Code, the hearing examiner shall submit a written report setting forth proposed findings of fact and conclusions of law and a recommendation of the action to be taken by the board. The hearing shall not be considered closed until such time as the record is complete, as determined by the hearing examiner.

(B) A copy of such written report shall be issued to each representative of record. The copy issued to the respondent's representative of record shall be accompanied by notice of the date the report and recommendation is to be considered by the board.

(C) Either representative of record may, within ten days of receipt of the hearing examiner's report and recommendation, file written objections to the report and recommendation. Only those objections filed in a timely manner shall be considered by the board before approving, modifying, or disapproving the hearing examiner's recommendation, unless otherwise determined by the board.

(D) Upon written request, the board may grant extensions of the time within which to file objections to the report and recommendation. In the event that the board is not in session, the president of the board may grant such extensions.

(E) Unless otherwise determined by the board based upon written motion of a party, the board shall consider the hearing examiner's report and recommendation and any objections thereto at its next regularly scheduled meeting after the time for filing objections has passed. At that time, the board may do any or all of the following: order additional testimony to be taken; permit the introduction of further documentary evidence; or act upon the report and recommendation. For purposes of taking such additional testimony or documentary evidence, the board may remand to the hearing examiner.

(F) Any motion to reopen the hearing record for purposes of introducing newly discovered material evidence that with reasonable diligence, could not have been discovered and produced at the hearing shall be filed in the manner provided in rules 4731-13-07 and 4731-13-08 of the Administrative Code. Such motion to reopen shall be filed not later than fourteen days prior to the scheduled consideration by the board of the hearing examiner's report and recommendation, unless the newly discovered material evidence, with reasonable diligence, could not have been discovered earlier than fourteen days prior to the scheduled consideration by the board. The other party shall have an opportunity to file, not later than seven days prior to the scheduled consideration by the board of the hearing examiner's report and recommendation, a memorandum contra to said motion.

Any submission of documentation or evidence received by the board after the close of the record and prior to the date of consideration of the hearing examiner's report is invalid.
and recommendation by the board shall be deemed a motion to reopen the record pursuant to this rule. If such motion is filed prior to the issuance of the hearing examiner’s report and recommendation, the hearing examiner shall rule on the motion. If such motion is filed subsequent to the issuance of the hearing examiner’s report and recommendation, the board shall rule on the motion. All submitted materials must be accompanied by an affidavit from the moving party that sets forth how the evidence is material, how the evidence is newly discovered, and why it could not have been produced at hearing. The affidavit must also show that the party made a reasonably diligent effort to obtain the material prior to hearing. Failure to comply with the requirements of this rule shall result in the exclusion of the submitted material unless the moving party shows good cause and the board votes to admit the document or evidence.

(G) Without leave of the board, no party shall be permitted to address the board at the time of consideration of the hearing examiner's report and recommendation. Any request for such leave shall be filed by motion no less than five days prior to the date the report and recommendation is to be considered by the board. No such leave shall be granted unless the opposing representative of record has been actually notified of the request, unless otherwise determined by the board.

(H) If a request to address the board is granted, the opposing party may also address the board.
4731-13-16 Reinstatement or restoration of certificate.

Any disciplinary action taken by the board which results in a suspension from practice shall either lapse by its own terms or contain a written statement of the conditions under which the certificate may be reinstated or restored, unless terms for reinstatement or restoration are otherwise governed by statute.

Such conditions may include but are not limited to:

(A) Submission of a written application for reinstatement or restoration;

(B) Payment of all appropriate fees, civil penalties, and fines as provided in Chapter 4731. of the Revised Code;

(C) Mental or physical examination;

(D) Additional education or training;

(E) Reexamination;

(F) Practice limitations;

(G) Participation in counseling programs;

(H) Demonstration that the respondent can resume practice in compliance with acceptable and prevailing standards.
Settlements, dismissals, and voluntary surrenders.

(A) Settlement shall be negotiated on behalf of the board by the secretary and supervising member of the board. Any settlement agreement containing terms not in conformity with the disciplinary guidelines adopted by the board must have the concurrence of the board's president prior to execution.

(B) Any matter which is the subject of a hearing may be settled by the parties. If settlement negotiations continue after the final day of hearing, the parties shall, within ten days of the final day of hearing, jointly present the hearing examiner with written notice specifying a period of time, not to exceed thirty days, during which the record shall be held open for purposes of negotiation.

(1) If the hearing record has closed or closes during the period of time specified in the parties' joint notice, such notice shall toll the hearing examiner's thirty-day time period for issuance of findings of fact and conclusions of law pursuant to section 4731.23 of the Revised Code.

(2) If, at the conclusion of the time period specified by the parties' joint notice, the hearing examiner has not received appropriate written notice that a settlement agreement has been executed, the tolling of the hearing examiner's thirty-day period for issuance of findings of fact and conclusions of law shall cease, no further settlement negotiations shall be undertaken, and no settlement agreement shall be executed in lieu of the filing of a report and recommendation by the hearing examiner and the issuance of a final order by the board.

(C) Before being submitted to the board for ratification, all settlement agreements shall be in writing and shall be signed by the respondent and by the respondent's attorney, if any. Counsel for the board shall sign the settlement agreement as follows:

(1) If the settlement agreement was negotiated prior to the issuance of a notice of opportunity for hearing, an appropriate board staff attorney shall sign the agreement.

(2) If the settlement agreement was negotiated subsequent to the issuance of a notice of opportunity for hearing, an attorney from the office of the attorney general shall sign the agreement.

(D) Signed settlement agreements shall be submitted to the board for ratification.

(E) If the board ratifies a settlement agreement, the secretary and supervising member of the board shall sign the ratified agreement, following shall sign the ratified...
**agreement:**

(1) The secretary and supervising member of the board shall sign the ratified agreement.

(2) If the settlement agreement was negotiated prior to the issuance of a notice of opportunity for hearing, an appropriate board staff attorney shall sign the ratified agreement.

(3) If the settlement was negotiated subsequent to the issuance of a notice of opportunity for hearing, an attorney from the office of the attorney general shall sign the ratified agreement.

(F) A notice of dismissal may be entered at any time prior to the filing of the report and recommendation. If negotiations continue after the final day of hearing, the procedures in paragraph (B) of this rule shall be followed. A notice of dismissal shall be authorized and signed by the board's secretary and supervising member.

(G) This rule shall neither apply to nor limit the authority granted the board under division (M) of section 4731.22 of the Revised Code with regard to the surrender of a license or certificate or the withdrawal of an application for a license or certificate.

(H) In the event that the board issues an amended notice of opportunity for hearing, the original notice of opportunity for hearing is automatically superseded by the amended notice. To request a hearing pursuant to Chapter 119. of the Revised Code, the respondent must file a new hearing request in response to the amended notice of opportunity for hearing. For purposes of this chapter of the Administrative Code, "amended cite" means a cite in which there has been a substantive alteration to one or more factual allegations or statutory charges, other than correction of a clerical or technical error, that relates to the allegations set forth in the original notice.
Exchange of documents and witness lists.

(A) At the time the hearing examiner schedules the hearing with input from the parties, a case management schedule shall be created which will include the deadline dates for each party to provide a list of both the witnesses and the documents intended to be introduced at hearing.

(B) Upon motion of any party, failure without good cause to provide the list of witnesses and documents by the deadline date established in the case management schedule may result in exclusion from the hearing of such testimony or documents.

(C) The hearing examiner shall set, in the case management schedule, the deadline dates by which the parties shall exchange hearing exhibits, identify lay and expert witnesses and exchange written reports from expert witnesses.

   (1) Absent extraordinary circumstances, the failure of a party to produce an exhibit under the terms of the case management schedule shall result in the exclusion of that exhibit from evidence at hearing.

   (2) Absent extraordinary circumstances, the failure of a party to identify a lay or expert witness under the terms of the case management schedule shall result in the exclusion of that witness' testimony at hearing.

   (3) Absent extraordinary circumstances, the failure of a party to produce a written report from an expert witness under the terms of the case management schedule shall result in the exclusion of the witness' expert testimony at hearing.

(D) A party shall notify the hearing examiner of any deficiency in the materials provided by the other party within a reasonable period of time after discovery of the deficiency.

(E) A party shall notify the hearing examiner of any failure by the other party to comply with a deadline imposed pursuant to this rule within seven days of the failure to comply.

(F) Any witness who intends to testify as an expert, including the respondent, must submit a written report. A written report by an expert shall set forth the opinions to which the expert witness will testify and the bases for such opinions. This paragraph will not preclude the respondent from testifying as a fact witness.

(G) Any exhibit exchanged by the parties which is a patient record or which contains information that is required to be kept confidential pursuant to any state or federal
law may be provided only to agents of the parties for purposes of the administrative hearing and shall not be disseminated to any other person or entity.
4731-13-20.1 **Electronic testimony.**

(A) Upon written motion of any party, and upon service of that motion to the other party’s representative of record, the hearing examiner may order that the testimony of a prospective witness be taken by telephonic or real-time video testimony. The hearing examiner may grant the motion if it appears probable that:

1. The prospective witness will be unavailable to attend or will be prevented from attending a hearing; and

2. The testimony of the prospective witness is material.

(B) The testimony shall be taken under such conditions and terms as the hearing examiner shall set forth. Moreover, the hearing examiner may order the production of any designated books, papers, documents or tangible objects, so long as not privileged, at the same time and place.

(C) The hearing examiner shall set the time and fix the place of telephonic or real-time video testimony.
Depositions in lieu of live testimony.

(A) Upon written motion of any party, and upon service of that motion to the other party's representative of record, the hearing examiner may order that the testimony of a prospective witness be taken by deposition in lieu of live testimony. The hearing examiner may grant the motion if it appears probable that:

(1) The prospective witness will be unavailable to attend or will be prevented from attending a hearing;

(2) The testimony of the prospective witness is material; and

(3) In the case of an expert witness, a showing of the unavailability of the expert to attend shall not be necessary for the hearing examiner's consideration of the motion to take a deposition in lieu of live testimony.

(B) The testimony shall be taken under such conditions and terms as the hearing examiner shall set forth. Moreover, the hearing examiner may order the production of any designated books, papers, documents or tangible objects, so long as not privileged, at the same time and place.

(C) The parties shall agree to the time and place for taking the deposition in lieu of live testimony. Depositions in lieu of live testimony shall be conducted in the same county in which the hearing is conducted unless otherwise agreed to by the parties. If the parties are unable to agree, the hearing examiner shall set the time or fix the place of deposition.

(D) At a deposition in lieu of live testimony taken under this rule, each party shall have the right, as at hearing, to fully examine witnesses.

(E) The transcript of a deposition in lieu of live testimony taken under this rule shall be offered into evidence at hearing. The cost of preparing a transcript of any testimony taken by deposition in lieu of live testimony which is submitted as evidence at the hearing shall be borne by the board.

(F) The expense of any video deposition shall be borne by the requestor.
Prior action by the state medical board.

The hearing examiner shall admit evidence of any prior action entered by the board against the respondent. Such evidence shall include a certified copy of the final order in that prior action, and may also include other certified documents pertaining to that action.
Stipulation of facts.

Parties may, by stipulation, agree on any or all facts involved in proceedings before the hearing examiner. The hearing examiner may thereafter require development of any fact the hearing examiner deems necessary.
Witnesses.

(A) All witnesses at any hearing before the hearing examiner shall testify under oath or affirmation.

(B) A witness may be accompanied and advised by legal counsel. Participation by counsel for a witness other than the respondent is limited to protection of that witness's rights, and that legal counsel may neither examine nor cross-examine any witnesses.

(C) The board may institute contempt proceedings pursuant to section 119.09 of the Revised Code, if a witness refuses to answer a question ruled proper at a hearing or disobey a subpoena.

(D) For purposes of this chapter:

1. A sitting board member is an individual who is currently a member of the board.

2. A presiding board member is a sitting board member who has a decisive role in the outcome of the matter in question and who is neither the secretary nor the supervising member as appointed pursuant to Chapter 4731. of the Revised Code.

3. A non-presiding board member is a sitting board member who does not have a decisive role in the outcome of the matter in question due to recusal, absence or other reason.

4. A presiding hearing examiner is a hearing examiner who is assigned to the matter in question pursuant to section 4731.23 of the Revised Code.

5. A non-presiding hearing examiner is a hearing examiner who is not assigned to the matter in question pursuant to section 4731.23 of the Revised Code.

(E) Neither a presiding board member nor a presiding hearing examiner shall be a competent witness in any adjudication proceeding. Evidence from other persons relating to the mental processes of a presiding board member or a presiding hearing examiner shall not be admissible.

(F) Unless the testimony of a non-presiding board member or a non-presiding hearing examiner is material to the factual allegations set forth in the notice of opportunity for hearing, neither a non-presiding board member nor a non-presiding hearing examiner shall be a competent witness in any adjudication proceeding.
(G) A sitting board member shall not be subpoenaed to provide expert testimony.

(H) Any party may move for a separation of witnesses. Expert witnesses shall not be separated.

(I) Upon commencement of a hearing, each party shall inform the hearing examiner of the identity of each potential witness for his or her cause who is present in the hearing room. Failure to so identify potential witnesses may be grounds for their later disqualification as witnesses.

(J) A witness may, in the discretion of the attorney hearing examiner, testify as to an ultimate issue of fact. An expert witness may testify regarding the appropriate treatment for impairment.
Conviction of a crime.

A certified copy of a plea of guilty to, or a judicial finding of guilt of any crime in a court of competent jurisdiction is conclusive proof of the commission of all of the elements of that crime.
Evidence.

(A) The "Ohio Rules of Evidence" may be taken into consideration by the board or its hearing examiner in determining the admissibility of evidence, but shall not be controlling. The "Ohio Rules of Evidence" are readily available to attorneys and may be found at libraries, bookstores and on the internet at www.supremecourt.ohio.gov/LegalResources/Rules/evidence/evidence.pdf.

(B) The hearing examiner may permit the use of electronic or photographic means for the presentation of evidence.
Broadcasting and photographing administrative hearings.

If the hearing examiner determines that broadcasting, televising, recording or taking of photographs in the hearing room would not distract participants, impair the dignity of the proceedings or otherwise materially interfere with the achievement of a fair administrative hearing, the broadcasting, televising, recording or taking of photographs during hearing proceedings open to the public may be permitted under the following conditions and upon request:

(A) Requests for permission for the broadcasting, televising, recording or taking of photographs in the hearing room shall be made in writing to the hearing examiner prior to the commencement of the hearing, and shall be made a part of the record of the proceedings;

(B) Permission is expressly granted prior to commencement of the hearing in writing by the hearing examiner and is made a part of the record of the proceedings;

(C) If the permission is granted, the hearing examiner shall specify the place or places in the hearing room where operators and equipment are to be positioned;

(D) The filming, videotaping, recording or taking of photographs of witnesses who object thereto shall not be permitted.
Sexual misconduct evidence.

In those cases where sexual misconduct has been alleged:

(A) Evidence of specific instances of the victim's sexual activity, opinion evidence of the victim's sexual activity, and reputation evidence of the victim's sexual activity shall not be admitted unless it involves evidence of the origin of semen, pregnancy, or disease, or the victim's sexual activity with the offender, and only to the extent that the evidence is material to a fact at issue in the case and that its inflammatory or prejudicial nature does not outweigh its probative value.

(B) Prior to taking testimony or receiving evidence of any sexual activity of the victim, the hearing examiner shall resolve the admissibility of the proposed evidence in a closed hearing. The victim may be represented by counsel in that hearing or other proceedings to resolve the admissibility of evidence upon approval by the hearing examiner.

(C) Nothing in this rule shall be construed as limiting the authority of the hearing examiner to close a hearing as provided under paragraph (B) of rule 4731-13-03 of the Administrative Code.
Supervision of hearing examiners.

The hearing examiners shall perform their duties under the supervision and direction of the board's executive director, provided that the board, other than the secretary and supervising member, shall have exclusive authority to impose discipline based on the substance of the hearing examiners' reports and recommendations.
Prehearing conference.

With or without written motion from any party, the hearing examiner may schedule a prehearing conference to address any matter related to preparation for or conduct of a hearing. The prehearing conference may be in person or by telephone. No witness testimony shall be taken during a prehearing conference. Any documents presented at the prehearing conference shall be made part of the hearing record. If a transcript of the proceeding is prepared, the transcript shall be made part of the hearing record.
4731-13-31 Transcripts of prior testimony.

(A) Any transcript of prior testimony of a witness may be used for the purpose of refreshing the recollection, contradicting the testimony or impeaching the credibility of that witness. If only a part of a transcript is offered into evidence by a party, the other party may offer any other part.

(B) A transcript of testimony and exhibits from a prior proceeding may be introduced for any purpose if that prior proceeding concerns the basis for the board's allegations against the respondent. Upon offering part of a transcript or exhibit from a prior proceeding, the offering party may be required by the other party to present any other part of the offered item which should in fairness be considered contemporaneously with it.

(C) Nothing in this paragraph shall be construed to permit the taking of depositions for purposes other than those set forth in rule 4731-13-20 of the Administrative Code.

(D) Nothing in this rule shall be construed to limit the use of a prior statement by a respondent as set forth in rule 4731-13-32 of the Administrative Code.
Prior statements of the respondent shall not be excluded on the basis of hearsay.
The board or its hearing examiner may utilize the "Physicians' Desk Reference" (PDR) for information regarding the FDA approved labeling for dangerous drugs. The edition(s) of the PDR utilized shall be the edition(s) contemporaneous with the allegations set forth in the notice of opportunity for hearing upon which the hearing is based. The "PDR" is a well-known and readily available text. It may be found at libraries, bookstores or on the internet at www.pdr.net. The board or its hearing examiner may also utilize the US National Library of Medicine at medlineplus.gov.
Ex parte communication.

(A) The members of the board shall base their decisions on any matter subject to hearing only on the evidence of record. No information acquired by a member of the board in any way other than by review of the evidence of record shall be considered by such member in that member's decision on a matter subject to hearing. The receipt of information about a matter subject to hearing outside the evidence of record shall not disqualify the member from participating in the decision on that matter unless the member excuses himself or herself from participation in the decision on the ground that he or she cannot restrict his or her decision on the matter to the evidence of record.

(B) Except as otherwise provided under this chapter or by statute, no hearing examiner or member of the board shall initiate or consider ex parte communications concerning a substantive matter related to a pending hearing. Nothing contained herein, however, shall preclude the hearing examiner from nonsubstantive ex parte communications on procedural matters and matters affecting the efficient conduct of adjudicatory hearings.

(C) The hearing examiner and members of the board shall disclose on the public record the source of any ex parte or attempted ex parte communications pertaining to a substantive issue. If the recipient of the ex parte communication determines that he or she can no longer render an impartial decision, the recipient shall recuse himself or herself from further participation in consideration of the matter.

(D) If requested by any party, the recipient of the ex parte communication shall file with the board an affidavit setting forth the substance of the ex parte communication. The affidavit shall be sealed, held as proffered material and maintained with the hearing record.
Severability.

(A) Except as otherwise provided under this chapter or by statute, a rule promulgated under this chapter shall apply only to those administrative proceedings for which the notice of opportunity for hearing was mailed to respondent, or his representative, on or after the effective date of the particular rule.

(B) If any provision of the rules in this chapter of the Administrative Code or if the application of any provision of the rules in this chapter of the Administrative Code is held invalid, the invalidity shall not affect any other provision of the rules in this chapter, or the application of any other provision of the rules in this chapter, that can be given effect without the invalid provision or application, and, to this end, the provisions of the rules in this chapter are hereby declared severable.
Disciplinary actions.

For purposes of Chapters 4730., 4731., 4759., 4760., 4761., 4762., 4774., and 4778. of the Revised Code and Chapters 4730., 4731., 4774., and 4778. of the Administrative Code:

(A) "Permanent revocation" means the permanent loss of a certificate to practice in Ohio and the inability, at any time, to reapply for or hold any certificate to practice in Ohio. An individual whose certificate has been permanently revoked shall forever thereafter be ineligible to hold any certificate to practice, and the board shall not accept from that individual an application for reinstatement or restoration of the certificate or for issuance of any new certificate.

(B) "Revocation" means the loss of a certificate to practice in Ohio. An individual whose certificate has been revoked shall be eligible to submit an application for a new certificate. The application for a new certificate shall be subject to all requirements for certification in effect at the time the application is submitted. In determining whether to grant such an application, the board may consider any violations of Chapters 4730., 4731., 4759., 4760., 4761., 4762., 4774., and 4778. of the Revised Code, whichever is applicable, that were committed by the individual before or after the revocation of the individual's certificate, including those that formed the basis for the revocation. All disciplinary action taken by the board against the revoked certificate shall be made a part of the board's records for any new certificate granted under this rule.

(C) "Suspension" means the temporary loss of a certificate to practice in Ohio. A suspension shall be imposed for either a definite term or an indefinite term.

(1) An order for a definite term of suspension shall specify the time period of the suspension. A certificate which has been suspended for a definite term shall be reinstated at the conclusion of the specified time period.

(2) An order for an indefinite term of suspension shall contain a written statement of the conditions under which the certificate may be reinstated. Such conditions may include, but are not limited to, the following:

(a) A minimum time period of suspension;

(b) Submission of a written application for reinstatement;

(c) Payment of all appropriate fees, civil penalties, and fines as provided in Chapters 4730., 4731., 4759., 4760., 4761., 4762., 4774., and 4778. of the Revised Code;
(d) Mental or physical examination;

(e) Additional education or training;

(f) Reexamination;

(g) Participation in counseling programs;

(h) Demonstration that the certificate holder can resume practice in compliance with acceptable and prevailing standards;

(i) Satisfactory completion of all terms, conditions or limitations placed upon the certificate holder through a board-approved consent agreement or board order;

(j) Passage of an examination to determine present fitness to resume practice, pursuant to section 4731.222 of the Revised Code; and

(k) Acceptance of conditions of probation or practice limitations.

(D) "Limitation" means to preclude the certificate holder from engaging in a particular conduct or activity, to impose conditions on the manner in which that conduct or activity may be performed, or to require the certificate holder to abide by specific conditions in order to continue practicing medicine. A limitation shall be either temporary or permanent.

(E) "Probation" means a situation whereby the certificate holder shall continue to practice only under conditions specified by the board. Failure of the certificate holder to comply with the conditions of probation may result in further disciplinary action being imposed by the board. The probation period shall be for either a definite or an indefinite term. If probation is for an indefinite term, the board shall establish a minimum probation period and the board shall release the certificate holder from the conditions of probation upon completion of the minimum probation period and upon the board's determination that the purpose of probation has been fulfilled.

(F) "Reprimand" means the certificate holder is formally and publicly reprimanded in writing.

(G) "No Further Action" means that the board finds that a violation occurred but declines to impose any disciplinary sanction. No further action shall be ordered by the board
under circumstances where the board finds that all necessary remedial measures have been completed by the certificate holder, future monitoring is unnecessary and reprimand is not warranted.

(H) "Dismissal" means that the board finds that no violation occurred.

(I) "Grant of Application for Certificate" means that the board grants an application for a certificate to practice. In matters where disciplinary violations have been alleged against an applicant for a certificate, the grant of an application for certificate may be accompanied by a suspension, limitation, probation, reprimand or no further action.

(J) "Permanent Denial" and "Permanent Refusal to Register or Reinstate" mean the permanent denial of an application for a certificate to practice in Ohio. An individual whose application for a certificate has been permanently denied shall forever thereafter be ineligible to apply to the board for any certificate to practice, and the board shall not accept from that individual an application for issuance of any certificate.

(K) "Denial" and "Refusal to Register to Reinstate" mean the denial of an application for a certificate to practice in Ohio. An individual whose application for a certificate has been denied shall be eligible to submit a new application for a certificate. The new application shall be subject to all requirements for certification in effect at the time the new application is submitted. In determining whether to grant a new application, the board may consider any violations of Chapters 4730., 4731., 4759., 4760., 4761., 4762., 4774., and 4778. of the Revised Code, whichever is applicable, that were committed by the individual before or after the denial of the individual's previous application, including those that formed the basis for the denial.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Hearing Rules-For initial circulation

DATE: June 2, 2020

Rules regarding hearings are due for the five-year rule review in 2021. The rules with some minor updates are attached for your review.

4731-13-01 Representatives; appearances-Amend to clarify required information in an attorney withdrawal notice in paragraph (F).

4731-13-02 Filing request for hearing-No change.

4731-13-03 Authority and duties of hearing examiners-No change.

4731-13-04 Consolidation-No change.

4731-13-05 Intervention-No change.

4731-13-06 Continuance of hearing-Amend to correct minor error.

4731-13-07 Motions-Amend to add “pdf” to attachments for clarification.

4731-13-07.1 Form and page limitations for briefs and memoranda-Amend to correct minor error and to clarify in paragraph (B) that memoranda filed in contravention of the rule will be permitted but pages beyond fifteen will not be considered.

4731-13-08 Filing-Amend to add a filing option through an electronic filing system implemented by the board.

4731-13-09 Service-Amended to add a service alternative through any electronic filing system utilized by the board.

4731-13-10 Computation and extension of time-no change.

4731-13-11 Notice of hearings-No change

4731-13-12 Transcripts-No change
Subpoenas for purposes of hearing-Amend regarding date of compliance. Note: this rule is currently at CSI for amendment. I would like to withdraw the rule from CSI and file with the entire group of rules. The suggested language revises the compliance date deadline to put it in accordance with the document exchange schedule set by the hearing examiner. The new language was suggested by the hearing unit.

Mileage reimbursement and witness fees-No change.

Reports and recommendations-No change.

Reinstatement or restoration of certificate-Amend to correct minor error.

Settlements, dismissals, and voluntary surrenders-Amend to accurately reflect the timing of the signature by the enforcement attorney or assigned assistant attorney general.

Exchange of documents and witness lists-No change

Depositions in lieu of live testimony-No change

Electronic testimony-No change.

Prior action by the state medical board-No change.

Stipulation of facts-No change.

Witnesses-No change.

Conviction of a crime-No change.

Evidence-No change.

Broadcasting and photographing administrative hearings-No change.

Sexual misconduct evidence-No change.

Supervision of hearing examiners-No change.

Prehearing conference-No change.

Transcripts of prior testimony-No change.

Prior statements of the respondent-No change.

Physicians’ Desk Reference-Amend to allow usage of the US National Library of Medicine at medlineplus.gov
4731-13-34 Ex parte communication-No change.

4731-13-35 Severability-No change.

4731-13-36 Disciplinary Actions-No change.

**Action Requested:** (1) Withdraw Rule 4731-13-13 from CSI review and include with initial circulation of chapter; (2) Circulate rules as amended for initial review by interested parties.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Exposure Prone Invasive Procedure Rules-For initial circulation

DATE: May 29, 2020

Rules regarding exposure prone invasive procedures are due for the five year rule review in 2021. The rules with some minor updates are attached for your review.

4731-17-01 Definitions-Update to include respiratory care practice.
4731-17-02 Universal Precautions-No change proposed.
4731-17-03 Hand washing-No changes proposed.
4731-17-04 Disinfection and Sterilization-Amend to correct minor errors.
4731-17-05 Handling and disposal of sharps and wastes-Amend to correct a minor error.
4731-17-06 Violations-Amend to add respiratory care code section.

Action Requested: Circulate rules as amended for initial review by interested parties
For purposes of this chapter of the Administrative Code:

(A) "Licensee" means any person holding or practicing pursuant to a certificate issued by the board under Chapter 4730., 4731., 4760., 4761., 4762., or 4774. of the Revised Code.

(B) "Invasive procedure" means any of the following:

1. Surgical or procedural entry into tissues, cavities, or organs or repair of major traumatic injuries associated with any of the following: an operating or delivery room, emergency department, or outpatient setting, including physicians' offices; cardiac catheterization and angiographic procedures; a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists.

2. Any entry into the hair follicle using an electric modality for the purpose of hair removal.

3. The practice of acupuncture as defined in section 4762.01 of the Revised Code.

4. The performance of fluoroscopic procedures pursuant to section 4774.08 of the Revised Code.

5. The performance of cosmetic procedures, such as the injection of botulinum toxin, dermal fillers, permanent makeup at a location that is not licensed under the rules in Chapter 3701-9 of the Administrative Code, laser hair removal, and hair replacement procedures.

6. The practice of respiratory care as defined in section 4761.01 of the Revised Code.

(C) "FDA" means the United States food and drug administration.

(D) "EPA" means the United States environmental protection agency.
Universal precautions.

Licensees who perform or participate in invasive procedures shall, in the performance of or participation in any such procedures or functions, be familiar with, observe and rigorously adhere to the acceptable and prevailing standards for universal blood and body fluid precautions to minimize the risk of being exposed to or exposing others to the hepatitis B virus (HBV), the hepatitis C virus (HCV), and the human immunodeficiency virus (HIV). The acceptable and prevailing universal blood and body fluid precautions which the licensee follows shall include at least the following:

(A) Appropriate use of hand washing;

(B) Effective disinfection and sterilization of equipment;

(C) Safe handling and disposal of needles and other sharp instruments; and

(D) Appropriate barrier techniques including wearing and disposal of gloves and other protective garments and devices.
Licensees who perform or participate in invasive procedures shall follow acceptable and prevailing standards for hand washing which shall include at least the following:

(A) Hands shall be washed appropriately prior to performing or participating in an invasive procedure and after performing or participating in an invasive procedure;

(B) Hands and other skin surfaces shall be washed immediately and thoroughly if contaminated with blood or other body fluids; and

(C) Hands shall be washed immediately after gloves are removed.
Disinfection and sterilization.

Instruments and other equipment classified by the FDA as reusable, used by licensees who perform or participate in invasive procedures shall be appropriately disinfected and sterilized according to acceptable and prevailing standards for disinfection and sterilization which shall include at least the following:

(A) Instruments and devices that enter the patient's vascular system or other normally sterile areas of the body shall be sterilized before being used for each patient;

(B) Instruments and devices that touch intact mucous membranes but do not penetrate the patient's body surfaces shall be sterilized when possible, or undergo high-level disinfection if they cannot be sterilized before using for each patient;

(C) Instruments and devices that are able to withstand repeated exposure to heat shall be heat sterilized. Sterilization shall be accomplished by autoclave, dry heat, unsaturated chemical vapor, ethylene oxide, hydrogen peroxide gas plasma, or any other FDA/EPA-approved method;

(D) Instruments and items that cannot withstand heat sterilization shall be subjected to a high-level disinfection process, including compliance with any manufacturer's instructions for disinfection;

(E) Heat sterilizing devices shall be tested for proper function on a weekly basis by means of a biological monitoring system that indicates microorganism kill. Documentation shall be maintained either in the form of a log reflecting dates and person(s) conducting the testing or copies of reports from an independent testing entity. The documentation shall be maintained for a period of at least two years. In the event of a positive biological spore test, the licensee must take immediate remedial action to ensure that heat sterilization is being accomplished;

(F) Surface disinfection:

(1) Environmental surfaces that are contaminated by blood or other body fluids shall be disinfected with a chemical germicide that is registered with the environmental protection agency as a "hospital disinfectant" or sodium hypochlorite and is mycobactericidal at use-dilution. The disinfection process shall be followed before each patient; and

(2) Impervious backed paper, aluminium foil or plastic wrap shall be used to cover surfaces that may be contaminated by blood or other body fluids and that are difficult or impossible to disinfect. The cover shall be removed, discarded and then replaced between patients.
(G) Single use items used in treating a patient, which have become contaminated by blood or other body fluids, shall be discarded and not reused, unless sterilized and reused in accordance with current guidelines established by the FDA. Single use items being reused in treating a patient shall be adequately cleaned and sterilized. Single use items shall not be reused if the items’ physical characteristics and quality have been adversely affected or if the items are incapable of being reused safely and effectively for their intended use.
Handling and disposal of sharps and wastes.

(A) To prevent injuries, no licensee performing or participating in invasive procedures shall recap needles, or purposely bend or break needles or other sharp instruments or items by hand.

(B) After a licensee who is performing or participating in an invasive procedure uses disposable needles, syringes, scalpel blades or other sharp items, the licensee shall place the disposable sharp items used in a puncture-resistant container for disposal. The puncture-resistant container shall be located as close as practicable to the use area.

(C) All sharp items and contaminated wastes shall be disposed of according to requirements established by federal, local and state environmental or regulatory agencies.
4731-17-07 Violations.

(A) A physician assistant who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(2), (B)(3), (B)(19) and (B)(21) of section 4730.25 of the Revised Code.

(B) An anesthesiologist assistant who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(2), (B)(3), (B)(4) and (B)(19) of section 4760.13 of the Revised Code.

(C) An acupuncturist or oriental medicine practitioner who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(2), (B)(3), (B)(4) and (B)(20) of section 4762.13 of the Revised Code.

(D) A radiologist assistant who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(2), (B)(3), (B)(4), and (B)(19) of section 4774.13 of the Revised Code.

(E) Any other licensee who violates any provision of this chapter shall be subject to discipline pursuant to divisions (B)(6), (B)(20) and (B)(29) of section 4731.22 of the Revised Code.

(F) A respiratory care professional or limited permit holder who violates any provision of this chapter shall be subject to discipline pursuant to division (B)(10) of section 4761.09 of the Revised Code.”
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Radiologist Assistant Rules

DATE: May 29, 2020

On April 29, 2020, the Radiologist Assistant rules were circulated to interested parties. One
comment, which is attached, was received.

The following rules are ready for filing with CSI:

• 4774-1-01 Definitions: No changes proposed.
• 4774-1-02 Application for a certificate to practice: Changes to align with licensure rules for
  other license types.
• 4774-1-02.1 Military provisions related to certificate to practice as a radiologist assistant: This
  rule is currently pending with CSI for rescission, as part of the rule package that
  consolidates all of the military rules into one chapter, 4731-36, OAC.
• 4774-1-03 Renewal of a certificate to practice: Proposed to be rescinded. Most
  provisions are repetitive of the statute and have been consolidated into 4774-1-
  02, OAC.
• 4774-1-04 Miscellaneous provisions: No changes proposed.

Action Requested: Approve filing with Common Sense Initiative
Definitions.

(A) “Board” means the state medical board of Ohio.

(B) For purposes of Chapter 4774. of the Revised Code, the following definitions apply:

1. “General Anesthesia” means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory functions is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

2. “Deep sedation” means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

3. “Moderate sedation” means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. Reflex withdrawal from a pain stimulus is not a purposeful response. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is maintained.

4. “Minimal sedation” means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected. Sedation achieved through intravenous administration of drugs is not a form of minimal sedation.
Military provisions related to certificate to practice as a radiologist assistant.

(A) Definitions

(1) "Armed forces" means any of the following:

(a) The armed forces of the United States, including the army, navy, air force, marine corps, and coast guard;

(b) A reserve component of the armed forces listed in paragraph (A)(1)(a) of this rule;

(c) The national guard, including the Ohio national guard or the national guard of any other state;

(d) The commissioned corps of the United States public health service;

(e) The merchant marine service during wartime;

(f) Such other service as may be designated by Congress; or

(g) The Ohio organized militia when engaged in full-time national guard duty for a period of more than thirty days.

(2) "Board" means the state medical board of Ohio.

(B) Eligibility for licensure

For the purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as a radiologist assistant.

(C) Renewal of an expired license

An expired license to practice as a radiologist assistant shall be renewed upon payment of the biennial renewal fee provided in section 4774.06 of the Revised Code and without a late fee or re-examination if the holder meets all of the following three requirements

(1) The licensee is not otherwise disqualified from renewal because of mental or physical disability;

(2) The licensee meets the requirements for renewal under section 4774.06 of the Revised Code;

(3) Either of the following situations applies:
(a) The license was not renewed because of the licensee's service in the armed forces, or

(b) The license was not renewed because the licensee's spouse served in the armed forces, and the service resulted in the licensee's absence from this state.

(4) The licensee or the licensee’s spouse, whichever is applicable, has presented satisfactory evidence of the service member’s discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.

(D) For purposes of sections 5903.12 and 5903.121 of the Revised Code, radiologist assistants are not required to report continuing education coursework to the board.
Application for a certificate to practice.

(A) An applicant for an initial certificate license to practice or renewal or restoration of a restored certificate license to practice as a radiologist assistant shall file an application under oath in the manner determined by the board provided in section 4774.03 of the Revised Code, and provide such other facts and materials as the board requires.

(B) No application shall be considered filed, and shall not be reviewed, until the non-refundable application fee of two hundred dollars has been received by the board. No application for an initial license to practice as a radiologist assistant, or for restoration of a license to practice as a radiologist assistant, submitted to the board shall be considered complete until the applicant has complied with the requirements of paragraph (A) of rule 4731-40-2 of the Administrative Code and the board has received the results of the criminal records checks.

(C) All application materials submitted to the board by applicants may be thoroughly investigated. The board may contact individuals, agencies, or organizations for recommendations or other information about applicants as the board deems necessary. Applicants may be requested to appear before the board or a representative thereof as part of the application process. The board reserves the right to thoroughly investigate all materials submitted as part of an application. The board may contact individuals, agencies, or organizations for recommendations or other information about applicants as the board deems necessary. Applicants may be requested to appear before the board or a representative thereof as part of the application process.

(D) An application shall be considered to be complete when all of the following requirements are met:

1. The application fee required pursuant to paragraph (B) of this rule has been received by the board;

2. The applicant has complied with the requirements of paragraph (A) of rule 4774-2-02 of the Administrative Code and the board has received the results of the criminal records checks and any other forms required to be submitted pursuant to paragraph (A) of rule 4774-2-02 of the Administrative Code;

3. Verification of the applicant’s current licensure as a radiographer has been received directly from the “Ohio Department of Health.”

4. Verification of the applicant’s current certification has been received by the board directly from the “American Registry of Radiologic Technologists.”

5. All information required by division (B) of section 4774.03 of the Revised Code, including such other facts and materials as the board requires, has been
received by the board; and

(6) The board is not conducting an investigation, pursuant to section 4774.14 of the Revised Code, of evidence appearing to show that the applicant has violated section 4774.13 of the Revised Code or applicable rules adopted by the board.

(E)(D) If the application is not complete within six months of the date the application is filed with the board because required information, facts, or other materials have not been received by the board, the board may notify the applicant by certified mail that it intends to consider the application abandoned if the application is not completed. If an applicant fails to complete the application process within six months of 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.

(1) The written notice shall:

(a) Specifically identify the information, facts, or other materials required to complete the application; and

(b) Inform the applicant that the information, facts, or other materials must be received by the deadline date specified; that if the application remains incomplete at the close of business on the deadline date the application may be deemed to be abandoned and no further review of the application will occur; and that if the application is abandoned the submitted fees shall neither be refundable or transferrable to a subsequent application.

(2) If all of the information, facts, or other materials are received by the board by the deadline date and the application is deemed to be complete, the board shall process the application and may require updated information as it deems necessary.

(E) If the application process extends for a period longer than six months, the board may require updated information as it deems necessary.

(F) No application being investigated under section 4774.13 of the Revised Code, may be withdrawn without approval of the board.

(G) Application fees are not refundable.
Renewal of a certificate to practice.

(A) Renewal, reinstatement, or restoration of a certificate to practice as a radiologist assistant shall be in the manner and according to the requirements of section 4774.06 of the Revised Code.

(1) An applicant for renewal, reinstatement, or restoration of a certificate to practice as a radiology assistant shall file an application under oath in the manner required by the board.

(2) An application for renewal, reinstatement, or restoration of a certificate to practice shall not be considered filed, and shall not be reviewed, until the board has received the nonrefundable renewal application fee of two hundred dollars.

(B) An application for renewal or reinstatement of a certificate to practice shall be considered complete upon the following:

(1) The board has received the renewal fee specified in paragraph (A) of this rule;

(2) For reinstatement, the monetary penalty required for reinstatement of a certificate to practice has been received by the board; and

(3) The board has received all information required by division (B) of section 4774.06 of the Revised Code.

(C) An application for restoration of a certificate to practice as a radiologist assistant shall be considered complete upon the following:

(1) The board has received the renewal fee specified in paragraph (A) of this rule;

(2) The monetary penalty required for restoration of a certificate to practice has been received by the board;

(3) The board has received all information required by division (B) of section 4774.06 of the Revised Code; and

(4) The applicant has complied with the requirements of paragraph (A) of rule 4774-2-02 of the Administrative Code and the board has received the results of the criminal records checks and any other forms required to be submitted pursuant to paragraph (A) of rule 4774-2-02 of the Administrative Code.

(D) To be considered as having appropriately filed an application for purposes of section 119.06 of the Revised Code, an applicant shall have filed, on or before January thirty first of the even numbered year in which the current certificate to practice will expire, a renewal application that is complete in accordance with the requirements of paragraph (B) of this rule.
4774-1-04  Miscellaneous provisions.

For purposes of Chapter 4774. of the Revised Code and rules promulgated there under:

(A) An adjudication hearing held pursuant to the provisions of Chapter 119. of the Revised Code shall be conducted in conformance with the provisions of Chapter 4731-13 of the Administrative Code.

(B) The provisions of Chapters 4731-13, 4731-14, 4731-15, 4731-16, 4731-17, 4731-19, 4731-26, and 4731-28 of the Administrative Code are applicable to the holder of a certificate to practice as a radiologist assistant issued pursuant to Chapter 4774. of the Revised Code, as though fully set forth in Chapter 4774-01 or 4774-02 of the Administrative Code.
Thank you for the email. Has informed consent been proposed?

The State Medical Board of Ohio seeks public input on proposed rules several times during the rule-making process. Public input is sought after the Medical Board has conducted its initial review of rules, after rules are filed with the Common Sense Initiative Office, and at the public hearing that occurs after the rules are formally filed with the Joint Committee on Agency Rule Review.

The Medical Board’s initial review of rules may result in a proposal to amend current rules, rescind current rules, make no changes to current rules, and/or adopt new rules. Comments received will be reviewed and possibly result in changes to the initially proposed language before the rules are then filed with the Common Sense Initiative Office.

At this time, public comment is being sought on the proposed language for the following rules.

- **Rule 4774-1-01**: Definitions (no changes proposed)
- **Rule 4774-1-02**: Application for a Certificate to Practice (Changes to align with licensure rules for other license types.)
- **Rule 4774-1-02.1**: Military Provisions Related to Certificate to Practice as a Radiologist Assistant (This rule is currently pending with CSI for rescission, as part of the rule package that consolidates all of the military rules into one chapter, 4731-36, OAC)
- **Rule 4774-1-03**: Renewal of a Certificate to Practice (Proposed to be rescinded. Most provisions are repetitive of the statute and have been consolidated into 4774-1-02, OAC)
- **Rule 4774-1-04**: Miscellaneous Provisions (No changes proposed)

Deadline for submitting comments: May 15, 2020

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

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

FROM:  Kimberly C. Anderson, Chief Legal Counsel

RE:  Personal Information System Rules

DATE:  May 29, 2020

On April 29, 2020, the Personal Information System rules were circulated to interested parties with a comment deadline of May 15, 2020. No comments were received.

The rules are being proposed as follows:

Rule 4731-8-01:  Personal Information Systems-No change
Rule 4731-8-02:  Definitions-No change
Rule 4731-8-03:  Procedures for Accessing Confidential Personal Information-No change
Rule 4731-8-04:  Valid Reasons for Accessing Confidential Personal Information-No change
Rule 4731-8-05:  Confidentiality Statutes-Amended to include additional confidentiality statutes
Rule 4731-8-06:  Restricting and Logging Access to Confidential Personal Information in Computerized Personal Information Systems-No change

Action Requested: Approve for filing with CSI.
Personal information systems.

(A) All personal information systems of the state medical board shall be maintained in accordance with Chapter 1347. of the Revised Code.

(B) The executive director of the state medical board shall designate one or more persons to be directly responsible for the personal information systems maintained by the state medical board;

(C) An employee who initiates or otherwise contributes to any disciplinary or other punitive action against any individual who brings to the attention of appropriate authorities, the press, or any member of the public, evidence of unauthorized use of information contained in the medical board's personal information systems shall be disciplined at the discretion of the executive director and in a manner which he or she deems appropriate.

(D) If personal information contained in the medical board's personal information systems is not accurate, relevant, timely, and complete, this fact shall be directed to the attention of the executive director's designee(s), who shall take such action as is deemed appropriate concerning the information system in order to assure fairness in any determination made with respect to the person on the basis of the information.

(E) The state medical board shall collect only personal information that is necessary and relevant to the functions that the board is required to perform by statute, ordinance, code, or rule. The executive director's designee(s) shall eliminate personal information from the system when it is determined that the information is no longer necessary and relevant to those functions.
Definitions.

For the purposes of administrative rules promulgated in accordance with section 1347.15 of the Revised Code, the following definitions apply:

(A) “Access” as a noun means an instance of copying, viewing, or otherwise perceiving whereas “access” as a verb means to copy, view, or otherwise perceive.

(B) “Acquisition of a new computer system” means the purchase of a "computer system," as defined in this rule, that is not a computer system currently in place nor one for which the acquisition process has been initiated as of the effective date of the board rule addressing requirements in section 1347.15 of the Revised Code.

(C) “Computer system” means a "system," as defined by section 1347.01 of the Revised Code, that stores, maintains, or retrieves personal information using electronic data processing equipment.

(D) “Confidential personal information” has the meaning as defined by division (A)(1) of section 1347.15 of the Revised Code and identified by rules promulgated by the board in accordance with division (B)(3) of section 1347.15 of the Revised Code that reference the federal or state statutes or administrative rules that make personal information maintained by the board confidential.

(E) “Employee” means each employee of the board regardless of whether he/she holds an elected or appointed office or position within the board. "Employee" is limited to the specific employing state agency.

(F) “Incidental contact” means contact with the information that is secondary or tangential to the primary purpose of the activity that resulted in the contact.

(G) “Individual” means a natural person or the natural person's authorized representative, legal counsel, legal custodian, or legal guardian.

(H) “Information owner” means the individual appointed in accordance with division (A) of section 1347.05 of the Revised Code to be directly responsible for a system.

(I) “Person” means a natural person.

(J) “Personal information” has the same meaning as defined in division (E) of section 1347.01 of the Revised Code.

(K) “Personal information system” means a "system" that "maintains" "personal information" as those terms are defined in section 1347.01 of the Revised Code.
"System" includes manual and computer systems.

(L) “Research” means a methodical investigation into a subject.

(M) “Routine” means commonplace, regular, habitual, or ordinary.

(N) “Routine information that is maintained for the purpose of internal office administration, the use of which would not adversely affect a person” as that phrase is used in division (F) of section 1347.01 of the Revised Code means personal information relating to employees and maintained by the board for internal administrative and human resource purposes.

(O) “System” has the same meaning as defined by division (F) of section 1347.01 of the Revised Code.

(P) “Upgrade” means a substantial redesign of an existing computer system for the purpose of providing a substantial amount of new application functionality, or application modifications that would involve substantial administrative or fiscal resources to implement, but would not include maintenance, minor updates and patches, or modifications that entail a limited addition of functionality due to changes in business or legal requirements.

(Q) “Board” means the “State Medical Board of Ohio.”

(R) “Secretary” means the member of the board who is elected under section 4731.02 of the Revised Code to serve as the secretary or a member of the board who is appointed by the board president to act on a temporary basis in lieu of the elected secretary.

(S) “Supervising Member” means the member of the board who is elected under section 4731.02 of the Revised Code to serve as supervising member or a member of the board appointed by the board president to act on a temporary basis in lieu of the elected supervising member.
4731-8-03  Procedures for accessing confidential personal information.

For personal information systems, whether manual or computer systems, that contain confidential personal information, the board shall do the following:

(A) Establish criteria for accessing confidential personal information. Personal information systems of the board are managed on a "need-to-know" basis whereby the information owner determines the level of access required for an employee of the board to fulfill his/her job duties. The determination of access to confidential personal information shall be approved by the employee's supervisor and the information owner prior to providing the employee with access to confidential personal information within a personal information system. The board shall establish procedures for determining a revision to an employee's access to confidential personal information upon a change to that employee's job duties including, but not limited to, transfer or termination. Whenever an employee's job duties no longer require access to confidential personal information in a personal information system, the employee's access to confidential personal information shall be removed.

(B) Respond to an individual's request for a list of confidential personal information. Upon the signed written request of any individual for a list of confidential personal information about the individual maintained by the board, the board shall do all of the following:

(1) Verify the identity of the individual by a method that provides safeguards commensurate with the risk associated with the confidential personal information;

(2) Provide to the individual the list of confidential personal information that does not relate to an investigation about the individual or is otherwise not excluded from the scope of Chapter 1347. of the Revised Code; and

(3) Inform the individual that the board has no confidential personal information about the individual that is responsive to the individual's request if all information maintained by the board relates to an investigation about that individual.

(C) Notify an individual whose confidential personal information maintained by the board is accessed for an invalid reason.

(1) Upon discovery or notification that confidential personal information of an individual has been accessed by an employee for an invalid reason, the board shall notify the individual whose information was invalidly accessed as soon as practical and to the extent known at the time. However, the board shall not
notify the individual if the information is possessed and maintained pursuant to division (F)(5) of section 4731.22 of the Revised Code.

(a) The board shall delay notification for a period of time necessary to ensure that the notification would not delay or impede an investigation of invalid access or jeopardize homeland or national security.

(b) The board may delay the notification consistent with any measures necessary to determine the scope of the invalid access, including which individuals' confidential personal information invalidly was accessed, and to restore the reasonable integrity of the manual or computer system that contains the confidential personal information that was invalidly accessed.

(2) Notification provided by the board shall inform the individual of the type of confidential personal information accessed and, if known, the date(s) of the invalid access.

(3) Notification may be made by any method reasonably designed to accurately inform the person of the invalid access, including written, electronic, or telephone notice.

(D) Appoint a data privacy point of contact. The executive director of the board shall designate an employee of the board to serve as the data privacy point of contact. The data privacy point of contact shall work with the chief privacy officer within the state of Ohio’s office of information technology to assist the board with both the implementation of privacy protections for the confidential personal information that the board maintains and compliance with section 1347.15 of the Revised Code and the rules adopted pursuant to the authority provided by that chapter.

(E) Complete a privacy impact assessment. The data privacy point of contact for the board shall timely complete the privacy impact assessment form developed by the office of information technology.
Valid reasons for accessing confidential person information.

Pursuant to the requirements of division (B)(2) of section 1347.15 of the Revised Code, this rule contains a list of valid reasons, directly related to the board’s exercise of its powers or duties, for which only employees of the board may access confidential personal information regardless of whether the personal information system is a manual system or computer system:

(A) Responding to a public records request;

(B) Responding to a request from an individual for the list of confidential personal information the board maintains on that individual;

(C) Administering a constitutional provision or duty;

(D) Administering a statutory provision or duty;

(E) Administering an administrative rule provision or duty;

(F) Complying with any state or federal program requirements;

(G) Processing or payment of invoices and other financial activities;

(H) Auditing purposes;

(I) Licensure, renewal, or verification of licensure processes;

(J) Investigation or law enforcement purposes;

(K) Administrative hearings or evidentiary review by a hearing examiner;

(L) Litigation, complying with an order of the court, or subpoena;

(M) Human resource matters (e.g., hiring, promotion, demotion, discharge, salary/compensation issues, leave requests/issues, time card approvals/issues, payroll, Federal Medical Leave Act issues, disability issues, employee assistance program issues);

(N) Complying with an executive order or policy;

(O) Complying with a board policy or resolution, or with a state administrative policy or
directive issued by the department of administrative services, the office of budget and management or other similar state board;

(P) Complying with a collective bargaining agreement provision;

(Q) Administering a board program;

(R) Facilitating operational efficiencies or responding to complaints about the board’s investigative, monitoring, or licensure processes; or

(S) Maintaining data systems or performing information technology responsibilities.
Confidentiality statutes.

With regard to confidential personal information maintained by the board, the following federal statutes or regulations or state statutes and administrative rules make the personal information confidential:

(A) Social security numbers of applicants, licensees, and board employees: 5 U.S.C. 552a., unless the individual was told that the number would be disclosed.

(B) "Bureau of Criminal Investigation and Information" criminal records check results: section 4776.04 of the Revised Code.

(C) Complaints, the names of complainants and patients, and information received in an investigation, including any medical records of the subject of the complaint: division (F) of section 4730.26, division (F) of section 4731.22, division (E) of section 4760.14, division (E) of section 4762.14, and division (E) of section 4774.14 of the Revised Code.

(D) Medical malpractice payouts reported by a professional liability insurer: division (F) of section 4730.32, division (F) of section 4731.224, division (F) of section 4760.16, division (F) of section 4762.16, and division (F) of section 4774.16 of the Revised Code.

(E) Formal disciplinary action reported by a health care facility: division (F) of section 4730.32, division (F) of section 4731.224, division (F) of section 4760.16, division (F) of section 4762.16, and division (F) of section 4774.16 of the Revised Code.

(F) A belief that a violation of law has occurred when reported by a licensee or professional society of licensees: division (F) of section 4730.32, division (F) of section 4731.224, division (F) of section 4760.16, division (F) of section 4762.16, and division (F) of section 4774.16 of the Revised Code.


(H) Employee assistance program records: section 124.88 of the Revised Code.


(K) “National Practitioner Data Bank” and “Healthcare and Integrity Protection Data Bank” reports: 45 CFR Part 60.

(L) Residential and familial information for covered licensees: sections 149.43(A)(1)(p), 149.43(A)(7), and 149.43(A)(8) of the Revised Code.
4731-8-06

Restricting and logging access to confidential personal information in computerized personal information systems.

For personal information systems that are computer systems and contain confidential personal information, the board shall do the following:

(A) Access restrictions. Access to confidential personal information that is kept electronically shall require a password or other authentication measure.

(B) Acquisition of a new computer system. When the board acquires a new computer system that stores, manages or contains confidential personal information, the board shall include a mechanism for recording specific access by employees of the board to confidential personal information in the system.

(C) Upgrading existing computer systems. When the board makes an upgrade to a computer system, as that term is defined in rule 4731-8-02 of the Administrative Code, to an existing computer system that stores, manages or contains confidential personal information, the upgrade shall include a mechanism for recording specific access by employees of the board to confidential personal information in the system.

(D) Logging requirements regarding confidential personal information in existing computer systems.

(1) Employees who access confidential personal information within computer systems shall maintain a log that records that access.

(2) Access to confidential information is not required to be entered into a log under the following circumstances:

(a) The employee is accessing confidential personal information for official board purposes, including research, and the access is not specifically directed toward a specifically named individual or a group of specifically named individuals.

(b) The employee is accessing confidential personal information for routine office procedures and the access is not specifically directed toward a specifically named individual or a group of specifically named individuals.

(c) The employee comes into incidental contact with confidential personal information and the access of the information is not specifically directed toward a specifically named individual or a group of specifically named individuals.
(d) The employee accesses confidential personal information about an individual based upon a request made under either of the following circumstances:

(i) The individual requests confidential personal information about himself/herself; or

(ii) The individual makes a request that the board take some action on that individual's behalf and accessing the confidential personal information is required in order to consider or process that request.

(E) Log management. The board shall issue a policy that specifies the following:

(1) The form or forms for logging;

(2) Who shall maintain the logs;

(3) What information shall be captured in the logs;

(4) How the logs are to be stored; and

(5) How long information kept in the logs is to be retained.

(F) Nothing in this rule limits the board from requiring logging in any circumstance that it deems necessary.
MEMORANDUM

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

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

DATE: May 29, 2020

RE: Dietetics rules on Continuing Education (4759-4-04) and Limited Permit (4759-4-08)

Proposed dietetics rules on Continuing Education (4759-4-04) and Limited Permit (4759-4-08) were sent for initial circulation and reviewed by the Dietetics Advisory Council.

Proposed amended rule 4759-4-04 Continuing Education

The rule seeks to improve the efficiency of the continuing education process for dietitians applying for license renewal or restoration by doing four things:

● Registered dietitians (“RDs”) must certify completion of the continuing education required to hold current registration with the Commission on Dietetic Registration. This is consistent with a recent statutory change for the Physician Assistant continuing education.

● Licensed dietitians who are not registered must certify completion of 30 hours of continuing education completed during every 2-year renewal period. These continuing education hours shall be from courses approved by the Commission on Dietetic Registration (“CDR”), Academy of Nutrition and Dietetics (“AND”), or the Ohio Academy of Nutrition and Dietetics (“OAND”). This means that the Licensure Committee and the full Medical Board will no longer be collecting and approving coursework for individual learning plans.

● All licensed dietitians (including RDs) must also complete one hour of ethics, laws, rules, and regulations governing the practice of dietetics for each 2-year renewal period. These continuing education hours shall be from courses approved by the CDR, AND, or the OAND. So, Medical Board staff will no longer be generating content for a Jurisprudence course and the Licensure Committee and full Board will no longer be reviewing and approving Jurisprudence courses. Further, RDs can use these ethics courses to meet their requirements with CDR and the Medical Board.

● Adds a provision informing all licensees that they are subject to the new statutory audit and disciplinary provisions of R.C. 4759.06 (E) and (F).

Proposed amended rule 4759-4-08 Limited Permit

This proposed rule strengthens the supervision of limited permit holders that have failed the CDR exam once. Also, it lays out the licensed dietitian’s responsibility to properly supervise these limited
permit holders and document that supervision. Failure to do so shall constitute a minimal standards of care violation by the licensed dietitian. Lastly, changes to the length of the term of the limited permit and number of renewals reflect that the CDR exam is administered much more frequently than twice a year.

**Initial Circulation Comments and Review by Dietetics Advisory Council**

Medical Board staff posted these proposed rules on the Medical Board website and circulated the rules to interested parties and all dietetics licensees by email. The Medical Board received a total of fifteen (15) written comments during the initial circulation comment period.

Four of the comments agreed with the proposed rules as drafted. An additional four comments asked questions or made comments not directly related to the text of the proposed rules.

Specific to proposed rule 4759-4-04, four comments perceived the proposed rule to be requiring increased ethics course work particularly to RDs. However, all dietitians licensed in Ohio are currently required to complete one hour of Jurisprudence per renewal period. The proposed changes substitute the one hour of ethics or laws, rules and regulations governing the practice of dietetics for the current one hour of Jurisprudence requirement. This allows a wider variety of courses that just need to have been approved by CDR, AND, and OAND. There is nothing in the proposed rule that prevents a RD from using a course in ethics or laws, rules, and regulations to meet CDR requirements as well as this Ohio licensure requirement. No changes resulted from this comment.

One comment mistakenly interpreted the rule to require RDs to have to report thirty hours every two-year renewal period rather than the rule’s requirement to certify completion of the continuing education required to hold current registration with CDR. No changes resulted from this comment.

The Ohio Academy of Nutrition and Dietetics (“OAND”) expressed concern that the proposed continuing education rule that no longer requires non-RD licensees to submit a 5-year individualized learning plan will no longer be as rigorous and is inconsistent with option offered by CDR. The comment further states, “[t]he inconsistency in process and requirements between non-RD licensees and RDs may entice RDs who dislike the PDP process to abandon the RD credential and opt to only maintain their license to practice in Ohio. If this occurs, it may result in growth of this previously dwindling small group of non-RD licensees and have negative effects upon CDR, The Academy, and the continued competence and career development of licensees.” The proposed rule requiring non-RD licensees to complete 30 hours of continuing education every two years from courses approved by CDR, AND, and OAND is consistent with the continuing education requirements adopted by CDR. Like RDs, the non-RD licensees must take 75 hours over a 5-year period from CDR and AND approved coursework. No change resulted from this comment.

OAND had additional concerns about the clarity of the language in the rule. Among the edits suggested is substitution of the term “activities” for “courses” to more accurately reflect the range of options offered by CDR, AND, and OAND. This change was also recommended by the Dietetics Advisory Council, and this change was made to the proposed rule.

OAND suggested additional language that non-licensese keep records of their continuing education hours on a form provided by the Board so that these non-RD licensees can keep accurate records of continuing education in a format that board staff will need to audit the information. The Dietetics Advisory Council discussed this suggested edit extensively and ultimately recommended that the following language should be added to the rule: “records of completion of activities shall be retained by the licensee.” This change was made to the proposed rule.
In addition, as to 4759-4-08, OAND suggested that the phrase “goals for competencies” in paragraph (G)(1) is confusing as to what kind of competencies. OAND’s suggested language of “specific goals and strategies for assuring competent entry level practice” was incorporated into the proposed rule.

Another commenter thought that the proposed rule placed too much of a burden on RDs to supervise limited permit holders to this extent and would discourage RDs from undertaking this duty. This level of supervision is necessary to provide meaningful supervision that protects the public and was developed with input from the Dietetics Advisory Council.

The Dietetics Advisory Council recommended that the Medical Board approve the filing of proposed rules 4759-4-04 and 4759-4-08 with CSI with the two proposed changes as described above.

**Conclusion**

Several changes have been made to the rule as described above based on written comments received in initial circulation as well as from recommendations by the Dietetics Advisory Council. These changes are in bold type in the proposed rules attached. In addition, a spreadsheet of the comments and a copy of each comment are also included for the Policy Committee to review.

**Action Requested:** Approve proposed rules 4759-4-04 and 4759-4-08 with the changes described for filing with CSI.
4759-4-04 Continuing education.

(A) Each applicant for renewal or restoration of a license shall demonstrate compliance with the continuing education/professional development requirements of this rule.

(B) Each applicant for license renewal or restoration shall:

1. If licensee is a registered dietitian, certify completion of the continuing education required to hold current registration with the commission on dietetic registration, and complete one hour of ethics or laws, rules, and regulations governing the practice of dietetics in the two-year renewal period. These continuing education hours shall be from activities approved by the commission on dietetic registration, academy of nutrition and dietetics, or the Ohio academy of nutrition and dietetics; or

2. If licensee is not a registered dietitian, establish a five year continuing education cycle with the board, and adhere to that schedule for meeting requirements consistent with the options offered by "The commission on dietetic registration," certify the completion of thirty hours of continuing education completed during the two-year renewal period. At least one hour in each renewal period shall relate to ethics or laws, rules, and regulations governing the practice of dietetics. These continuing education hours shall be from activities approved by the commission on dietetic registration, academy of nutrition and dietetics, or the Ohio academy of nutrition and dietetics.

For each five year cycle an individual learning plan shall be submitted and approved by the board and a log of learning activities maintained by the licensee. A copy of the log shall be submitted directly to the Ohio board of dietetics postmarked by June thirtieth of the year that the cycle ends, and shall demonstrate successful completion of at least seventy-five continuing professional education units.

(C) Beginning in two thousand five, on odd numbered calendar years, each applicant for renewal, reactivation, or reinstatement of a license shall report to the board completion of at least one continuing education unit of board approved education in jurisprudence.

Board approved programs in jurisprudence shall include approved programs and activities relating to current laws, rules, and regulations dealing with the practice of dietetics and recent changes that have occurred to those laws, rules, and regulations. A list of approved programs and activities will be posted on the board's web site.

(C) All licensees are subject to the audit and disciplinary provisions of divisions (E) and (F) of section 4759.06 of the Revised Code for failure to comply with this rule. Licensees are responsible for retaining records of completion of the continuing education hours required.
4759-4-08 Limited permit.

(A) The board may grant a limited permit to a person who has completed the education and preprofessional requirements for licensure upon the following conditions:

(1) The person has filed a completed application for a limited permit and paid the appropriate fee;

(2) The application contains any required statements or transcripts verifying completion of the academic and preprofessional requirements in order to qualify to take the examination for licensure; and

(3) The applicant indicates intent to take the examination for licensure within seven six months of the issuance of the limited permit.

(B) The permit shall expire if the permit holder fails to take the examination in a timely manner or fails the examination twice.

(C) Limited permits shall expire six months after the date of issuance. The following October thirty-first for those issued between April first and September thirtieth and the following April thirtieth for those issued between October first and March thirty-first.

(D) A limited permit may be renewed once.

(E) A limited permit holder who fails the examination must report the results to the board office immediately.

(1) The first time the limited permit holder fails, the limited permit holder shall practice only under the direct supervision of an Ohio licensed dietitian as approved by the board.

(2) The second time the limited permit holder fails, the limited permit expires immediately.

(F) A limited permit shall not be issued to a person who has failed the examination two or more times.

(G) The licensed dietitian who provides direct supervision of a person who has failed the examination and holds a limited permit shall provide sufficient guidance and direction to enable the person to perform competently and to protect the public.

(1) The licensed dietitian shall document a supervision plan for the limited permit holder to include specific goals and strategies for assuring competent entry level practice. The supervising dietitian shall periodically document the limited permit holder’s progress. Documentation shall include, but is not limited to, dates of conferences, supervisory notes, written evaluations and recommendations. Documentation should be maintained in the licensed dietitian’s records and be available upon request of the board.

(2) Direct supervision means that the licensee providing the supervision needs to be readily available by telecommunication, or in person and the licensee must review the work of the supervisee at least every fourteen seven days. When reviewing the work of a supervisee, the licensee shall comply with standards for professional responsibility and practice set forth in Chapter 4759-6 of the Administrative Code.
(H) It is the licensed dietitian’s responsibility to supervise the limited permit holder and to adequately document that supervision. Failure to do so shall be considered a violation of the minimal standards of care for the licensed dietitian and may result in discipline of the licensed dietitian by the state medical board.
Ms. Assenheimer,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
med.ohio.gov

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-----Original Message-----
From: Tracy Lynn<hobbins.4@gmail.com>
Sent: Monday, August 26, 2019 7:54 AM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: Proposed Rule

Good morning Mr. Smith,

I read through the proposed changes. The language and adjustments are acceptable.

Thank you,

Tracy Assenheimer RD, CSG, LD
Registered Dietitian
Presidential Post Acute
Dining and Nutrition Services
Mr. Burkholder,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
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-----Original Message-----
From: Derek Burkholder <derek.burkholder@yahoo.com>
Sent: Monday, August 26, 2019 7:55 AM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: Comments on proposed rule change

In regards to rule changes for limited permit dietitians I fell there is too much burden placed on the registered dietitians who would guide them. So much regulatory burden that in practice no RD would want a limited permit dietitian under them.

I think a rule change to make it easier for those that fail the exam to work as dietetic technicians in the meanwhile would be of more benefit to the profession and the public.
Ms. Burton,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

If you are a registered dietitian, paragraph (B)(1) of the proposed rule 4759-4-04 would be applicable to you. This proposed rule states that an applicant for license renewal or restoration who is a registered dietitian shall:

“certify completion of the continuing education required to hold current registration with the commission on dietetic registration, and complete one hour of ethics or laws, rules, and regulations governing the practice of dietetics in the two-year renewal period. These continuing education hours shall be from courses approved by the commission on dietetic registration, academy of nutrition and dietetics, or the Ohio academy of nutrition and dietetics.”

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
med.ohio.gov

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Hello Nathan,

I am writing you in regards to the proposed rule 4759-4-04 regarding registered dietitians and their continuing education requirements. I am strongly against this proposed rule. Our current certification cycle allows us working dietitians time to reflect on our next 5 years of practice and allows us to then make choices for our continuing education that will aid in achieving our 5 year goals. 75 CEU’s in 5 years would be equivalent to 30 every 2, however, often we attend conferences at certain times of the year which may account for well over the 30 hours, but then upon the next certification cycle it may be hard to get the 30 depending upon conference and seminar schedules.

Thank you for your time,

Raenette Burton, RDN, LDN
Regional Dietitian- OH South
HCF Management Inc.
1100 Shawnee Rd
Lima, Ohio 45805
Raenette.burton@hcfmanagement.com
(cell) 419-302-4583
www.hcfinc.com

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Thank You.
Ms. Chapman,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

As a point of clarification, registered dietitians licensed in Ohio are currently required to complete one hour of Jurisprudence per renewal period. The proposed changes substitute the one hour of ethics or laws, rules and regulations governing the practice of dietetics for the current one hour of Jurisprudence requirement.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
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I am writing to comment on the aspect of the Proposed Dietitians Rule change below. Per the Commission on Dietetic Registration Dietitians are required to have 1 ceu per 5 year period. I would suggest the requirement of the Medical Board of the State of Ohio to align with the CDR rules and Dietitians be required to complete one hour of an ethics course every other 2 year period.

● All licensed dietitians (including those registered) must also complete one hour of ethics, laws, rules, and regulations governing the practice of dietetics for each 2-year renewal period. These
continuing education hours shall be from courses approved by the Commission on Dietetic Registration, Academy of Nutrition and Dietetics, or the Ohio Academy of Nutrition and Dietetics. This means that the Medical Board staff will no longer be generating content for a Jurisprudence course and the Licensure Committee and full Board will no longer be reviewing and approving Jurisprudence courses. Further, registered dietitians can use these ethics courses to meet their requirements with CDR and the Medical Board.

Thank You,
Nancy Chapman RDN,LD
Ms. Cook,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
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PROPOSED RULES: Seeking comments on the Medical Board’s initial review of proposed Dietetics rules for continuing education and limited permits

The State Medical Board of Ohio seeks public input on proposed rules several times during the rule-making process. Public input is sought after the Medical Board has conducted its initial review of rules, after rules are filed with the Common Sense Initiative Office, and at the public hearing that occurs after the rules are formally filed with the Joint Committee on Agency Rule Review.

The Medical Board’s initial review of rules may result in a proposal to amend current rules, rescind current rules, make no changes to current rules, and/or adopt new rules. Comments received will be reviewed and possibly result in changes to the initially proposed language before the rules are then filed with the Common Sense Initiative Office.

At this time, public comment is being sought on the proposed language for these proposed rules, which can be found on the Medical Board’s website using the button below.

Deadline for submitting comments: September 13, 2019

Comments to: Nathan Smith, Senior Legal & Policy Counsel
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Click here to read the rules
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This message was sent to jmcook97@yahoo.com by contact@med.ohio.gov
30 East Broad Street, 3rd Floor, Columbus, Ohio 43215

Unsubscribe | Manage Subscription | Forward Email | Report Abuse
Ms. Finney,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH  43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
med.ohio.gov

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From: Julie Finney <julie.finney77@gmail.com>
Sent: Wednesday, August 28, 2019 8:31 AM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: Proposed Changes to Ohio Dietetics Rules

I am in support of the proposed changes to the ethics education requirement. The Ohio-specific learning activity has generated confusion among some practitioners and they are often surprised to learn that an ethics learning activity that counts for the Commission on Dietetic Registration hasn’t been approved for the renewal of their Ohio license. While I have already completed the Ohio Board’s ethics training, I have also completed my CDR ethics training and there are multiple options offered by CDR that are applicable in various practice settings.

I am also in support of the second proposed change that requires individuals with limited permits that have previously not passed the RD exam to be supervised by a Licensed Dietitian. In my most recent hiring experiences, I have found that new grads are waiting to apply for employment until they have passed their RD exam and can then apply for the Ohio License as well but if someone is employed under a limited permit, it is reasonable to expect that their work will be monitored by a Licensed Dietitian.
Ms. Haffke,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith  
Senior Legal & Policy Counsel  
State Medical Board of Ohio  
30 East Broad St., 3rd Floor  
Columbus, OH 43215  
(614) 466-4341  
Nathan.Smith@med.ohio.gov  
med.ohio.gov

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From: Lindsey Haffke <haffkelm@gmail.com>  
Sent: Monday, August 26, 2019 12:52 PM  
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>  
Subject: Dietetics Amendment

Nathan,

I disagree with the ethics, law, and regulation amendment that states a course needs to be completed every 2 years.

The Academy of Nutrition and Dietetics and CDR requires 1 ethics course every 5 years. I recommend this same rule be implemented with the state of Ohio or no course at all since dietitians are already fulfilling the national requirements.

If the amendment passes as is currently written, I would request the Jurisprudence course be available to dietitians to meet this stringent requirement.

Thank you,  
Lindsey Haffke
Ms. Kraeutle,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

As a point of clarification, these are still just proposed rules. The proposed rules must go through a multi-step rulemaking process in which they could be amended or changed along the way.

The current rule still requires 1 hour of jurisprudence.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
med.ohio.gov

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Thanks!

The Ethics of Hunger
This webinar is pre-approved by the CDR for 1 ethics credit.

Hunger is an ethical issue first — it isn't just a philanthropic or moral issue. Bringing assumptions and perceptions about a person's access to healthy food hurts our clients' health. If we don't ask the right questions about food insecurity we inadvertently encourage the stigma associated with food assistance; we contribute to the increase in 10 major chronic diseases and exacerbate existing chronic disease; and we perpetuate the cycle of poor food access.

In the second of this two-part series, Clancy Cash Harrison, MS, RDN, FAND, will bridge the knowledge gap between the overall health of our clients and food insecurity. She will dive deep into the ethics of the food insecurity epidemic, focusing on the symptoms, risk factors, and the costs of allowing food insecurity to go untreated. Clancy will also discuss the important dynamic of patient care, sharing coping mechanisms, all-important techniques to screen patients with sensitivity, and how to use patient-centered language to reduce the stigma of food insecurity.

Learning Objectives
1. Explain the ethics of food insecurity as it relates to personal beliefs and the specialized role of nutrition and dietetics professionals.
2. Distinguish individuals at risk for malnutrition related to food insecurity and explain the ethics behind nutrition education.
3. Learn, understand and apply ethics when screening for food insecurity.
4. List resources to improve food access and health outcomes.

1 CEU FREE  Suggested CDR Learning Needs Codes: 1050, 1070, 4070, 6080
Performance Indicators: 1.1.1, 1.1.8, 3.3.2, 7.2.3
Level: 2

Megan Kraeutle RDN, LD
Clinical Dietitian
Good Samaritan Hospital
Phone: 862-3380

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Ms. Youngpeter,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
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From: Bethany Muniak <bnlmuniak@gmail.com>
Sent: Tuesday, August 27, 2019 10:06 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: Dietetics rules for continuing education and limited permits

I am a dietitian and reviewed: Dietetics rules for continuing education and limited permits. I am commenting that I am in favor of the new language!!!

Bethany Muniak RDN, LD
Ms. Mavko,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH  43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
med.ohio.gov

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Nate,

I goofed up ! I just found my comments that I thought I had sent to you on 9/18 in my drafts box on my computer (they were due 9/13) and I don’t think they got sent out to you.

As you may recall, I broke my left arm and badly sprained my right wrist and was typing one finger at a time.  I requested a little extension to send the comments in when we spoke, but I did not intend to be this late.  I am sorry.

I hope that they are not too late and respectfully request your consideration of their content.

Kay Mavko
The Ohio Academy of Nutrition and Dietetics appreciates the opportunity to review the draft rules 4759-4-04 OAC and 4759-08 OAC and would like to offer the following comments and concerns for your consideration.

4759-4-04 Continuing education.

1. Although the summary page of the draft rule 4759-4-04 expressed intent that dietitians can use the required law related continuing education to meet their requirements with CDR the proposed language in paragraphs (B)(1) and (2) is confusing. It appears that RDs must complete their 75 hours in five years of ce’s to maintain registration “and” an additional 1 hour in ethics, law continuing education in order to meet their biennial license renewal requirements. While the non-RD licensees now can clearly include the ethics, law ce’s in the 30 hours that they are certifying to the board.

2. Non-RD dietitians in Ohio have always been held to the same rigorous standards for continuing education as the RD licensees. The proposed amendments in this rule no longer require that Non-RD licensees complete continuing education “in a manner consistent with the options offered by CDR”. Non-RD licensees appear to now be simply reporting completion of CDR and Academy approved continuing education programs but are not required to engage in the Professional Portfolio Process required of RD licensees – which requires self-reflection, learning needs assessment in the development of learning plans based on competencies, and performance indicators and evaluation of meeting individual learning needs.

3. The inconsistency in process and requirements between non-RD licensees and RDs may entice RDs who dislike the PDP process to abandon the RD credential and opt to only maintain their license to practice in Ohio. If this occurs, it may result in growth of this previously dwindling small group of non-RD licensees and have negative effects upon CDR, The Academy, and the continued competence and career development of licensees.

   We recommend that the rule include a statement in 4759-4-04 (B)(2) that instructs non-RD licensees to continue to record their hours on a form provided by the board (in a standardized format – contents of which is developed by the board). This would encourage licensees to at least keep accurate records of continuing education in a format that board staff will need to audit the information.

4. Licensees are informed in paragraph 4759-4-04(C) that they are subject to audit and disciplinary provisions of recently amended in 4759.06 ORC. But no mention is made of the civil penalties specified in that section – including fines of up to $5,000!! for failure to comply with continuing education requirements. Licensees under the old OBD were not subject to civil penalties (fines) for failure to comply with continuing education. OAND strongly suggests that 4759-4-04 (C) include language that a civil penalty (fine) may also be imposed by the board.

The OAND recommends that the proposed rule 4759-4-04 be amended as follows. Proposed changes are in red.
In consideration of the previous comments and concerns OAND suggests the following changes to Draft 4759-4-04 Continuing education.

(A) Each applicant for renewal or restoration shall demonstrate compliance with the continuing education/professional development requirements of this rule.

(B) Each applicant for license renewal or restoration shall:

1. Be if licensee is a registered dietitian, certify completion of the continuing education required to hold current registration with the commission on dietetic registration, and complete including at least one hour of related to ethics or laws, rules, and regulations governing the practice of dietetics completed during the two-year license renewal period. These continuing education hours shall be from courses activities approved by the commission on dietetic registration, academy of nutrition and dietetics, or the Ohio academy of nutrition and dietetics; or

2. If licensee is not a registered dietitian, establish a five year continuing education cycle with the board, and adhere to that schedule for meeting requirements consistent with the options offered by "The commission on dietetic registration." certify the completion of thirty hours of continuing education completed during the two-year license renewal period—including A at least one hour in each renewal period shall related to ethics or laws, rules, and regulations governing the practice of dietetics. These continuing education hours shall be from courses activities approved by the commission on dietetic registration, academy of nutrition and dietetics, or the Ohio academy of nutrition and dietetics and shall be recorded on forms provided by the board on its website.

For each five year cycle an individual learning plan shall be submitted and approved by the board and a log of learning activities maintained by the licensee. A copy of the log shall be submitted directly to the Ohio board of dietetics postmarked by June thirty of the year that the cycle ends, and shall demonstrate successful completion of at least seventy-five continuing professional education units.

(C) Beginning in two thousand-five, on odd numbered calendar years, each applicant for renewal, reactivation, or reinstatement of a license shall report to the board completion of at least one continuing education unit of board approved education in jurisprudence.

Board approved programs in jurisprudence shall include approved programs and activities relating to current laws, rules, and regulations dealing with the practice of dietetics and recent changes that have occurred to those laws, rules, and regulations. A list of approved programs and activities will be posted on the board's web site.

(C) All licensees are subject to the audit, and disciplinary and civil penalty provisions of divisions (E) and (F) of section 4759.06 of the Revised Code for failure to comply with this rule.
4759-4-08 Limited permit.

1. OAND recommends that the board add language at 4759-4-08 (G) (1) suggesting that the supervising dietitian first assess (evaluate) the performance of the limited permit holder who has failed the examination in order to identify any deficiencies prior to developing and documenting a plan for supervision.

2. The phrase “goals for competencies” is confusing in 4759-4-08(G)(1). If the intent is to reference the Essential Practice Competencies developed by CDR for its continuing competence program, or Entry-Level competencies which focus on preparation and evaluation for minimum competence upon completion of an ACEND education program then a specific reference should be included. Additionally, employers may also have job related competencies that are based on the focused area of employment.

OAND suggests that the language be changed to permit the supervision plan to be develop in a more general manner, and that it would include specific goals and strategies to assure competent practice by the LP holder who has failed the exam. We suggest letting the supervising licensed dietitian choose a relevant method to evaluate performance from among all resources and performance standards available to them. (and so that the board does not have to update a specified reference that would be included in this rule)

In consideration of the previous comments and concerns OAND suggests the following changes to Draft 4759-4-08 Limited permit.

(A) The board may grant a limited permit to a person who has completed the education and preprofessional requirements for licensure upon the following conditions:

(1) The person has filed a completed application for a limited permit and paid the appropriate fee;

(2) The application contains any required statements or transcripts verifying completion of the academic and preprofessional requirements in order to qualify to take the examination for licensure; and

(3) The applicant indicates intent to take the examination for licensure within seven six months of the issuance of the limited permit.

(B) The permit shall expire if the permit holder fails to take the examination in a timely manner or fails the examination twice.

(C) Limited permits shall expire six months after the date of issuance, the following October thirty-first for those issued between April first and September thirtieth and the following April thirtieth for those issued between October first and March thirty-first.

(D) A limited permit may be renewed once.

(E) A limited permit holder who fails the examination must report the results to the board office immediately.
(1) The first time the limited permit holder fails, the limited permit holder shall practice only under the direct supervision of an Ohio licensed dietitian as approved by the board.

(2) The second time the limited permit holder fails, the limited permit expires immediately.

(F) A limited permit shall not be issued to a person who has failed the examination two or more times.

(G) The licensed dietitian who provides direct supervision of a person who has failed the examination and holds a limited permit shall provide sufficient guidance and direction to enable the person to perform competently and to protect the public.

(1) The licensed dietitian shall initially assess the performance of the limited permit holder then develop and document a supervision plan for the limited permit holder that is based on any deficiencies identified and includes specific goals and strategies for assuring competencies in entry-level practice. The supervising dietitian shall periodically document the limited permit holder’s progress. Documentation shall include, but is not limited to, dates of conferences, supervisory notes, written evaluations and recommendations. Documentation should be maintained in the licensed dietitian’s records and be available upon request of the board.

(2) Direct supervision means that the licensee providing the supervision needs to be readily available by telecommunication, or in person and the licensee must review the work of the supervisee at least every fourteen seven days. When reviewing the work of a supervisee, the licensee shall comply with standards for professional practice set forth in Chapter 4759-6 of the Administrative Code.

(H) It is the licensed dietitian’s responsibility to supervise the limited permit holder and to adequately document that supervision. Failure to do so shall be considered a violation of the minimal standards of care for the licensed dietitian and may result in discipline of the licensed dietitian by the state medical board.
From: Smith, Nathan
Sent: Thursday, August 29, 2019 5:12 PM
To: Peschiera, Claudia <Claudia.Peschiera@chs.trihealth.com>
Subject: RE: Comments

Ms. Peschiera,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

As a point of clarification, registered dietitians licensed in Ohio are currently required to complete one hour of Jurisprudence per renewal period. The proposed changes substitute the one hour of ethics or laws, rules and regulations governing the practice of dietetics for the current one hour of Jurisprudence requirement for each licensure renewal period.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
med.ohio.gov

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From: Peschiera, Claudia <Claudia.Peschiera@chs.trihealth.com>
Sent: Thursday, August 29, 2019 4:53 PM
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>
Subject: Comments

I disagree with the ethics, law, and regulation amendment that states a course needs to be completed every 2 years.
The Academy of Nutrition and Dietetics and CDR requires 1 ethics course every 5 years. I recommend this same rule be implemented with the state of Ohio or no course at all since dietitians are already fulfilling the national requirements.
If the amendment passes as is currently written, I would request the Jurisprudence course be
available to dietitians to meet this stringent requirement.

Claudia Peschiera MS, RD, LD, CNSC
Nutrition Support Dietitian
9961 Cincinnati Dayton Road, West Chester, OH 45069
Phone - 513 942-3670 / Fax – 513- 942- 2846
Claudia.peschiera@chs.trihealth.com

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Ms. Swinehart-Alspach,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith
Senior Legal & Policy Counsel
State Medical Board of Ohio
30 East Broad St., 3rd Floor
Columbus, OH 43215
(614) 466-4341
Nathan.Smith@med.ohio.gov
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For continuing education and limited permits.

Hello,

I agree to continue on the “odd” years the Dietetics Rules for continuing education (1 CEU) of jurisprudence to be continued for licensed Dietitians in Ohio, within a 2-yr renewal basis.

This procedure was practiced in the past for Dietitians’ Licensure renewals during the “odd” years, (when Licensing renewal was on a yearly basis.)

I have no comments regarding limited permits at this time.
Thank you for your time.

Regards,
Jeanne
LD 2947, Ohio

Jeanne Swinehart-Alspach, MS RDN LD
Dietary Administrator
Central Office

Ohio
Department of Youth Services

4545 Fisher Road, “Suite D”
Columbus, Ohio 43228
Office: 1-614-995-9913
Ms. Turnwald,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

As a point of clarification, dietitians licensed in Ohio are currently required to complete one hour of Jurisprudence per renewal period. The proposed changes substitute the one hour of ethics or laws, rules and regulations governing the practice of dietetics for the current one hour of Jurisprudence requirement. This allows a wider variety of courses that just need to have been approved by one of the three organizations listed in the proposed rule. Paragraph (B)(2) of proposed rule 4759-4-04 identifies these organizations as the Academy of Nutrition and Dietetics, the Commission on Dietetics Registration, and the Ohio Academy of Nutrition and Dietetics. There is nothing in the proposed rule that prevents a registered dietitian from using a course in ethics or laws, rules, and regulations to meet CDR requirements as well as this Ohio licensure requirement.

Sincerely,

Nathan T. Smith  
Senior Legal & Policy Counsel  
State Medical Board of Ohio  
30 East Broad St., 3rd Floor  
Columbus, OH 43215  
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Nathan.Smith@med.ohio.gov  
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for the course?

Thank you,
Ann Turnwald, RD/LD
Ms. Wachaya,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

To answer your questions:

1. If you are a registered dietitian licensed in Ohio who is seeking license renewal you simply have to certify completion of the continuing education required to hold current registration with CDR. This means that you are stating on the application that you have completed the hours. It does not require the submission of additional documents unless you are audited.

2. Registered dietitians licensed in Ohio are currently required to complete one hour of Jurisprudence per renewal period. The proposed changes substitute the one hour of ethics or laws, rules and regulations governing the practice of dietetics for the current one hour of Jurisprudence requirement. This allows a wider variety of courses that just need to have been approved by one of the three organizations listed in the proposed rule.

3. Divisions E and F of R.C. 4759.06 allow the Board to conduct a random sample of licensed dietitians to audit to see if they have completed their continuing education. If the Board finds through the audit that the continuing education has not been completed, the statute further specifies disciplinary options for this failure to complete the continuing education. The Board could take discipline against the individual under R.C. 4759.07, impose a civil penalty, or both; or permit the individual to agree in writing to complete the continuing education and pay a civil penalty.

Sincerely,

Nathan T. Smith  
Senior Legal & Policy Counsel  
State Medical Board of Ohio  
30 East Broad St., 3rd Floor  
Columbus, OH 43215  
(614) 466-4341  
Nathan.Smith@med.ohio.gov  
med.ohio.gov

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Good morning, Nathan,

I have a couple of questions about this information.

1. When it says, "Registered dietitians must certify completion of the continuing education required to hold current registration with the Commission on Dietetic Registration" does it mean we will provide the proof of completion for each 5 year renewal rather than just submitting a log as we do now?

2. In the part about ethics, laws, rules, and regulations, which I believe we currently complete, is the change merely that the provider is restricted to those specifically named?

3. A link to the new statutory audit information would have been helpful. Can you tell me more about it please? Is the audit only for failure to comply?

Thanks very much,

Jane Wachaya, RD, LD

-----------------------------------------

From: "State Medical Board of Ohio"
To: mwachaya@insight.rr.com
Cc:
Sent: Monday August 26 2019 7:02:52AM
Subject: Comment on Proposed Dietetic Rules by 9/13/19
PROPOSED RULES: Seeking comments on the Medical Board’s initial review of proposed Dietetics rules for continuing education and limited permits

The State Medical Board of Ohio seeks public input on proposed rules several times during the rule-making process. Public input is sought after the Medical Board has conducted its initial review of rules, after rules are filed with the Common Sense Initiative Office, and at the public hearing that occurs after the rules are formally filed with the Joint Committee on Agency Rule Review.

The Medical Board’s initial review of rules may result in a proposal to amend current rules, rescind current rules, make no changes to current rules, and/or adopt new rules. Comments received will be reviewed and possibly result in changes to the initially proposed language before the rules are then filed with the Common Sense Initiative Office.

At this time, public comment is being sought on the proposed language for these proposed rules, which can be found on the Medical Board’s website using the button below.

Deadline for submitting comments: September 13, 2019

Comments to: Nathan Smith, Senior Legal & Policy Counsel
State Medical Board of Ohio
Nathan.Smith@med.ohio.gov

Click here to read the rules
Ms. Youngpeter,

Thank you for submitting comments on the proposed rules. All comments will be reviewed.

Sincerely,

Nathan T. Smith  
Senior Legal & Policy Counsel  
State Medical Board of Ohio  
30 East Broad St., 3rd Floor  
Columbus, OH 43215  
(614) 466-4341  
Nathan.Smith@med.ohio.gov  
med.ohio.gov

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From: Krista Youngpeter <kyoungpeter1@gmail.com>  
Sent: Monday, August 26, 2019 12:34 PM  
To: Smith, Nathan <Nathan.Smith@med.ohio.gov>  
Subject: Comment on Proposed Dietetic Rules

Hi,

I reviewed the proposed rules for continuing education and limited permits and my comments for consideration are below.

I was wondering why we must complete one hour of ethics, laws, rules and regulations for each 2-year renewal period? CDR only requires one hour continuing education related to ethics every 5 years.

Will we need to submit the ethics continuing education requirement to the medical board since the proposed rule is requiring 1 hour for each 2-year renewal period which is more than CDR's one hour requirement every 5 years?

Thank you for your consideration.

Sincerely,

Krista Youngpeter RDN, LD
<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Organization</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assenheimer, Tracy, RD, CSG, LD</td>
<td><a href="mailto:hobbins.4@gmail.com">hobbins.4@gmail.com</a></td>
<td>Presidential Post Acute Dining and Nutrition Services</td>
<td>I read through the proposed changes. The language and adjustments are acceptable.</td>
</tr>
<tr>
<td>Burkholder, Derek</td>
<td><a href="mailto:derek.burkholder@yahoo.com">derek.burkholder@yahoo.com</a></td>
<td>Presidential Post Acute Dining and Nutrition Services</td>
<td>For limited permit rule, there is too much burden placed on the registered dietitians who would guide them. So much regulatory burden that in practice no RD would want a limited permit dietitian under them. I think a rule change to make it easier for those that fail the exam to work as dietetic technicians in the meanwhile would be of more benefit to the profession and the public.</td>
</tr>
<tr>
<td>Burton, Raenette, RDN, LD</td>
<td><a href="mailto:Raenette.Burton@hcfmanagement.com">Raenette.Burton@hcfmanagement.com</a></td>
<td>HCF Management Inc.</td>
<td>I am writing you in regards to the proposed rule 4759-4-04 regarding registered dietitians and their continuing education requirements. I am strongly against this proposed rule. Our current certification cycle allows us working dietitians time to reflect on our next 5 years of practice and allows us to then make choices for our continuing education that will aid in achieving our 5 year goals. 75 CEU’s in 5 years would be equivalent to 30 every 2, however, often we attend conferences at certain times of the year which may account for well over the 30 hours, but then upon the next certification cycle it may be hard to get the 30 depending upon conference and seminar schedules.</td>
</tr>
<tr>
<td>Chapman, Nancy RDN, LD</td>
<td><a href="mailto:nancy.chapman@sanctuaryhealthnetwork.com">nancy.chapman@sanctuaryhealthnetwork.com</a></td>
<td>Sanctuary Health Network</td>
<td>Per the Commission on Dietetic Registration Dietitians are required to have 1 ceu per 5 year period. I would suggest the requirement of the Medical Board of the State of Ohio to align with the CDR rules and Dietitians be required to complete one hour of an ethics course every other 2 year period.</td>
</tr>
<tr>
<td>Cook, Marcy, RDN, LD</td>
<td><a href="mailto:jmcook37@yahoo.com">jmcook37@yahoo.com</a></td>
<td>Presidential Post Acute Dining and Nutrition Services</td>
<td>The changes seem sufficient to support our constantly evolving profession.</td>
</tr>
<tr>
<td>Finney, Julie MS, RDN, LD</td>
<td><a href="mailto:julie.finney77@gmail.com">julie.finney77@gmail.com</a></td>
<td>Presidential Post Acute Dining and Nutrition Services</td>
<td>I am in support of the proposed changes to the ethics education requirement. The Ohio-specific learning activity has generated confusion among some practitioners and they are often surprised to learn that an ethics learning activity that counts for the Commission on Dietetic Registration hasn't been approved for the renewal of their Ohio license. While I have already completed the Ohio Board's ethics training, I have also completed my CDR ethics training and there are multiple options offered by CDR that are applicable in various practice settings. I am also in support of the second proposed change that requires individuals with limited permits that have previously not passed the RD exam to be supervised by a Licensed Dietitian. In my most recent hiring experiences, I have found that new grads are waiting to apply for employment until they have passed their RD exam and can then apply for the Ohio License as well but if someone is employed under a limited permit, it is reasonable to expect that their work will be monitored by a Licensed Dietitian.</td>
</tr>
<tr>
<td>Haffke, Lindsey</td>
<td><a href="mailto:haffkelm@gmail.com">haffkelm@gmail.com</a></td>
<td>Presidential Post Acute Dining and Nutrition Services</td>
<td>I disagree with the ethics, law, and regulation amendment that states a course needs to be completed every 2 years. The Academy of Nutrition and Dietetics and CDR requires 1 ethics course every 5 years. I recommend this same rule be implemented with the state of Ohio or no course at all since dietitians are already fulfilling the national requirements. If the amendment passes as is currently written, I would request the Jurisprudence course be available to dietitians to meet this stringent requirement.</td>
</tr>
<tr>
<td>Kraeutle, Megan, RDN, LD</td>
<td><a href="mailto:Megan.Kraeutle@trihealth.com">Megan.Kraeutle@trihealth.com</a></td>
<td>Good Samaritan Hospital</td>
<td>I have reviewed the proposed Dietetics rules for continuing education and limited permits that were recently released. I understand that Jurisprudence will no longer be offered to fulfill the Ethics education requirement and that we are to find one approved by CDC, AND or the Ohio Academy. I wanted to check if continuing education offered through Today's Dietitian would count towards this requirement. Below is the information regarding the webinar, it appears that it has been &quot;pre-approved &quot; by CDR. What kind of information do we need to save after this is completed for our credit and do we submit this when we go to renew our license each year? (gives course info in email)</td>
</tr>
<tr>
<td>Muniak, Bethany, RDN, LD</td>
<td><a href="mailto:bnlmuniak@gmail.com">bnlmuniak@gmail.com</a></td>
<td>Presidential Post Acute Dining and Nutrition Services</td>
<td>I am commenting that I am in favor of the new language!</td>
</tr>
<tr>
<td>Name</td>
<td>Email</td>
<td>Comments</td>
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<tr>
<td>Ohio Academy of Nutrition and Dietetics</td>
<td><a href="mailto:kmavko@columbus.rr.com">kmavko@columbus.rr.com</a></td>
<td>Provided suggested draft changes that address the following concerns raised in their comments for 4759-4-04: (1) clarify for all licensees that one hour ethics or laws, rules, and regulations requirement is included within the total required hours for each renewal period rather than in addition to those required hours; (2) amendment to rule that no longer requires non-RD licensees to submit a 5 year individualized learning plan makes the requirements less rigorous and not consistent with the options offered by CDR; (3) “The inconsistency in process and requirements between non-RD licensees and RDs may entice RDs who dislike the PDP process to abandon the RD credential and opt to only maintain their license to practice in Ohio. If this occurs, it may result in growth of this previously dwindling small group of non-RD licensees and have negative effects upon CDR, The Academy, and the continued competence and career development of licensees.” Non-RD licensees should have to continue to record their hours on a form provided by the Board. (4) 4759-4-04(C) should include language to let licensees know that a civil penalty may be imposed by the Board if an audit process shows a deficiency in continuing education. For 4759-4-08: (1) add language to 4759-4-08(G)(1) “suggesting that the supervising dietitian first assess (evaluate) the performance of the limited permit holder who has failed the examination in order to identify any deficiencies prior to developing and documenting a plan for supervision.” 2. states that phrase “goals for competencies” is confusing in 4759-4-08(G)(1) and suggests draft language involving “assuring competent entry-level practice”.</td>
<td></td>
</tr>
<tr>
<td>Peschiera, Claudia MS, RD, LD, CNSC</td>
<td><a href="mailto:claudia.peschiera@chs.trihealth.com">claudia.peschiera@chs.trihealth.com</a></td>
<td>I disagree with the ethics, law, and regulation amendment that states a course needs to be completed every 2 years. The Academy of Nutrition and Dietetics and CDR requires 1 ethics course every 5 years. I recommend this same rule be implemented with the state of Ohio or no course at all since dietitians are already fulfilling the national requirements. If the amendment passes as is currently written, I would request the Jurisprudence course be available to dietitians to meet this stringent requirement.</td>
<td></td>
</tr>
<tr>
<td>Swinehart-Alspach, Jeanne, MS, RDN, LD</td>
<td><a href="mailto:Jeannie.Swinehart-Alspach@dys.ohio.gov">Jeannie.Swinehart-Alspach@dys.ohio.gov</a></td>
<td>I agree to continue on the “odd” years the Dietetics Rules for continuing education (1 CEU) of jurisprudence to be continued for licensed Dietitians in Ohio, within a 2-yr renewal basis. This procedure was practiced in the past for Dietitians’ Licensure renewals during the “odd” years, (when Licensing renewal was on a yearly basis.)</td>
<td></td>
</tr>
<tr>
<td>Turnwald, Ann RD, LD</td>
<td><a href="mailto:ajrjturw@bright.net">ajrjturw@bright.net</a></td>
<td>Since the Medical Board staff will no longer be generating content for a Jurisprudence course and the Licensure Committee and full Board will no longer be reviewing and approving Jurisprudence courses, how do we find these approved courses? Will we be notified of these approved courses by a third party? Are they free or do we have to pay for the course?</td>
<td></td>
</tr>
<tr>
<td>Wachaya, Jane, RD, LD</td>
<td><a href="mailto:mwachaya@insight.rr.com">mwachaya@insight.rr.com</a></td>
<td>1. When it says, ” Registered dietitians must certify completion of the continuing education required to hold current registration with the Commission on Dietetic Registration” does it mean we will provide the proof of completion for each 5 year renewal rather than just submitting a log as we do now? 2. In the part about ethics, laws, rules, and regulations, which I believe we currently complete, is the change merely that the provider is restricted to those specifically named? 3. A link to the new statutory audit information would have been helpful. Can you tell me more about it please? Is the audit only for failure to comply?</td>
<td></td>
</tr>
<tr>
<td>Youngpeter, Krista, RDN, LD</td>
<td><a href="mailto:kyoungpeter1@gmail.com">kyoungpeter1@gmail.com</a></td>
<td>I was wondering why we must complete one hour of ethics, laws, rules and regulations for each 2-year renewal period? CDR only requires one hour continuing education related to ethics every 5 years. Will we need to submit the ethics continuing education requirement to the medical board since the proposed rule is requiring 1 hour for each 2-year renewal period which is more than CDR’s one hour requirement every 5 years?</td>
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MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Comments received on Proposed Rule for Temporary Expedited Licensure for Members of the Military and Spouses Licensed in Another State or Jurisdiction

DATE: May 29, 2020

On February 14, 2020, the proposed rule implementing SB 7 was filed with CSI. The Board received twenty comments on the rule. The comments were very supportive of the rule and the concept of providing temporary expedited licensure to members of the military and their spouses licensed in another state or jurisdiction. Attached please find a spreadsheet outlining the comments, the comments and my responses. At this time, I am not recommending any changes to the rule language. The rule is pending with CSI. When the determination is received from CSI, I will file with JCARR.

Action Requested: No action requested.
From: Anderson, Kimberly  
To: "Allyson Cochet"  
Cc: CSIPublicComments  
Subject: RE: Military Spouse Licensure  
Date: Monday, March 2, 2020 5:27:00 PM

Dr. Cochet:

Thank you for your comments. They will be shared with the Board.

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: Allyson Cochet <allysonecochet@gmail.com>
Sent: Wednesday, February 26, 2020 6:44 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: Military Spouse Licensure

Hi,
This would be a great benefit to active duty spouses. As a prior service Army Physician, I now work at University Hospitals (a very, very welcoming place for Veterans!) as a Gastroenterologist. I had plenty of heads up regarding our move from Texas to Ohio to accompany my active duty spouse. That said, getting a medical license in hand for Ohio was critical to being employed in Cleveland. The proposed rule here would help a lot. I think it will promote employment of active duty spouses and do nothing but benefit the states they move to. Please move forward with this idea. Please contact me any time!

Very Respectfully,

Allyson Cochet, MD
Gastroenterologist
University Hospitals.
3173707998

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Lieutenant Colonel Gardiner:

Thank you for your comments. They will be shared with the Board.

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

-----Original Message-----
From: John Gardener <johngardinerpa62@yahoo.com>
Sent: Tuesday, February 18, 2020 1:53 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: Military Expedited Temporary License

As a military Physician Assistant whom the Ohio Medical Board has helped I wish to convey to you my avid support for this rule change. When I was deployed in a combat zone as a battalion PA (providing medical care to 600-800 soldiers) expedited processing for my license really was a big help in relieving my mind of this important issue for me. So yes I am in complete support for this rule change.

John Gardiner, PA-C  
Lieutenant Colonel, USA

Sent from my iPhone

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From:  Anderson, Kimberly
To:  Gary Gechlik
Cc:  CSIPublicComments
Subject:  RE: Common Sense Initiative
Date:  Tuesday, February 18, 2020 2:19:06 PM

Dr. Gechlik:

Thank you for your comments. They will be shared with the Board.

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

From:  Gary Gechlik <garygech@gmail.com>
Sent:  Tuesday, February 18, 2020 1:14 PM
To:  Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject:  Common Sense Initiative

The State Medical Board of Ohio has filed a proposed rule with the Common Sense Initiative Office concerning temporary licensure for members of the military and spouses who are licensed in another jurisdiction. The proposed rule can be viewed at the link below and is available for public comment:

Rule 4731-36-04: Temporary Expedited Licensure for Members of the Military and Spouses who are Licensed in Another Jurisdiction

"Serving our country in the United States Military is a selfless and tremendously honorable activity often beyond the experience of those who have not been called to National Service."
Those who serve are future Veterans, served at risk to self in service to our country voluntarily, need all of our support and civilian accommodation, for two reasons. The first is practical, it is hard to serve others in the United States Military, far from family, friends, and our great American Culture. But for a second reason, we do not want to ever dissuade those who desire to serve, but might not serve voluntarily out of a hidden fear that they would be judged negatively in any capacity. It is for this reason, we finally must apply Common Sense to our law within the Ohio Jurisdiction. While we cannot speak to other State Jurisdictions, we can always make clear that in the proud State of Ohio, will always support our Soldiers, our Military Physicians, and our Military Families by lending them the helping hand those service providers voluntarily and honorably lent us in our time of need." Gary Gechlik, M.D., J.D., Ohio State Emergency Residency Class of 1998.

Thanks,

Gary

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"The State Medical Board of Ohio has filed a proposed rule with the Common Sense Initiative Office concerning temporary licensure for members of the military and spouses who are licensed in another jurisdiction". I fully support such a measure. In fact, my thoughts and sentiment go even further. Read on.

In the wake of the mass shooting in Las Vegas, the Governor of Nevada declared a state of emergency, begging for "out of state" physicians and nurses to go to Las Vegas and help treat the hundreds of victims at the local hospitals, the staffs of which were overwhelmed by the sudden massive caseload of patients in the ERs and ORs.

Thanks to a mass murderer, the Governor of Nevada – and the rest of society— had a double epiphany; 1) a gunshot injury in Nevada is no different from a gunshot injury anywhere else in America, and 2) skilled health care providers (especially trauma surgeons and trauma nurses) outside Nevada state borders are qualified to practice in the State of Nevada without going through the prejudicial, tedious, time-consuming and expensive process of formal licensure.

Prior the that fateful evening, those out-of-state doctors and nurses were not considered qualified to ply their skills to the citizenry of Nevada until they completed the state’s application process for a license and received formal approval from the State Board of Medicine or Nursing. In fact it was a criminally offense for them to do so. But all of a sudden they were not only qualified, they were desired, qualified, and legal, simply on the verbal say-so of the Governor.

Admittedly, the situation was an emergency of unprecedented proportions, allowing the Governor to dispense with the formalities and requirements of established Nevada State laws, rules, regulations, and procedures in order to meet the needs of the
situation. But why must the people of Nevada, or any state for that matter, be forced to wait for an emergency situation to have access to something as important as health care and medical treatment? Why cannot there be NATIONAL licensure of all health care providers already in place not only to anticipate and deal with catastrophic health situations, but also to meet the needs of the health care marketplace as the nation grows and changes? Instead, we have a cumbersome system that resembles fifty separate countries, each with its own set of rules and regulations as pertains to health care providers. As far as health care provider licensure goes, we have not the UNITED States of America, but the DISJOINTED States of America.

For years there have been efforts made to establish national licensure for health care providers, so that they can move seamlessly from state to state where their skills may be needed, only to be repelled by forces (political and medical) that control the practice of medicine and the flow of health care dollars in each state. Supporters of national licensure for physicians have always argued that diseases and modern medical treatment are virtually no different across the artificial boundaries of states, but states' rights activists have played Russian roulette with the health of their residents simply for political and financial purposes. The events of recent years, such as 9/11 and Las Vegas, and hurricanes Katrina, Harvey, and Maria, prove that political gambling with people's health can be fatal due to such restrictions on health care providers.

Furthermore, when the only medical forces that can legally be mobilized in a local or national emergency situation to practice across state borders are active duty military and veterans administration (ie: federally employed) physicians, a de facto nation-wide state of discrimination against civilian (non-federal employee) doctors exists. This interference with the interstate
practice of medicine (ie: interstate trade) should be considered undesirable and illegal, and should be abolished.

Natural disasters and man-made emergencies have exposed how antiquated and dangerous states’ rights thinking with respect to health provider licensure is totally inappropriate for the present and future needs of this nation. It should be clear from recent events that health care providers comprise a critical national resource, not a state’s resource with which political games can be played. There already exist nation-wide organizations (e.g. medical specialty boards and specialty societies) that determine, promote, review and provide for quality of providers and standards of care to ensure public health and safety across the nation. There already exist federal government offices (e.g. Food and Drug Administration) and functions (e.g. National Practitioner Data Bank, Medicare and Medicaid reviews) that likewise provide for protection of the nation's health. There already exist federal government institutions (e.g. National Health Institute, Center for Disease Control) that perform health and medical research and issue recommendations for national health policies.

The time for national licensure of physicians, nurses, and all other health care providers is here. States’ rights be damned!!

Thomas Hillman MD

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Mr. Montavon:

Thank you for your comments. They will be shared with the Board.

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

From: LMontavon15 Montavon <lmontavon15@gmail.com>  
Sent: Thursday, February 20, 2020 4:01 PM  
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>  
Subject: Temporary Expedited Licensure

Hello, I am in total agreement for the temporary license for military families. I believe military families who are serving our county and any member of their family who has a current license or certificate from another jurisdiction wishing to work as a LMT in Ohio should be given the opportunity to work.

--

Len Montavon
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Dr. Hillman:

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Admittedly, the situation was an emergency of unprecedented proportions, allowing the Governor to dispense with the formalities and requirements of established Nevada State laws, rules, regulations, and procedures in order to meet the needs of the situation. But why must the people of Nevada, or any state for that matter, be forced to wait for an emergency situation to have access to something as important as health care and medical treatment? Why cannot there be NATIONAL licensure of all health care providers already in place not only to anticipate and deal with catastrophic health situations, but also to meet the needs of the health care marketplace as the nation grows and changes? Instead, we have a cumbersome system that resembles fifty separate countries, each with its own set of rules and regulations as pertains to health care providers. As far as health care provider licensure goes, we have not the UNITED States of America, but the DISJOINTED States of America.
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Furthermore, when the only medical forces that can legally be mobilized in a local or national emergency situation to practice across state borders are active duty military and veterans administration (ie: federally employed) physicians, a de facto nation-wide state of discrimination against civilian (non-federal employee) doctors exists. This interference with the interstate practice of medicine (ie: interstate trade) should be considered undesirable and illegal, and should be abolished.

Natural disasters and man-made emergencies have exposed how antiquated and dangerous states’ rights thinking with respect to health provider licensure is totally inappropriate for the present and future needs of this nation. It should be clear from recent events that health care providers comprise a critical national resource, not a state’s resource with which political games can be played. There already exist nation-wide organizations (e.g. medical specialty boards and specialty societies) that determine, promote, review and provide for quality of providers and standards of care to ensure public health and safety across the nation. There already
exist federal government offices (e.g. Food and Drug Administration) and functions (e.g. National Practitioner Data Bank, Medicare and Medicaid reviews) that likewise provide for protection of the nation’s health. There already exist federal government institutions (e.g. National Health Institute, Center for Disease Control) that perform health and medical research and issue recommendations for national health policies.

The time for national licensure of physicians, nurses, and all other health care providers is here. States’ rights be damned!!
Thank you for your comments. They will be shared with the Board.

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

From: Fine, Edward <efine@buffalo.edu>
Sent: Thursday, February 27, 2020 1:21 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: Common Sense Initiative

Dear Ms Anderson: I am in favor of granting temporary licensing of spouses of military personnel attached to members of the military based in Ohio. It is fair and will help to provide more physicians to cover the loss of Ohio licensed physicians projected over the years 0f 2020 to 2030 due to retirement or burnout.

Edward J. Fine, MD, FAAN
Associate Professor of Neurology  University at Buffalo
Ohio License #29225

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Ms. Martin:

Thank you for your comments. They will be shared with the Board.

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

From: Hali Martin <haliweiser@gmail.com>
Sent: Wednesday, February 19, 2020 10:33 AM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: Expedited licensure

I think this is wonderful for military families! I realize how difficult it can be for spouses that have to move around. The less stress for those families the better! Kudos to the board for recognizing this. Looking forward to this being passed!
Hali Martin RRT/SDS

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Mr. Millhouse:

Thank you for your comments. They will be shared with the Board.

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

From: Tyrone Millhouse II <tymillhouse@att.net>
Sent: Sunday, February 23, 2020 5:55 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: RE: Regarding expedited licensures

Dear Kim,

If the coronavirus should continue to spread, we will definitely need greater latitude in helping one another from State to State...

God Bless,

Ty
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Dr. Entwistle:

Thank you for your comments. They will be shared with the Board.

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

Greetings!

What an EXCELLENT idea! I was once a military physician and I transitioned to working in the Lodi, Ohio ER for several years. But I waited quite a while to obtain an Ohio license—which just delayed my working in an underserved area. I already had more than one state license, all in good standing, with many years of practice.

Enacting this rule will be of benefit to both parties—the physicians and the Ohio patients.

Celia B. Entwistle, MD
Ohio medical licence 35.129749
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Ms. Jolly:

Thank you for your comments. They will be shared with the Board.

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

---

To Whom It May Concern:

Thank you for proposing this new rule that includes expedited licensure of military members and their spouses.

As a military family, we moved eight times in fifteen years. This is the norm for many military families. Particularly for spouses this makes it very difficult to attain licensure in their new home state with every move and within a timeline that allows for them to practice in their field before the next move.
This new proposed rule will significantly impact military families for the better! Please adopt this rule.

Sincerely,

Laurel K. Jolly, MS, LCGC  
Genetic Counselor I  
Myriad Genetics, Inc.

320 Wakara Way, Salt Lake City, Utah 84108

Office: 888.268.6795

laurel.jolly@myriad.com | www.myriad.com
Dr. Martin:

Thank you for your comments. They will be reviewed and shared with the Board.

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

---

Kimberly,  
As a member of the military for the past 22 years I thank the state for trying to make it easier! Other states never charge for the Military so that is another idea!

Thanks  
LTC Kevin Martin  
Army  
Kevin D. Martin DO  
Orthopedic Foot & Ankle Surgeon  
Associate Professor  
@drkevinmartin_ortho
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Dr. Martin:

Thank you again for your comments on the rule for temporary expedited licensure for members of the military and spouses. To follow up on your comment that other states waive licensure fees for all license types for members of the military, that is something that the Board can consider for the future. The statute that authorizes the fee waiver for this particular rule is limited to the temporary, expedited licensure.

Kimberly C. Anderson  
Chief Legal Counsel  
State Medical Board of Ohio  
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Columbus, Ohio 43215-6127  
O: 614-466-7207  
C: 614-230-9077  
Kimberly.Anderson@med.ohio.gov  
Med.ohio.gov
Kimberly,
As a member of the military for the past 22 years I thank the state for trying to make it easier! Other states never charge for the Military so that is another idea!

Thanks
LTC Kevin Martin
Army
--
Kevin D. Martin DO
Orthopedic Foot & Ankle Surgeon
Associate Professor
@drkevinmartin_ortho

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Dr. Plantes:

Thank you again for your comments on the proposed rule for temporary expedited licensure for members of the military and spouses. The statute authorizing the rule requires the Board to license members of the military and spouses so long as they hold a license in good standing in another state. NCQA standards are not required for Board licensure, although they are likely utilized for hospital credentialing.

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
From: Peter J. Plantes, MD (from Gmail) <peterplantesmd@gmail.com>
Sent: Tuesday, February 18, 2020 6:12 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Cc: CSIPublicComments <CSIPublicComments@governor.ohio.gov>
Subject: Military licensure initiative

This is a good idea IF, AND ONLY IF the other jurisdiction that licensed each individual Physician is using NCQA Standards to credential.

If the physician happened to get originally enrolled in the military physician corps via an outlying entity (eg. Virgin Island, Guam, PR, certain various states, etc.) they may, or may not, have been fully credentialed to NCQA standards. Ohio wants to keep a uniform standard if accepting delegated credentialing sources. The Ohio Physician licensure pool quality is only as strong as the weakest link.

I would advise to move forward on this but understand and scrutinize that standards of each entity that inserts another Physician into the Ohio credentialed Physician network.

Call or text if I can be of any help. I have credentialed over 25,000 physicians into NCQA qualified networks or states.

Peter J Plantes, MD
(817) 946.3751
PeterPlantesMD@Gmail.com
https://www.linkedin.com/in/peterplantesmd

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attachments if the email looks suspicious. Forward to csc@ohio.gov.
Dr. Bhat:

Thank you again for your comment on the proposed rule for temporary, expedited licensure for members of the military and spouses. You suggested changing paragraph (E) to make it more clear that the application for temporary license would be considered abandoned after six months. The entire paragraph does address the temporary licensure.

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

Dr. Bhat:

Thank you for your comments. They will be shared with the Board.

Kimberly C. Anderson  
Chief Legal Counsel  
State Medical Board of Ohio  
30 E. Broad Street, 3rd Floor
From: Bhat, Sunil V. <Sunil.Bhat@kch.org>
Sent: Monday, February 24, 2020 2:01 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Cc: CSIPublicComments <CSIPublicComments@governor.ohio.gov>
Subject: rule 4731-36-04

I have read over the transcript of Rule 4731-36-04. I am in agreement with it as it should help ease the burden of moving for our men and women in Uniform.

One question: final page – letter “(E)”. I presume it means finishing the application for the temporary license (not the permanent, which is alluded to in section “(H)”.
Perhaps could be reworded to be more clear (i.e. – “fails to complete the application process for a temporary license…”).

Thank you,

Sunil V Bhat, MD
Infectious Diseases
Knox Community Hospital

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From: Anderson, Kimberly
To: John Gillen
Cc: CSIPublicComments
Subject: RE: Rule 4731-36-04
Date: Monday, May 18, 2020 4:27:00 PM

Mr. Gillen:

Thank you again for your comments regarding the proposed rule on temporary, expedited licensure for members of the military and spouses. You asked whether jurisdiction includes a state or foreign country. The statute does not define “jurisdiction”. It is important to note that the individuals eligible for this licensure type are members of the U.S. military and their spouses. You asked what happens if the military stay in Ohio exceeds two years. The military member or spouse would be able to apply for a full license, in the event that they meet the eligibility requirements. You also asked whether the temporary, expedited license would apply to moonlighting, which I believe would be practice outside the military program. The temporary expedited license is only available to member of the military and their spouses licensed in another state, but there is no requirement that the practice is confined to a particular facility or program. I hope that this answers your questions.

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

From: Anderson, Kimberly
Sent: Wednesday, February 19, 2020 9:32 AM
To: John Gillen <jbgillen@gmail.com>
Subject: RE: Rule 4731-36-04

Mr. Gillen:

Thank you for your comments. They will be shared with the Board.
From: John Gillen <jbgillen@gmail.com>
Sent: Tuesday, February 18, 2020 5:29 PM
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>
Subject: Rule 4731-36-04

1. I assume "other" jurisdiction is synonymous with "State" as opposed to foreign country.
2. Sometimes, military personnel remain in a billet in excess of "2 years". What then?
3. Does the licence apply to "moonlighting"

--
Thanks.

Please use jbgillen@gmail.com as my primary email address. Thank you.

John Gillen
513-891-7345
513-236-3810 cell

CAUTION: This is an external email. This message might not be safe. Do not click links or open attachments if the email looks suspicious. Forward to csc@ohio.gov.
Dr. Dean:

Thank you again for your comments on the rule for temporary expedited licensure for members of the military and spouse. To respond to your question about national licensure for all practitioners who hold a license in one state, the statute authorizing this particular rule is limited to members of the military and their spouses.

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
I would like to see Ohio and all states follow the thought if your licensed in one state, the license is
good in all states...
Regards:
Brian S. Dean, DO, FACOEP
Dr. Sanor:

Thank you again for your comments on the rule regarding temporary, expedited licensure for members of the military and spouses. You raised a question regarding hospital recognition for physicians with ABIM certification, rather than limiting recognition to ABMS certification. Please note that the Medical Board does not have jurisdiction over hospitals and their credentialing requirements.

Kimberly C. Anderson
Chief Legal Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, Ohio 43215-6127
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Kimberly.Anderson@med.ohio.gov
Med.ohio.gov

Dr. Sanor:

Thank you for your comments. They will be shared with the Board.

Kimberly C. Anderson
Chief Legal Counsel
State Medical Board of Ohio
I think your proposal for temporary licensure for military makes sense.

Would you please introduce a Common Sense Initiative on another topic ie: physicians who do not have ABIM Board Certification? Many hospitals require ABIM yet it has never been shown to be evidence based improved care.

I have ABPS Board Certification and found it much more useful since it is for Hospitalists. ABIM should not have a monopoly.

Thank you and have a great week,
Teri
Teri Sanor, MD
Dr. Graham:

Thank you again for your comments regarding the proposed rule for expedited licensure for members of the military and spouses. You also provided comments regarding a discount for medical marijuana. The statute authorizing the rule and the rule itself deal only with temporary expedited licensure for members of the military and spouses. The statute and rule do not authorize a discount for medical marijuana.

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

From: Anderson, Kimberly  
Sent: Tuesday, February 18, 2020 2:16 PM  
To: susan graham <susanjoyg60@gmail.com>  
Cc: CSIPublicComments <CSIPublicComments@governor.ohio.gov>  
Subject: RE: Proposed rule for expedited licensure for Military and spouses

Dr. Graham:

Thank you for your comments. They will be shared with the Board.

Kimberly C. Anderson  
Chief Legal Counsel  
State Medical Board of Ohio
From: susan graham <susanjoyg60@gmail.com>  
Sent: Tuesday, February 18, 2020 1:38 PM  
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>  
Subject: Proposed rule for expedited licensure for Military and spouses

than the need of a non-military individual in the queue. For example, how do you del have no objection to military personnel having expedited licensure per se as these men and women and their spouses have often sacrificed their health and wellness for the greater good of all Americans. I feel that these individuals are owed something by society. I appreciate the discount given to our military for the cost of the card and, at least in some areas, a discount on their marijuana supplies.

But I would add that there would be circumstances when a non-military individual has a greater need. A military member may deserve enhanced accessibility to the medical card as long as the need of that individual is greater than a non-military person in the queue. How do you decide who to see first... a patient with cancer or someone who has served in the military?

It seems to me that the Physician should have the right to triage people based on the severity of their condition. Giving preferential treatment would have to be because the soldier had a more severe condition and was in greater need, a caveat that should apply to everyone equally.

Also the list of qualifying conditions is not the same in every state. Someone coming from a state in which Lupus is a qualifying condition would not necessarily qualify in Ohio. Each person needs to be evaluated on their individual condition and not as a member of any given group.

Thank you for giving me an opportunity to offer my thoughts.

Susan Graham, M.D.
CAUTION: This is an external email. This message might not be safe. Do not click links or open attachments if the email looks suspicious. Forward to csc@ohio.gov.
Dr. Graham:

Thank you for your comments. They will be reviewed and shared with the Board. With respect to your concern about the abandonment of the application, the temporary license will not be granted if the applicant fails to complete the application in 6 months.

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: Larry <lgraham553@gmail.com>  
Sent: Tuesday, February 18, 2020 12:54 PM  
To: Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>  
Subject: Military temporary licensure

I have 2 concerns. If the applicant fails to complete the full application in 6 months it will be considered abandoned, yet they will be in possession of a 2 year temporary license. It seems like that gives them a 2 year period not just 6 months. Why are these time frames not the same. Secondly, there can be quality concerns about an applicant that has not yet progressed to a formal board enquiry. It seems prudent to have the applicants superior officer furnish a letter of recommendation.

Thanks for listening

Larry A Graham MD

Sent from my iPhone

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Mr. Newdow:

Thank you for your comment. It will be reviewed and shared with the Medical Board. To more specifically answer your question, the statute authorizing this rule is limited to temporary expedited licensure for members of the military and spouses who are licensed in another jurisdiction.

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

From: Mike Newdow <mikenewdow@gmail.com>
Sent: Tuesday, February 18, 2020 12:44 PM
To: Contact <Contact@med.ohio.gov>; Anderson, Kimberly <Kimberly.Anderson@med.ohio.gov>; CSIPublicComments <CSIPublicComments@governor.ohio.gov>
Subject: Re: Temporary Expedited Licensure for Military Members/Spouses Rule - Comment by 2/28/20

Why not temporary expedited licensure for anyone who needs it?
The State Medical Board of Ohio has filed a proposed rule with the Common Sense Initiative Office concerning temporary licensure for members of the military and spouses who are licensed in another jurisdiction. The proposed rule can be viewed at the link below and is available for public comment:

**Rule 4731-36-04: Temporary Expedited Licensure for Members of the Military and Spouses who are Licensed in Another Jurisdiction**

Comments must be received no later than February 28, 2020. Please provide comments to both:
Medical Board at: Kimberly.Anderson@med.ohio.gov
and Common Sense Initiative at: CSIPublicComments@governor.ohio.gov
--

Michael Newdow

2985 Lakeshore Blvd
Upper Lake, CA 95485

916-201-6078 (cell)
707-739-6837 (Google voice)
MikeNewdow@gmail.com

CAUTION: This is an external email. This message might not be safe. Do not click links or open attachments if the email looks suspicious. Forward to csc@ohio.gov.
Thank you for your comment. It will be reviewed and shared with the Medical Board. To more specifically answer your question, the statute authorizing this rule is limited to temporary expedited licensure for members of the military and spouses who are licensed in another jurisdiction.

Thanks for the specific answer. I understand that the statute is written that way. I just wanted to give my input that - as a locums physician who has often needed expedited temporary licensure in order to help fill a given need - I don't see why (if expedited temporary licensure can be done for members of the military and/or their spouses) the expedited temporary licensure can’t be done for everyone who needs it.

- Mike
Why not temporary expedited licensure for anyone who needs it?

On Tue, Feb 18, 2020 at 9:30 AM State Medical Board of Ohio <contact@med.ohio.gov> wrote:
The State Medical Board of Ohio has filed a proposed rule with the Common Sense Initiative Office concerning temporary licensure for members of the military and spouses who are licensed in another jurisdiction. The proposed rule can be viewed at the link below and is available for public comment:

**Rule 4731-36-04: Temporary Expedited Licensure for Members of the Military and Spouses who are Licensed in Another Jurisdiction**

Comments must be received no later than February 28, 2020. Please provide comments to both:
Medical Board at: Kimberly.Anderson@med.ohio.gov
and Common Sense Initiative at: CSIPublicComments@governor.ohio.gov
Upper Lake, CA  95485

916-201-6078  (cell)
707-739-6837  (Google voice)
MikeNewdow@gmail.com

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--
Michael Newdow

2985 Lakeshore Blvd
Upper Lake, CA  95485

916-201-6078  (cell)
707-739-6837  (Google voice)
MikeNewdow@gmail.com
Dr. Bhat:

Thank you for your comments. They will be shared with the Board.

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

---

I have read over the transcript of Rule 4731-36-04. I am in agreement with it as it should help ease the burden of moving for our men and women in Uniform.  
One question: final page – letter “(E)”. I presume it means finishing the application for the temporary license (not the permanent, which is alluded to in section “(H)”).  
Perhaps could be reworded to be more clear (i.e. – “fails to complete the application process for a temporary license…”).  
Thank you,

Sunil V Bhat, MD  
Infectious Diseases  
Knox Community Hospital
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<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Organization</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allyson Cochet, M.D.</td>
<td><a href="mailto:allysonecochet@gmail.com">allysonecochet@gmail.com</a></td>
<td></td>
<td>This is a great benefit to military and veterans.</td>
</tr>
<tr>
<td>Kevin Martin, M.D.</td>
<td><a href="mailto:dr.kevin.d.martin@gmail.com">dr.kevin.d.martin@gmail.com</a></td>
<td></td>
<td>Thank you for making licensure easier. Other states never charge military members for licensure.</td>
</tr>
<tr>
<td>Edward Fine, M.D.</td>
<td><a href="mailto:efine@buffalo.edu">efine@buffalo.edu</a></td>
<td></td>
<td>In favor of granting temporary licensure to military and spouses.</td>
</tr>
<tr>
<td>Hali Martin RRT</td>
<td><a href="mailto:haliweiser@gmail.com">haliweiser@gmail.com</a></td>
<td></td>
<td>This is wonderful for military families.</td>
</tr>
<tr>
<td>Peter Plantes, M.D.</td>
<td><a href="mailto:peterplantesmd@gmail.com">peterplantesmd@gmail.com</a></td>
<td></td>
<td>In favor of rule if other states are using NCQA standards to credential.</td>
</tr>
<tr>
<td>Tyrone Millhouse, II</td>
<td><a href="mailto:tymillhouse@att.net">tymillhouse@att.net</a></td>
<td></td>
<td>In favor of rule, if COVID-19 spreads, greater latitude is needed.</td>
</tr>
<tr>
<td>Celia Entwistle, M.D.</td>
<td><a href="mailto:mduke1982@gmail.com">mduke1982@gmail.com</a></td>
<td></td>
<td>This rule is beneficial to physicians and patients.</td>
</tr>
<tr>
<td>Sunil Bhat, M.D.</td>
<td><a href="mailto:sunil.bhat@kch.org">sunil.bhat@kch.org</a></td>
<td></td>
<td>Change (E) so that it states &quot;fails to complete application process for temporary licensure&quot;</td>
</tr>
<tr>
<td>Richard Bakker</td>
<td><a href="mailto:bakkerg@gmail.com">bakkerg@gmail.com</a></td>
<td></td>
<td>Provided substantive response to questions regarding foreign jurisdiction and fee waiver.</td>
</tr>
<tr>
<td>Laurel Jolly</td>
<td><a href="mailto:laurel.jolly@myriad.com">laurel.jolly@myriad.com</a></td>
<td></td>
<td>This rule will help military families</td>
</tr>
<tr>
<td>Brian Dean, D.O.</td>
<td><a href="mailto:thebigdeaner@gmail.com">thebigdeaner@gmail.com</a></td>
<td></td>
<td>Would like to see all states honor license in any one state.</td>
</tr>
<tr>
<td>John Gardiner, PA.</td>
<td><a href="mailto:johngardinerpa62@yahoo.com">johngardinerpa62@yahoo.com</a></td>
<td></td>
<td>Conveys avid support for the rule.</td>
</tr>
<tr>
<td>Gary Gechlik</td>
<td><a href="mailto:garypech@gmail.com">garypech@gmail.com</a></td>
<td></td>
<td>Supports rule for military families</td>
</tr>
<tr>
<td>John Gillen</td>
<td><a href="mailto:jbgillen@gmail.com">jbgillen@gmail.com</a></td>
<td></td>
<td>1-is other jurisdiction a state; 2-what if military svc is more than 2 yrs; 3- does the lic. apply to moonlighting?</td>
</tr>
<tr>
<td>Larry Graham, M.D.</td>
<td><a href="mailto:lgraham553@gmail.com">lgraham553@gmail.com</a></td>
<td></td>
<td>Concern with temp. lic. Abandonment and what if issue in other state has not risen to formal action?</td>
</tr>
<tr>
<td>Nosrat Hillman</td>
<td><a href="mailto:hillman79@gmail.com">hillman79@gmail.com</a></td>
<td></td>
<td>In favor of the rule and national licensure (2 comments)</td>
</tr>
<tr>
<td>Len Montavon</td>
<td><a href="mailto:lmontavon15@gmail.com">lmontavon15@gmail.com</a></td>
<td></td>
<td>In favor of the rule.</td>
</tr>
<tr>
<td>Mike Newdow</td>
<td><a href="mailto:mikenewdow@gmail.com">mikenewdow@gmail.com</a></td>
<td></td>
<td>Wants temporary licensure for all license types. Provided a response that the statute is limited.</td>
</tr>
<tr>
<td>Teri Sanor</td>
<td><a href="mailto:tisanor@gmail.com">tisanor@gmail.com</a></td>
<td></td>
<td>In favor of the rule. Added an unrelated comment regarding board certification.</td>
</tr>
<tr>
<td>Susan Graham</td>
<td><a href="mailto:susanjoye60@gmail.com">susanjoye60@gmail.com</a></td>
<td></td>
<td>In favor of the rule and seems to be confusing with treatment for patients and MM qualifying conditions.</td>
</tr>
</tbody>
</table>
MEMORANDUM

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

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

DATE: May 29, 2020

RE: Dietetics rule 4759-6-02

The Policy Committee is asked to review proposed amended Dietetics rule 4759-6-02 Standards of Professional Performance. Previously, this rule had been proposed to be amended with very minor grammatical or spelling changes. The rule had passed through CSI and was about to be filed along with many other Dietetics rules that were filed with JCARR in the Fall of 2019. However, changes to the statutes defining the requirements for incorporation by reference (Senate Bill 221 -effective August 18, 2019) necessitated redrafting.

The new draft of the rule (attached to this memo) addresses the incorporation by reference issues by adding extra details such as dates of a version of a document referenced and citations to the Medical Board website where the document can be found. Other external references have been deleted where they are unnecessary, overly vague, or redundant of other rules such as 4759-6-03 Interpretation of standards (which requires that “the standards in this chapter are interpreted in a manner consistent with the “Revised 2017 Standards of Practice in Nutrition Care and Standards of Professional Performance for Registered Dietitian Nutritionists” adopted by the academy of nutrition and dietetics”).

Lastly, the current rule details many requirements for licensees, but contains no enforcement mechanism for violations of the rule. Accordingly, this proposed amended rule adds the following enforcement paragraph:

(O) A violation of any provision of this rule, as determined by the board, shall constitute “a departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established” as that clause is used in division (A)(11) of section 4759.07 of the Revised Code.

Action Requested: Approve proposed amended rule 4759-6-02 for refiling with CSI.
4759-6-02 Standards of professional performance.

Every licensee shall comply with the following standards of professional performance in accordance consistent with the June 1, 2018 "Code of Ethics for the Nutrition and Dietetics Profession" adopted by the Academy of Nutrition and Dietetics which is available from the website of the state medical board at the following link: https://www.med.ohio.gov.

(A) Credentials.

(1) The licensee shall accurately present professional qualifications and credentials.

(2) The licensee shall permit use of that licensee's name for the purpose of certifying that dietetic services have been rendered only if the licensee has provided or supervised those services.

(B) Provision of service.

The licensee shall provide professional service based on client expectations and needs. Quality service is provided, facilitated and promoted based on the licensee's knowledge, experience and understanding of client needs and expectations.

(1) The licensee shall avoid discrimination on the basis of factors that are irrelevant to the provision of professional services, including, but not limited to race, creed, sex, age, or handicap.

(2) The licensee shall assure that sufficient information is available to enable a client to establish mutual goals and make informed decisions.

(C) Quality in practice.

(1) The licensee shall systematically evaluate the quality of service and improve practice based on evaluation results.

(2) Quality practice requires regular performance evaluation and continuous improvement.

(3) The licensee shall adhere to acceptable standards for that licensee's area of practice and be designated to deliver services as approved by their facility. The authority and privilege to practice within the scope shall be consistent with all state and federal laws and rules governing the practice of dietetics the standards of practice of the "Academy of Nutrition and Dietetics" and other regulatory agencies such as, but not limited to, the "Centers for Medicare and Medicaid Services" (CMS) guidelines as published in the Federal Register.

(4) The licensee shall generate, interpret and effectively apply evidence based interventions substantiated by research.

"Evidence based" interventions means the conscientious, explicit judicious use of current best evidence in making decisions about the care of patients and is consistent with the Centre for
evidence based medicine definition in "Evidence based medicine; what it is and what it isn't", Sackett, DL et. al. 1996.

(D) Competence and accountability.

(1) The licensee shall assume responsibility and accountability for personal competence in practice and engage in lifelong learning. Competent and accountable practice includes continuous acquisition of knowledge and skill development.

(a) The licensee shall establish performance criteria, compare actual performance with expected performance, document results and take appropriate action.

(b) The licensee shall conduct self-assessment of strengths and weaknesses at regular intervals and develop, implement and evaluate an individual plan for practice based on assessment of client needs, current knowledge, and clinical experience.

(2) The licensee shall maintain knowledge and skills required for continued professional competence in a manner consistent with the requirements of the Commission on dietetic registration.

(3) The licensee shall recognize the limits of that licensee's qualifications and seek counsel or make referrals as appropriate.

(E) Conflict.

(1) The licensee shall remain free of conflict of interest while fulfilling the objectives and maintaining the integrity of the dietetic profession.

(2) The licensee shall advance and promote the profession while maintaining professional judgment, honesty, integrity, loyalty, and trust to colleagues, clients and the public.

(F) Endorsement.

The licensee shall promote or endorse products only in a manner that is true and not misleading.

(G) Communication and application of knowledge.

The licensee shall effectively apply knowledge and communicate with others to achieve common goals by effective sharing and application of their unique knowledge and skills in food, human nutrition and management services.

(H) Utilization and management of resources.

The licensee shall use resources effectively and efficiently.
The licensee shall use a systematic approach to identify, monitor, analyze and justify the use of time, money, facilities, staff and other resources while considering safety, effectiveness and cost in planning and delivering interventions.

(I) Approval of a general program of weight control.

A "general program of weight control" as defined in rule 4759-5-06 of the Administrative Code must be approved by either a registered or licensed dietitian or physician licensed in Ohio. For purposes of division (J) of section 4759.10 of the Revised Code, the licensee shall provide written approval of all components of the general program of weight control and assume responsibility for the following:

(1) Guidelines for instruction: Program content and written step-by-step information that the presenter provides to customers to enable them to follow the meal plan and other aspects of a general program of weight control.

(2) Meal plans: General categories or groups of foods and suggested combinations of specific foods. Meal plans shall not be individualized for specific persons, conditions, or disease states.

(3) Handouts: Any information distributed in conjunction with the general program of weight control.

(4) Supplements: Products, including vitamins, minerals, herbs and other substances used as part of, or an enhancement to, a general program of weight control. The use of these products shall be substantiated by current scientific evidence.

(J) Supervision.

When providing supervision of another for purposes of division (H) (G) of section 4759.06 and divisions (B) and (E) of section 4759.10 of the Revised Code, and rule 4759-5-02 of the Administrative Code, a licensee shall assume responsibility for the supervision in a manner that protects the public.

(K) Compliance.

The licensee shall comply with all laws and regulations concerning the profession, but shall seek to change them if the laws or regulations are inconsistent with the best interest of the public and the profession. The licensee:

(1) Shall accept the obligation to protect society and the profession by upholding the standards of practice and standards of professional performance; and

(2) Shall report alleged violations of the laws, rules and standards to the state medical board of dietetics.

(L) Interpretation of information and application of research.
(1) The licensee shall present substantiated information and interpret controversial information without personal bias, recognizing that a legitimate difference of opinion may exist.

(2) The licensee applies, participates in, or generates research to enhance practice and to improve safety and quality of dietetic practice and services.

(M) Confidentiality.

The licensee shall maintain information consistent with legal obligations and client confidentiality.

(N) Professional conduct.

(1) The licensee shall conduct all practices with honesty, integrity, and fairness; and

(2) The licensee shall make and fulfill professional commitments in good faith; and

(3) The licensee shall inform the public and colleagues of services by use of factual information.

(4) The licensee shall make reasonable efforts to avoid bias in professional evaluation.

(O) A violation of any provision of this rule, as determined by the board, shall constitute “a departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established” as that clause is used in division (A)(11) of section 4759.07 of the Revised Code.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: CSI Determination-Standards and Procedures for Withdrawal Management for Drug or Alcohol Addiction

DATE: May 28, 2020

On May 20, 2020, the Common Sense Initiative provided the Board with its determination regarding the rules establishing the Standards and Procedures for Withdrawal Management for Drug or Alcohol Addiction. A copy of the determination is attached for your review. The rules will be filed with JCARR.

Action Requested: No Action Requested
MEMORANDUM

TO: Kim Anderson, State Medical Board of Ohio

FROM: Ethan Wittkorn, Regulatory Policy Advocate

DATE: May 20, 2020

RE: CSI Review – Standards and procedures for withdrawal management for drug or alcohol addiction (OAC 4130-4-01, 4730-4-02, 4731-33-01, and 4731-33-02)

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 State Medical Board of Ohio (Board) rule package consists of two new and two amended rules. This rule package was submitted to the CSI Office on November 15, 2019, and the public comment period was open through December 2, 2019. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on November 15, 2019.

This rule package covers detoxification requirements, including definitions, standards, and procedures for withdrawal management. Amendments to the rules include the addition of definitions for “ambulatory detoxification” and “withdrawal management or detoxification.” The two new rules have been drafted to set standards and procedures for detoxification treatment. The rules are split into both OAC Chapter 4730-4 and 4731-33 as they apply to physicians’ assistants, and physicians, respectively. The requirements laid out in the rules are consistent throughout both chapters.

During the period of early stakeholder outreach, the Board worked with the Ohio Department of Mental Health and Addiction Services and the Ohio Board of Nursing on the initial creation of the
rules. Additionally, the draft rules were shared with members of the Physician Assistant Policy Committee and physician members of the Medical Board at public meetings in June and July 2019. As a result of input received, the Board made changes to the rules including updating the definition of “withdrawal management,” additions to clarify that the rules do not forbid non-pharmacological treatments, and changes to the definition of “ambulatory detoxification.” During the CSI public comment period, three comments were received from members of the public and representatives of the Cleveland Clinic. Comments concerned time necessary to comply with the rules and concerns regarding references to treatments using Naltrexone in the rule. No changes were made due to the comments.

Impacted communities include physicians and physician assistants that provide medication-assisted treatment for opioid addiction. Potential adverse impacts include the time necessary for required assessments and to formulate appropriate treatment plans, as well as required documentation of compliance. Additionally, federal regulations require physicians that wish to prescribe certain controlled substances for detoxification purposes to receive a waiver from the U.S. Drug Enforcement Administration (DEA), which includes an application fee of $731 and a $731 fee every three years for renewal. To obtain the required certification for the DEA waiver, physicians must hold specialty certificates that require continuing education courses of varying cost. The Board states that the rules are necessary to set minimum standards and procedures for medication-assisted treatment, and to prevent possible abuse of the drugs that are used for the maintenance and treatment of opioid dependence.

**Recommendations**

Based on the information above, the CSI Office has no recommendations on this rule package.

**Conclusion**

The CSI Office concludes that the Board should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Delegation of Micro needling

DATE: June 4, 2020

The question presented is whether micro needling is a medical procedure or a task which physicians may delegate micro needling to unlicensed individuals under the Board’s delegation rules. This question came up after the Cosmetology Board responded to an attorney that while licensed cosmetologists and estheticians are prohibited from providing micro needling services under Rules 4713-8-03 and 4731-8-04, it is possible that they could act as unlicensed individuals and perform micro needling under the supervision of a physician.

In 2018, the FDA approved a micro needling device for aesthetic use into class II (special controls). See attached. A class II device requires specific controls as follows:

If general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use. 21 CFR Part 878.

The Cosmetology Board has recently clarified that micro needling is excluded from the scope of practice of cosmetologists and estheticians. See Rules 4713-8-03 and 4731-8-04, OAC. The Cosmetology Board has provided information that it is possible that micro needling could be delegated to unlicensed individuals, including cosmetologists and estheticians acting as unlicensed individuals, if the individuals are supervised by a physician. Historically, the Medical Board has indicated that micro needling is a medical procedure which cannot be delegated to unlicensed individuals under the Board’s delegation rules. See, 4731-23, OAC.

The question for the Board becomes whether micro needling is a procedure or a task. Rule 4731-23-01(E) defines a medical task as a routine medical service not requiring the special skills of a licensed provider. Rule 4731-23-02(B) states that prior to a physician’s delegation of the performance of a medical task, that physician shall determine each of the following:

(1) That the task is within that physician’s authority;
(2) That the task is indicated for the patient;
(3) The appropriate level of supervision;
(4) That no law prohibits the delegation;
(5) That the person to whom the task will be delegated is competent to perform that task;
(6) That the task itself is one that should be appropriately delegated when considering the following factors:

   (a) That the task can be performed without requiring the exercise of judgment based on medical knowledge;
   (b) That the results of the task are reasonably predictable;
   (c) That the task can safely be performed according to exact, unchanging directions;
   (d) That the task can be performed without a need for complex observations or critical decisions;
   (e) That the task can be performed without repeated medical assessments; and
   (f) That the task, if performed improperly, would not present life threatening consequences or the danger of immediate and serious harm to the patient.

I consulted with Dr. Bechtel on this issue since his area of specialty is dermatology. He indicated that micro needling pierces deeply into dermal tissues and there are several risks in the procedure, including a risk of infection, scarring, nerve injury, and transmittal of blood-borne pathogens if the equipment is not properly cleaned.

**Action Requested: Discussion on this issue and whether micro needling is a medical procedure or a medical task which may be delegated to unlicensed individuals.**
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 878
[Docket No. FDA–2018–N–1900]
Medical Devices; General and Plastic Surgery Devices; Classification of the Microneedling Device for Aesthetic Use
AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the microneedling device for aesthetic use into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the microneedling device for aesthetic use’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 8, 2018. The classification was applicable on March 1, 2018.


SUPPLEMENTARY INFORMATION:
I. Background
Upon request, FDA has classified the microneedling device for aesthetic use as class II (special controls), which we
have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

### II. De Novo Classification

On July 5, 2016, Bellus Medical, LLC, submitted a request for De Novo classification of the SkinPen Precision System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 1, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4430. We have named the generic type of device microneedling device for aesthetic use, and it is identified as a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

### TABLE 1—MICRONEEDLING DEVICE FOR AESTHETIC USE RISKS AND MITIGATION MEASURES

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
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<tbody>
<tr>
<td>Adverse tissue reaction</td>
<td>Biocompatibility evaluation and Labeling.</td>
</tr>
<tr>
<td>Cross-contamination and infection</td>
<td>Sterilization validation, Reprocessing validation, Non-clinical performance testing, Shelf life testing, and Labeling.</td>
</tr>
<tr>
<td>Electrical shock or electromagnetic interference with other devices</td>
<td>Electromagnetic compatibility testing, Electrical safety testing, and Labeling.</td>
</tr>
<tr>
<td>Damage to underlying tissue including nerves and blood vessels, scarring, and hyper/hypopigmentation due to:</td>
<td>Non-clinical performance testing, Technological characteristics, Shelf life testing, Labeling, and Software verification, validation, and hazard analysis.</td>
</tr>
<tr>
<td>• Exceeding safe penetration depth</td>
<td></td>
</tr>
<tr>
<td>• Mechanical failure</td>
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<tr>
<td>• Software malfunction</td>
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</tbody>
</table>

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final
order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

§ 878.4430 Microneedling device for aesthetic use.

(a) Identification. A microneedling device for aesthetic use is a device using one or more needles to mechanically puncture and injure skin tissue for aesthetic use. This classification does not include devices intended for transdermal delivery of topical products such as cosmetics, drugs, or biologics.

(b) Classification. Class II (special controls). The special controls for this device are:

1. The technical specifications and needle characteristics must be identified, including needle length, geometry, maximum penetration depth, and puncture rate.

2. Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

   (i) Accuracy of needle penetration depth and puncture rate;

   (ii) Safety features built into the device to protect against cross-contamination, including fluid ingress protection; and

   (iii) Identification of the maximum safe needle penetration depth for the device for the labeled indications for use.

3. Performance data must demonstrate the sterility of the patient-contacting components of the device.

4. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life.

5. Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of all electrical components of the device.

6. Software verification, validation, and hazard analysis must be performed for all software components of the device.

7. The patient-contacting components of the device must be demonstrated to be biocompatible.

8. Performance data must validate the cleaning and disinfection instructions for reusable components of the device.

9. Labeling must include the following:

   (i) Information on how to operate the device and its components and the typical course of treatment;

   (ii) A summary of the device technical parameters, including needle length, needle geometry, maximum penetration depth, and puncture rate;

   (iii) Validated methods and instructions for reprocessing of any reusable components;

   (iv) Disposal instructions; and

   (v) A shelf life.

10. Patient labeling must be provided and must include:

   (i) Information on how the device operates and the typical course of treatment;

   (ii) The probable risks and benefits associated with use of the device; and

   (iii) Postoperative care instructions.

Dated: June 4, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[PR Doc. 2018–12335 Filed 6–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2018–N–1863]

Medical Devices; Orthopedic Devices; Classification of the In Vivo Cured Intramedullary Fixation Rod

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the in vivo cured intramedullary fixation rod into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the in vivo cured intramedullary fixation rod’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 8, 2018. The classification was applicable on December 19, 2017.

FOR FURTHER INFORMATION CONTACT: Peter Allen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1512, Silver Spring, MD 20993–0002, 301–796–6402, Peter.Allen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the in vivo cured intramedullary fixation rod as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by
(A) A cosmetologist shall provide cosmetology services within a salon where the license is current, active, and appropriate to the scope of practice of cosmetology for a cosmetologist as set forth in section 4713.01 of the Revised Code and the rules of the board.

(B) A cosmetologist shall maintain knowledge of the duties, responsibilities, and accountabilities of practice and shall practice in accordance with the following:

1. The laws regulating the practice of cosmetology;
2. The rules of the board;
3. Any other applicable federal, state, and local laws and rules; and
4. Position statements, standards for practice, or guidelines for practice from nationally recognized professional cosmetology entities; provided these statements, standards, or guidelines are consistent with existing laws or rules.

(C) A cosmetologist shall demonstrate competence and accountability in all areas of practice in which the cosmetologist is engaged which includes, but is not limited to, the following:

1. Consistent performance of all aspects of cosmetology services according to acceptable and prevailing standards,
2. Appropriate recognition, referral or consultation, and intervention, when a complication arises during or after the performance of a specific service or procedure;
3. The cosmetologist demonstrates appropriate knowledge, skills, and abilities to provide the cosmetology service, and
4. The cosmetology service does not involve a function or procedure, which is prohibited by any other law or rule and does not exceed the definition of the practice of cosmetology in section 4713.01 of the Revised Code.

(D) Cosmetologists shall not provide any service that claims to have a medical or healing benefit. The scope of practice is limited to beautification, relaxation, and non-invasive services only. The term "therapy" shall only be used for services described in paragraph (PP) of rule 4713-1-01 of the Administrative Code.
(E) Cosmetologists may exfoliate stratum corneum cells only. With proper training, cosmetologists may use any chemical, mechanical or electrical service to exfoliate cells of the stratum corneum.

(F) Cosmetologists may use a sterile, single-use, disposable lancet to enhance the opening in a comedo or to create a small opening in the dead surface corneum to facilitate extraction of a milia. Cosmetologists shall not pierce the stratum corneum or use a lancet for any other purpose. Cosmetologists shall not perform a comedo enhancement or milia extraction with a lancet unless they have had specific, documented training for the procedure. Used lancets shall be immediately disposed of in a sharps disposal container.

(G) Licensees using a device, equipment, chemical, or a product shall comply with the manufacturers' directions when using the device, equipment, chemical, or product;

(H) Cosmetologists working under the direct supervision of a licensed physician shall provide only services within their scope of practice as set forth in Chapter 4713. of the Revised Code and the rules promulgated thereunder.

(I) Chemical peels performed by a cosmetologist shall be mixed and used at an ingredient concentration of thirty per cent solution or less at final formulation with a pH value not less than three, unless all of the following conditions are met:

1. The chemical peel preparation is a commercially available product approved for use by cosmetologists and/or estheticians;

2. The licensee can provide documentation from the manufacturer that the specific product does not penetrate below the stratum corneum when used as directed;

3. The licensee can provide documentation of training and/or certification in the use of the product;

4. The licensee follows all manufacturer's directions in the use of the chemical peel preparation; and

5. The preparation is stored according to the manufacturer's specifications and is discarded after its expiration date.

(J) Cosmetologists shall not provide services using any device that produces or amplifies electromagnetic radiation at wavelengths equal to or greater than one hundred eighty nanometers.
(K) Cosmetologists shall not provide services that ablate, damage, or alter any living cells. This includes, but is not limited to, cryosculpting/coolsculpting, removal of skin tags, moles, or angiomas, microneedling, and plasma/fibroblast skin tightening.

(L) A license in cosmetology supersedes the licenses of any branch of cosmetology, and an individual shall surrender all branch licenses to the board when the board issues the individual a cosmetology license, with the exception of an esthetician license, which may be held simultaneously with the cosmetology license.
Standards relating to competent practice as an esthetician.

(A) An esthetician shall provide cosmetology services within a salon where the license is current, active, and appropriate to the scope of practice of esthetics for an esthetician as set forth in section 4713.01 of the Revised Code and the rules of the board.

(B) An esthetician shall maintain knowledge of the duties, responsibilities, and accountabilities of practice and shall practice in accordance with the following:

1. The laws regulating the practice of esthetics;

2. The rules of the board;

3. Any other applicable federal, state, and local laws and rules; and

4. Position statements, standards for practice, or guidelines for practice from nationally recognized professional esthetic entities; provided these statements, standards, or guidelines are consistent with existing laws or rules.

(C) An esthetician shall demonstrate competence and accountability in all areas of practice in which the esthetician is engaged which includes, but is not limited to, the following:

1. Consistent performance of all aspects of esthetic services according to acceptable and prevailing standards;

2. Appropriate recognition, referral or consultation, and intervention, when a complication arises during or after the performance of a specific service or procedure;

3. The esthetician demonstrates appropriate knowledge, skills, and abilities to provide the cosmetology service, and

4. The esthetician service does not involve a function or procedure, which is prohibited by any other law or rule and does not exceed the definition of the practice of esthetics in section 4713.01 of the Revised Code.

(D) Estheticians shall not provide any service that claims to have a medical or healing benefit. The scope of practice is limited to beautification, relaxation, and non-invasive services only. The term "therapy" shall only be used for services described in paragraph (PP) of rule 4713-1-01 of the Administrative Code.
(E) Estheticians may exfoliate stratum corneum cells only. They may use any chemical, mechanical or electrical service to exfoliate cells of the stratum corneum.

(F) Estheticians may use a sterile, single-use, disposable lancet to enhance the opening in a comedo or to create a small opening in the dead surface corneum to facilitate extraction of a milia. Estheticians shall not pierce the stratum corneum or use a lancet for any other purpose. Estheticians shall not perform a comedo enhancement or milia extraction with a lancet unless they have had specific, documented training for the procedure. Used lancets shall be immediately disposed of in a sharps disposal container.

(G) Estheticians working under the direct supervision of a licensed physician shall only provide services within their scope of practice as set forth in Chapter 4713. of the Revised Code and the rules promulgated thereunder.

(H) Chemical peels performed by an esthetician shall be mixed and used at an ingredient concentration of thirty per cent solution or less at final formulation with a pH value not less than three, unless all of the following conditions are met:

1. The chemical peel preparation is a commercially available product approved for use by cosmetologists and/or estheticians;

2. The licensee can provide documentation from the manufacturer that the specific product does not penetrate below the stratum corneum when used as directed;

3. The licensee can provide documentation of training and/or certification in the use of the product;

4. The licensee follows all manufacturer's directions in the use of the chemical peel preparation; and

5. The preparation is stored according to the manufacturer's specifications and is discarded after its expiration date.

(I) Estheticians shall not provide services using any device that produces or amplifies electromagnetic radiation at wavelengths equal to or greater than one hundred eighty nanometers.

(J) Estheticians shall not provide services that ablate, damage, or alter any living cells. This includes, but is not limited to, cryosculpting/coolsculpting, removal of skin tags, moles, or angiomas, microneedling, and plasma/fibroblast skin tightening.
Chapter 4731-23 Delegation of Medical Tasks

4731-23-01 Definitions.

As used in Chapter 4731-23 of the Administrative Code:

(A) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means to a person.

(B) "Delegate" means to transfer authority for the performance of a medical task to an unlicensed person.

(C) "On-site supervision" means that the physical presence of the physician is required in the same location (e.g., the physician's office suite) as the unlicensed person to whom the medical task has been delegated while the medical task is being performed. "On-site supervision" does not require the physician's presence in the same room.

(D) "Physician" means an individual authorized by Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.

(E) "Task" includes, but is not limited to, a routine medical service not requiring the special skills of a licensed provider.

(F) "Unlicensed person" means an individual who is not licensed or otherwise specifically authorized by the Revised Code to perform the delegated medical task.

(G) "Drug" means the same as in division (E) of section 4729.01 of the Revised Code.

Effective: 11/30/2016
Five Year Review (FYR) Dates: 08/16/2016 and 11/30/2021
Promulgated Under: 119.03
Statutory Authority: 4731.05, 4731.053
Rule Amplies: 4731.053, 4731.22, 4731.34
Prior Effective Dates: 9/30/01

4731-23-02 Delegation of medical tasks.

(A) A physician shall not delegate the performance of a medical task unless that physician has complied with all of the requirements of this chapter of the Administrative Code and the delegation otherwise conforms to minimal standards of care of similar physicians under the same or similar circumstances.

(B) Prior to a physician's delegation of the performance of a medical task, that physician shall determine each of the following:

1. That the task is within that physician's authority;

2. That the task is indicated for the patient;

3. The appropriate level of supervision;

4. That no law prohibits the delegation;

5. That the person to whom the task will be delegated is competent to perform that task; and,

6. That the task itself is one that should be appropriately delegated when considering the following factors:

   a. That the task can be performed without requiring the exercise of judgment based on medical knowledge;
(b) That results of the task are reasonably predictable;

(c) That the task can safely be performed according to exact, unchanging directions;

(d) That the task can be performed without a need for complex observations or critical decisions;

(e) That the task can be performed without repeated medical assessments; and,

(f) That the task, if performed improperly, would not present life threatening consequences or the danger of immediate and serious harm to the patient.

(C) When a physician delegates the administration of drugs, that physician shall provide on-site supervision, except in the following situations:

(1) When the physician has transferred responsibility for the on-site supervision of the unlicensed person who is administering the drug to another physician and that physician has knowingly accepted that responsibility on a patient-by-patient basis; or

(2) In the routine administration of a topical drug, such as a medicated shampoo.

(3) When delegation occurs pursuant to section 5126.36 of the Revised Code within the programs and services offered by a county board of developmental disabilities.

(4) When delegation occurs pursuant to section 5123.42 of the Revised Code.

(5) When written policies and procedures have been adopted for the distribution of drugs by an unlicensed person to individuals incarcerated in state correctional institutions as defined in division (A) of section 2796.01 of the Revised Code, other correctional facilities including county and municipal jails, workhouses, minimum security jails, halfway houses, community residential centers, regional jails and multi-county jails, or any other detention facility as defined in division (F) of section 2921.01 of the Revised Code.

(D) This chapter of the Administrative Code shall not apply if the rules contained herein:

(1) Prevent an individual from engaging in an activity performed for a handicapped child as a service needed to meet the educational needs of the child, as identified in the individualized education program developed for the child under Chapter 3323. of the Revised Code;

(2) Prevent delegation from occurring pursuant to section 5126.36 of the Revised Code within the programs and services offered by a county board of developmental disabilities;

(3) Conflict with any provision of the Revised Code that specifically authorizes an individual to perform a particular task;

(4) Conflict with any rule adopted pursuant to the Revised Code that is in effect on the effective date of this section, as long as the rule remains in effect, specifically authorizing an individual to perform a particular task;

(5) Prohibit a perfusionist from administering drugs intravenously while practicing as a perfusionist.

Effective: 11/30/2016
Five Year Review (FYR) Dates: 08/16/2016 and 11/30/2021
Promulgated Under: 119.03
Statutory Authority: 4731.05, 4731.053
Rule Amplies: 4731.22, 4731.053, 4731.34
Prior Effective Dates: 9/30/01, 5/31/02

4731-23-03 Delegation of medical tasks; Prohibitions.
(A) A physician shall not delegate the practice of medicine as defined in section 4731.34 of the Revised Code unless specifically authorized to do so in the Revised Code or by an administrative rule adopted pursuant to the Revised Code and which became effective prior to April 10, 2001. Nothing in this chapter of the Administrative Code shall prohibit the performance of emergency medical tasks.

(B) A physician shall not delegate a task to an unlicensed person if the task is beyond that person's competence. In a hospital, as defined in section 3727.01 of the Revised Code, or an ambulatory care center affiliated with the hospital (if the center meets the same credentialing, quality assurance, and utilization review standards as the hospital) wherein unlicensed persons are employed or otherwise authorized by the governing authority of the institution to perform specific medical tasks, one factor the physician shall take into account is the policies by which the employer or the governing authority of the institution seeks to ensure that competent persons will be performing the delegated tasks.

(C) A physician shall not delegate a medical task that is not within the authority of that physician or is beyond the physician's training, expertise, or normal course of practice.

(D) A physician shall not transfer his or her responsibility for supervising an unlicensed person in the performance of a delegated medical task, except to another physician who has knowingly accepted that responsibility.

(E) A physician shall not authorize or permit an unlicensed person to whom a medical task is delegated to delegate the performance of that task to another person.

(F) Except as provided in divisions (D)(4) to (D)(8) of section 4731.053 of the Revised Code, a physician shall not delegate to an unlicensed person the administration of anesthesia, controlled substances, or drugs administered intravenously.

(G) The supervising physician retains responsibility for the manner in which the delegated task is carried out.

Five Year Review (FYR) Dates: 08/17/2016 and 08/17/2021
Promulgated Under: 119.03
Statutory Authority: 4731.05, 4731.053
Rule Amplifies: 4731.22, 4731.34
Prior Effective Dates: 9/30/01, 5/31/02

4731-23-04 Violations.

(A) A violation of any provision of any rule in this chapter of the Administrative Code, as determined by the board, 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.

(B) A violation of any provision of any rule in this chapter of the Administrative Code that pertains to the administration of drugs, as determined by the board, shall constitute "failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code.

Five Year Review (FYR) Dates: 08/17/2016 and 08/17/2021
Promulgated Under: 119.03
Statutory Authority: 4731.05, 4731.053
Rule Amplifies: 4731.22, 4731.34
Prior Effective Dates: 9/30/01
Kim,

Just FYI.

Sincerely,

Charley L. Yaniko
Administrative Compliance Manager/Agency Counsel
Ohio State Cosmetology and Barber Board
Direct: (614) 644-6511

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Eric,

I’m doing well. I hope things are the same on your end. The new language for Ohio Adm.Code 4713-8-03 and 4713-8-04 (which took effect today) does not change my prior position that cosmetologists/estheticians working under a licensed physician, but not holding themselves out as practicing under their cosmetologist/esthetician license, are governed by the medical delegation rules. That being said, I would suggest, to be on the safe side, that you consult with counsel for the State Medical Board of Ohio on the scope of a physician’s delegation authority. It’s my understanding, based on conversations with their counsel over the past several years, that certain services that many physicians may consider to be delegable medical tasks (such as micro-needling) are actually non-delegable medical procedures. I received input from the Medical Board during the drafting and promulgation of these rules, and I know that they consider all of the specific services
listed in the rules to be part of the practice of medicine.

I hope this is helpful. Please let me know if you have any questions or need any additional information.

Sincerely,

Charley L. Yaniko
Administrative Compliance Manager/Agency Counsel
Ohio State Cosmetology and Barber Board
Direct: (614) 644-6511

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From: Plinke, Eric <eric.plinke@dinsmore.com>
Sent: Wednesday, December 18, 2019 4:55 PM
To: Yaniko, Charley <Charley.Yaniko@cos.ohio.gov>
Subject: Proposed rule

Charley, I hope you are well. We spoke a few years back on persons trained and licensed as estheticians working under a physician’s supervision and the Medical Board delegation rule relative to the performance of certain tasks, including micro-needling. You sent me the attached email then that was helpful in resolving some questions I had from clients. I have recently received the information also attached re the proposed rule amendment to OAC 4713-8-03. In reviewing this I noted that the commentary was that this was intended to be a clarification. Can you tell me what impact this would have on services being provided under the physician delegation rule? Does this change the prior position on that for the performance of some of these services mentioned in this memo? Thank you for your time and I look forward to your response.
Thanks,
Eric
MEMORANDUM

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

FROM: Stephanie Loucka, Executive Director

RE: House Bill 679, Telehealth

DATE: June 10, 2020

House Bill 679 was recently introduced and had its second hearing on June 3rd.

Your board materials include an attorney-client privilege memo that analyzes specific considerations for the Board.

As we have discussions with legislators, Board staff requests guidance on the following points in the bill:

- The current legislation only references video for telehealth. Would the Board like to propose additional telehealth delivery means?

- Is the Board comfortable with the out of state provisions (allowing broad delivery)?

- R.C. 4743.09 focuses on the general logistics of telehealth services without specific requirements for special situations which impact public health such as prescribing, recommending medical marijuana, and office based opioid treatment. Will the Board want to more narrowly define requirements or want ability for rule-making surrounding this?

- The Board may have limited ability to set requirements in rule on standard of care due to the limitations. Does the board want specific rule making authority or standards in statute?

- Are the one initial in person visit and at least one in person visit per year requirements adequate for the Board?
To: Members of the Ohio House Insurance Committee

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

Da: June 2, 2020

Re: HB 679

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

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

**Lines 82-84**

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

**Lines 89-94**

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

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

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

**Lines 223-225**

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

**Lines 240 – 242**

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

**Lines 244-246**

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

**Line 267 – 281**

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

**Lines 324-327**

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

**Lines 447 – 479**

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

We would be remiss not to mention reimbursement parity for telehealth services, which has been one of our highest priorities in the efforts to facilitate telehealth access. OSMA continues to strongly
encourage that health plans be required to reimburse health care professionals for telehealth services at the same rate as in-person services. Provided that such services are clinically appropriate to be delivered via telehealth, these services should be reimbursed at the same level as they would be reimbursed if delivered in-person. This would be a strong tool to empower more widespread utilization of telehealth across the state.

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

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

To amend sections 3902.30, 4723.94, 4732.33, 5123.60, and 5164.95; to amend, for the purpose of adopting a new section number as indicated in parentheses, section 4731.2910 (4743.09); and to enact sections 3721.60, 4730.60, 4753.20, 4755.90, 4757.50, 4758.80, 4759.20, 5119.368, and 5123.603 of the Revised Code to establish and modify requirements regarding the provision of telehealth services and to declare an emergency.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3902.30, 4723.94, 4732.33, 5123.60, and 5164.95 be amended; section 4731.2910 (4743.09) be amended for the purpose of adopting a new section number as indicated in parentheses; and sections 3721.60, 4730.60, 4753.20, 4755.90, 4757.50, 4758.80, 4759.20, 5119.368, and 5123.603 of the Revised Code be enacted to read as follows:

Sec. 3721.60. (A) As used in this section, "long-term care facility" means all of the following:
(1) A home, as defined in section 3721.10 of the Revised Code;

(2) A residential facility licensed by the department of mental health and addiction services under section 5119.34 of the Revised Code;

(3) A residential facility licensed by the department of developmental disabilities under section 5123.19 of the Revised Code;

(4) A facility operated by a hospice care program licensed by the department of health under Chapter 3712. of the Revised Code that is used exclusively for care of hospice patients.

(B) During any declared disaster, epidemic, pandemic, public health emergency, or public safety emergency, each long-term care facility shall provide residents and their families with a video-conference visitation option if the governor, the director of health, other government official or entity, or the long-term care facility determines that allowing in-person visits at the facility would create a risk to the health of the residents.

Sec. 3902.30. (A) As used in this section:

(1) "Cost-sharing" means the cost to a covered individual under a health benefit plan according to any coverage limit, copayment, coinsurance, deductible, or other out-of-pocket expense requirements imposed by the plan.

(2) "Health benefit plan," "health care services," and "health plan issuer" have the same meanings as in section 3922.01 of the Revised Code.

(3) "Health care professional" means any of the
following:

(a) A physician licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(b) A physician assistant licensed under Chapter 4731. of the Revised Code;

(c) An advanced practice registered nurse as defined in section 4723.01 of the Revised Code.

(3) "In-person health care services" means health care services delivered by a health care professional through the use of any communication method where the professional and patient are simultaneously present in the same geographic location.

(4) "Recipient" means a patient receiving health care services or a health care professional with whom the provider of health care services is consulting regarding the patient.

(5) "Telemedicine services" means a mode of providing health care services through synchronous or asynchronous information and communication technology by a health care professional, within the professional's scope of practice, who is located at a site other than the site where the recipient is located.

(B)(1) A health benefit plan shall provide coverage for telemedicine services on the same basis and to the same extent that the plan provides coverage for the provision of in-person health care services.

(2) A health benefit plan shall not exclude coverage for a service solely because it is provided as a telemedicine service.
(C) A health benefit plan shall not impose any annual or lifetime benefit maximum in relation to telemedicine services other than such a benefit maximum imposed on all benefits offered under the plan.

(D) A health plan issuer may impose cost-sharing requirements with regard to telehealth services in accordance with both of the following:

(1) A health benefit plan shall not impose a cost-sharing requirement for telehealth services provided via telephone or electronic mail.

(2) A health benefit plan shall not impose a cost-sharing requirement for telehealth services that exceeds the cost-sharing requirement for comparable in-person health care services.

(E) Telehealth services provided by electronic mail or telephone shall be tallied using the minutes spent per patient on a running total. Health plan issuers shall reimburse providers for a block of time spent on such services that is equivalent to the standard amount of time spent on a telehealth service.

(F) This section shall not be construed as doing any of the following:

(1) Prohibiting a health benefit plan from assessing cost-sharing requirements to a covered individual for telemedicine services, provided that such cost sharing requirements for telemedicine services are not greater than those for comparable in-person health care services;

(2) Requiring a health plan issuer to reimburse a health care professional for any costs or fees associated with the
provision of telemedicine-telehealth services that would be in addition to or greater than the standard reimbursement for comparable in-person health care services;

(3) Requiring a health plan issuer to reimburse a telemedicine-telehealth provider for telemedicine-telehealth services at the same rate as in-person services.

(E) This section applies to all health benefit plans issued, offered, or renewed on or after January 1, 2021.

(G) Except as provided in division (D) of this section, coverage for telehealth services shall be provided on the same terms and the same basis as in-person health care services.

(H) The superintendent of insurance may adopt rules in accordance with Chapter 119. of the Revised Code as necessary to carry out the requirements of this section. Any such rules shall be exempted from the requirements of division (F) of section 121.95 of the Revised Code.

Sec. 4723.94. (A) As used in this section:

(1) "Facility fee" means any fee charged or billed for telemedicine services provided in a facility that is intended to compensate the facility for its operational expenses and is separate and distinct from a professional fee.

(2) "Health plan issuer" has the same meaning as in section 3922.01 of the Revised Code.

(3) "Telemedicine services" has the same meaning as in section 3902.30 of the Revised Code.

(B) An advanced practice registered nurse providing telemedicine may provide telehealth services shall not charge a facility fee, an origination fee, or any fee associated with the
cost of the equipment used to provide telemedicine services to a health plan issuer covering telemedicine services under in accordance with section 4902.30–4743.09 of the Revised Code.

Sec. 4730.60. A physician assistant may provide telehealth services in accordance with section 4743.09 of the Revised Code.

Sec. 4732.33. (A) The state board of psychology shall adopt rules governing the use of telepsychology for the purpose of protecting the welfare of recipients of telepsychology services and establishing requirements for the responsible use of telepsychology in the practice of psychology and school psychology, including supervision of persons registered with the state board of psychology as described in division (B) of section 4732.22 of the Revised Code. The rules shall be consistent with section 4743.09 of the Revised Code.

(B) A psychologist or school psychologist may provide telehealth services in accordance with section 4743.09 of the Revised Code.

Sec. 4731.2910 4743.09. (A) As used in this section:

(1) "Facility fee" has the same meaning as in section 4723.94 of the Revised Code means any fee charged or billed for telehealth services provided in a facility that is intended to compensate the facility for its operational expenses and is separate and distinct from a professional fee.

(2) "Health care professional" means:

(a) An advanced practice registered nurse, as defined in section 4723.01 of the Revised Code;

(b) A physician assistant licensed under Chapter 4730. of the Revised Code;
(c) A physician licensed under this chapter to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(b) A physician assistant licensed under Chapter 4730.

(d) A psychologist or school psychologist licensed under Chapter 4732. of the Revised Code;

(e) An audiologist or speech-language pathologist licensed under Chapter 4753. of the Revised Code;

(f) An occupational therapist or physical therapist licensed under Chapter 4755. of the Revised Code;

(g) A professional clinical counselor, independent social worker, or independent marriage and family therapist licensed under Chapter 4757. of the Revised Code;

(h) An independent chemical dependency counselor licensed under Chapter 4758. of the Revised Code;

(i) A dietitian licensed under Chapter 4759. of the Revised Code.

(3) "Health care professional licensing board" means any of the following:

(a) The board of nursing;

(b) The state medical board;

(c) The state board of psychology;

(d) The state speech and hearing professionals board;

(e) The Ohio occupational therapy, physical therapy, and athletic trainers board;

(f) The counselor, social worker, and marriage and family
therapist board;

(g) The chemical dependency professionals board.

(4) "Health plan issuer" has the same meaning as in
section 3922.01 of the Revised Code.

(4) (5) "Telemedicine—Telehealth services" has the same
meaning as in section 3902.30 of the Revised Code.

(B) Each health care professional licensing board shall
permit a health care professional under its jurisdiction to
provide the professional's services as telehealth services in
accordance with this section. The board may adopt any rules it
considers necessary to implement this section. The rules shall
be adopted in accordance with Chapter 119. of the Revised Code.

(C) With respect to the provision of telehealth services,
all of the following apply:

(1) A health care professional shall conduct an initial
in-person visit with a patient before providing telehealth
services to the patient, except that the professional may waive
this requirement if the professional determines that a situation
is critical and an in-person visit is not practical.

(2) A health care professional may deny a patient
telehealth services and, instead, require the patient to undergo
an in-person visit.

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

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

(a) The professional may provide telehealth services to a patient located outside of this state if permitted by the laws of the state in which the patient is located.

(b) The professional may provide telehealth services through the use of medical devices that enable remote monitoring, including such activities as monitoring a patient's blood pressure, heart rate, or glucose level.

(D) When a patient has consented to receiving telehealth services, the health care professional who provides those services is not liable in damages under any claim made on the basis that the services do not meet the same standard of care that would apply if the services were provided in-person.

(E)(1) A health care professional providing telemedicine telehealth services shall not charge a health plan issuer covering telehealth services under section 3902.30 of the Revised Code any of the following: a facility fee, an origination fee, a fee associated with the administrative costs incurred in providing telehealth services, or any fee associated with the cost of the equipment used to provide telemedicine telehealth services to a health plan issuer covering
telemedicine services under section 3902.30 of the Revised Code.

(2) A health care professional providing telehealth services is not required to receive a patient's consent before billing for the cost of providing the services.

(F) Nothing in this section eliminates or modifies any other provision of the Revised Code that requires a health care professional who is not a physician to practice under the supervision of, in collaboration with, in consultation with, or pursuant to the referral of another health care professional.

Sec. 4753.20. An audiologist or speech-language pathologist may provide telehealth services in accordance with section 4743.09 of the Revised Code.

Sec. 4755.90. An occupational therapist or physical therapist may provide telehealth services in accordance with section 4743.09 of the Revised Code.

Sec. 4757.50. A professional clinical counselor, independent social worker, or independent marriage and family therapist may provide telehealth services in accordance with section 4743.09 of the Revised Code.

Sec. 4758.80. An independent chemical dependency counselor may provide telehealth services in accordance with section 4743.09 of the Revised Code.

Sec. 4759.20. A dietitian may provide telehealth services in accordance with section 4743.09 of the Revised Code.

Sec. 5119.368. (A) As used in this section, "telehealth services" has the same meaning as in section 3902.30 of the Revised Code.

(B) The following services may be provided as telehealth
services and are considered to have been provided on a face-to-face basis:

(1) General services;

(2) Community psychiatric supportive treatment services;

(3) Therapeutic behavioral services and psychosocial rehabilitation services;

(4) Peer recovery services;

(5) Substance use disorder case management services;

(6) Crisis intervention services;

(7) Assertive community treatment services;

(8) Intensive home-based treatment services.

(C) Each provider shall establish a written policy and procedures describing how the provider will ensure that staff assisting clients with receiving telehealth services or providing telehealth services are fully trained in using equipment necessary for providing the services.

(D) Prior to providing telehealth services to a client, a provider shall describe to the client the potential risks associated with receiving treatment through telehealth services and shall document that the client was provided with the risks and agreed to assume those risks. The risks communicated to a client must address the following:

(1) Clinical aspects of receiving treatment through telehealth services;

(2) Security considerations when receiving treatment through telehealth services;
(3) Confidentiality for individual and group counseling.

(E) It is the responsibility of the provider, to the extent possible, to ensure contractually that any entity or individuals involved in the transmission of information through telehealth mechanisms guarantee that the confidentiality of the information is protected.

(F) Every provider shall have a contingency plan for providing telehealth services to clients in the event that technical problems occur during the provision of those services.

(G) Providers shall maintain, at a minimum, the following information pertaining to local resources:

(1) The local suicide prevention hotline, if available, or the national suicide prevention hotline.

(2) Contact information for the local police and fire departments.

The provider shall provide the client written information on how to access assistance in a crisis, including one caused by equipment malfunction or failure.

(H) It is the responsibility of the provider to assure that equipment meets standards sufficient to do the following:

(1) To the extent possible, ensure confidentiality of communication;

(2) Provide for interactive communication between the provider and the client;

(3) Ensure that both picture and audio are sufficient to enable real-time interaction between the client and the provider and to ensure the quality of the service provided.
(I) The client site shall be maintained in such a manner that appropriate staff persons are on hand in the event of a malfunction with the equipment used to provide telehealth services.

(J)(1) All telehealth services provided by interactive videoconferencing shall meet both of the following conditions:

(a) Begin with the verification of the client through a name and password or personal identification number when treatment services are being provided;

(b) Be provided in accordance with state and federal law.

(2) Each provider shall ensure that any username or password information and any electronic communications between the provider and a client are securely transmitted and stored.

(K) The department of mental health and addiction services may adopt rules as it considers necessary to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code. Any such rules are not subject to the requirements of division (F) of section 121.95 of the Revised Code.

Sec. 5123.60. (A) As used in this section and section in sections 5123.601 to 5123.603 of the Revised Code, "Ohio protection and advocacy system" means the nonprofit entity designated by the governor in accordance with Am. Sub. H.B. 153 of the 129th general assembly to serve as the state's protection and advocacy system and client assistance program.

(B) The Ohio protection and advocacy system shall provide both of the following:

(1) Advocacy services for people with disabilities, as


(C) The Ohio protection and advocacy system may establish any guidelines necessary for its operation.

Sec. 5123.603. During any declared disaster, epidemic, pandemic, public health emergency, or public safety emergency, an individual with a developmental disability or any other permanent disability who is in need of surgery or any other health care procedure, any medical or other health care test, or any clinical care visit shall be given the opportunity to have at least one parent or legal guardian present if the presence of the individual's parent or legal guardian is necessary to alleviate any negative reaction that may be experienced by the individual who is the patient.

The Ohio protection and advocacy system may enforce this section.

Sec. 5164.95. (A) As used in this section, "telehealth service" means a health care service delivered to a patient through the use of interactive audio, video, or other telecommunications or electronic technology from a site other than the site where the patient is located.

(B) The department of medicaid shall establish standards for medicaid payments for health care services the department determines are appropriate to be covered by the medicaid program when provided as telehealth services. The standards shall be established in rules adopted under section 5164.02 of the...
In accordance with section 5162.021 of the Revised Code, the medicaid director shall adopt rules authorizing the directors of other state agencies to adopt rules regarding the medicaid coverage of telehealth services under programs administered by the other state agencies. Any such rules adopted by the medicaid director or the directors of other state agencies are not subject to the requirements of division (F) of section 121.95 of the Revised Code.

(C)(1) The following practitioners are eligible to render telehealth services covered pursuant to this section:

(a) A physician licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(b) A psychologist licensed under Chapter 4732. of the Revised Code;

(c) A physician assistant licensed under Chapter 4730. of the Revised Code;

(d) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner licensed under Chapter 4723. of the Revised Code;

(e) An independent social worker, independent marriage and family therapist, or professional clinical counselor licensed under Chapter 4757. of the Revised Code;

(f) An independent chemical dependency counselor licensed under Chapter 4758. of the Revised Code;

(g) A supervised practitioner or supervised trainee;
(h) An audiologist or speech-language pathologist licensed under Chapter 4753. of the Revised Code;

(i) An audiology aide or speech-language pathology aide, as defined in section 4753.072 of the Revised Code, or an individual holding a conditional license under section 4753.071 of the Revised Code;

(j) An occupational therapist or physical therapist licensed under Chapter 4755. of the Revised Code;

(k) An occupational therapy assistant or physical therapist assistant licensed under Chapter 4755. of the Revised Code.

(l) A dietitian licensed under Chapter 4759. of the Revised Code;

(m) A medicaid school program;

(n) Any other practitioner the medicaid director considers eligible to provide the services.

(2) The following provider types are eligible to submit claims for medicaid payments for providing telehealth services:

(a) Any practitioner described in division (B)(1) of this section, except for those described in divisions (B)(1)(g), (i), and (k) of this section;

(b) A professional medical group;

(c) A federally qualified health center or rural health clinic;

(d) An ambulatory health care clinic;

(e) An outpatient hospital;
(f) A medicaid school program;

(g) Any other provider type the medicaid directors considers eligible to submit the claims for payment.

(D)(1) When providing telehealth services under this section, a practitioner shall comply with all requirements under state and federal law regarding the protection of patient information. A practitioner shall ensure that any username or password information and any electronic communications between the practitioner and a patient are securely transmitted and stored.

(2) When providing telehealth services under this section, every practitioner site shall have access to the medical records of the patient at the time telehealth services are provided.

(E) Payment may be made only for the following medically necessary health care services when delivered as telehealth services:

(1) Evaluation and management of a new patient described with medical decision making not to exceed moderate complexity;

(2) Evaluation and management of an established patient described with medical decision making not to exceed moderate complexity;

(3) Inpatient or office consultation for a new or established patient when providing the same quality and timeliness of care to the patient is not possible other than by telehealth;

(4) Mental health or substance use disorder services described as psychiatric diagnostic evaluation or psychotherapy;

(5) Remote evaluation of recorded video or images
submitted by an established patient;

(6) Virtual check-in by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient;

(7) Online digital evaluation and management service for an established patient;

(8) Remote patient monitoring;

(9) Audiology, speech-language pathology, physical therapy, and occupational therapy services;

(10) Medical nutrition services;

(11) Lactation counseling provided by dietitians;

(12) Psychological and neuropsychological testing;

(13) Smoking and tobacco use cessation counseling;

(14) Developmental test administration;

(15) Services provided under the specialized recovery services program;

(16) Any other services designated by the medicaid director.

Section 2. That existing sections 3902.30, 4723.94, 4732.33, 5123.60, 5164.95, and 4731.2910 of the Revised Code are hereby repealed.

Section 3. Section 3902.30 of the Revised Code, as amended by this act, shall apply to health benefit plans, as defined in section 3922.01 of the Revised Code, that are in effect on the effective date of the amendment to that section and to plans that are issued, renewed, modified, or amended on or after the
effective date of that amendment.

**Section 4.** This act is hereby declared to be an emergency measure necessary for the immediate preservation of the public peace, health, and safety. The reason for such necessity is that increased access to and use of telehealth services is vital during the global health emergency related to COVID-19. Therefore, this act shall go into immediate effect.
H.B. 679
133rd General Assembly

Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. Fraizer and A. Holmes

Yosef Schiff, Attorney
Jason Hoskins, Attorney

SUMMARY

Insurance coverage of telehealth services

- Prohibits a health benefit plan from imposing cost sharing for telehealth services provided via telephone or email.
- Requires telehealth services provided via telephone or email to be tallied using minutes spent per patient on a running total and reimbursed for a block of time in a manner equivalent to the standard amount of time spent on a telehealth service.
- Allows the Superintendent of Insurance to adopt rules as necessary to carry out the bill’s provisions governing insurance coverage of telehealth services.

Medicaid coverage of telehealth services

- Provides that specified health care practitioners may provide telehealth services to a patient participating in the Medicaid program and that specified providers are eligible to submit claims to the Ohio Department of Medicaid for payment for telehealth services rendered.
- Establishes requirements that must be satisfied when providing telehealth services to an individual in the Medicaid program.
- Specifies certain telehealth services that are eligible for payment by the Medicaid program.
- Requires the Department to adopt rules authorizing the directors of other state agencies that administer portions of the Medicaid program to adopt rules regarding the provision of telehealth services.
Provision of telehealth services by health care professionals

- Permits specified health care professionals to provide telehealth services.
- Requires telehealth services provided by health care professionals to be done so according to specified conditions and standards.
- Permits certain health care licensing boards to adopt rules as necessary to carry out the bill’s provisions regarding the provision of telehealth services.
- Provides that a health care professional is not liable in damages under a claim that telehealth services provided do not meet the standard of care that would apply if services were provided in-person.
- Prohibits a health care professional from charging a fee associated with the administrative costs of providing telehealth services.

Certified community mental health, addiction service providers

- Permits community mental health service providers and community addiction service providers certified by the Ohio Department of Mental Health and Addiction Services (OhioMHAS) to provide specified services through telehealth.
- Specifies requirements and standards that must be satisfied when telehealth services are provided.
- Permits OhioMHAS to adopt rules necessary to carry out the bill’s provisions.

Video-conference visitation in long-term care facilities

- Specifies that during a declared disaster, epidemic, pandemic, public health emergency, or public safety emergency, long-term care facilities must provide residents and their families with video-conference visitation options.

Assistance at health care appointments

- Provides that during a declared disaster, epidemic, pandemic, public health emergency, or public safety emergency, an individual who with a developmental disability or other permanent disability may have a parent or guardian present during a health care procedure, test, or other care visit.

Emergency

- Declares an emergency.

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DETAILED ANALYSIS

Insurance coverage of telehealth services

The bill prohibits a health benefit plan (a policy, contract, certificate, or agreement offered by a health plan issuer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services) from imposing a cost-sharing requirement for telehealth services (called “telemedicine services” under current law) that are provided via telephone or email.¹

Under the bill, telehealth services that are provided via telephone or email must be tallied using the minutes spent per patient on a running total. A health plan issuer (an entity that contracts to provide or reimburse any of the costs of health care services under a health benefit plan, including a health insuring corporation, sickness and accident insurer, public employee benefit plan, self-funded multiple employer welfare arrangement, or third-party administrator) must reimburse a provider for a block of time spent on such telephone or email services that is equivalent to the standard amount of time spent on a telehealth service.²

¹ R.C. 3902.30(D).
² R.C. 3902.30(E).
The bill allows the Superintendent of Insurance to adopt rules as necessary to carry out the bill’s requirements relating to insurance coverage of telehealth services. These rules are exempted from the continuing requirement that an agency remove two rules for each new rule it implements.³

The telemedicine provisions in current law apply to health benefit plans issued, offered, or renewed on or after January 1, 2021. The bill changes this to apply to all health benefit plans in effect as of the bill’s effective date, and to any health benefit plan issued, renewed, modified, or amended on or after the bill’s effective date (see COMMENT).⁴

Lastly, the bill renames the existing term “telemedicine services” as “telehealth services,” but retains the existing definition: a mode of providing health care services through synchronous or asynchronous information and communication technology by a health care professional (a physician, physician assistant, or advanced practice registered nurse), within the professional’s scope of practice, who is located at a site other than the site where the recipient is located.⁵

**Provision of telehealth services**

**Authorized health care professionals**

The bill specifies that certain health care professionals may provide their services as telehealth services, subject to several requirements. All of the following licensed health care professionals are authorized to provide telehealth services under the bill:⁶

- Advanced practice registered nurses;
- Physician assistants;
- Physicians;
- Psychologists;
- Audiologists and speech-language pathologists;
- Occupational therapists and physical therapists;
- Professional clinical counselors, independent social workers, and independent marriage and family therapists;
- Independent chemical dependency counselors;
- Dietitians.

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³ R.C. 3902.30(H); R.C. 3922.01 and 121.95, not in the bill.
⁴ Section 3 of the bill.
⁵ R.C. 3902.30(A).
⁶ R.C. 4743.09(A)(2); see also R.C. 4723.94, 4730.60, 4732.33, 4753.20, 4755.90, 4757.50, 4758.80, and 4759.20.
A licensing board that has jurisdiction over any of these health care professionals is required to permit the licensed health care professional to provide their services as telehealth services. Each board may adopt rules that it considers necessary for implementing the bill’s provisions as it relates to the provision of telehealth services by a health care professional over which the board has jurisdiction.\(^7\)

**Conditions for providing telehealth services**

The bill establishes several conditions regarding the provision of telehealth services by a health care professional. Each professional must conduct an initial in-person visit with a patient before providing telehealth services, and must conduct at least one in-person visit annually with a patient who receives telehealth services. However, a health care professional may waive either of these requirements if the health care professional determines that a patient’s situation is critical and an in-person visit would not be practical.\(^8\) A health care professional may also deny any patient telehealth services and instead require the patient to undergo an in-person visit.\(^9\)

Telehealth services provided by a health care professional must be provided using secure video capabilities. Additionally, a health care professional providing telehealth services must ensure that any username or password information and electronic communications transmitted between a health care professional and a patient are securely transmitted and stored.\(^10\)

The bill specifies that if a health care professional is a physician, physician assistant, or advanced practice registered nurse, the health care professional may provide telehealth services to a patient located outside of Ohio if the health care professional is permitted to do so by the laws of the state in which the patient is located. Under the bill, these health care professionals may also provide telehealth services through the use of medical devices that enable remote monitoring of a patient.\(^11\)

The bill notes that its provisions do not eliminate or modify any other provisions of the Revised Code that require a health care professional, who is not a physician, to practice under the supervision of, in collaboration with, in consultation with, or pursuant to the referral of another health care professional.\(^12\)

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\(^7\) R.C. 4743.09(B).
\(^8\) R.C. 4743.09(C)(1) and (4).
\(^9\) R.C. 4743.09(C)(2).
\(^10\) R.C. 4743.09(C)(3).
\(^11\) R.C. 4743.09(C)(5).
\(^12\) R.C. 4743.09(F).
Health care professional immunity from liability

Under the bill, when a patient has consented to receiving telehealth services, a health care professional who provides those services to that patient is not liable in damages under any claim made that alleges that the services provided do not meet the same standard of care that would apply if the services were provided in-person.13

Fees and billing

Under existing law, a health care professional (physician, physician assistant, or advanced practice registered nurse) may not charge a facility fee, an origination fee, or any fee associated with the cost of equipment used to provide telehealth services. In addition to these prohibited fees, the bill prohibits any of the health care professionals covered by the bill from charging any of the above-described fees or a fee associated with the administrative costs incurred in the provision of telehealth services. The bill also specifies that a health care professional is not required to obtain a patient’s consent before billing for the cost of the telehealth services provided.14

Medicaid coverage of telehealth services

Rulemaking

Existing law requires the Ohio Department of Medicaid to establish, through rulemaking, standards for Medicaid payments for health care services that the Department determines are appropriate to be covered by the Medicaid program when those services are provided as telehealth services. The bill requires the Department to adopt rules to authorize the directors of other state agencies that administer portions of the Medicaid program to adopt rules regarding Medicaid coverage of telehealth services. These rules are exempted from the continuing requirement that an agency remove two rules for each new rule it implements.15

Eligible providers

For purposes of the Medicaid program, the bill provides that all of the following practitioners are eligible to provide telehealth services:16

- Physicians;
- Psychologists;
- Physician assistants;
- Clinical nurse specialists, certified nurse-midwives, and certified nurse practitioners;

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13 R.C. 4743.09(D).
14 R.C. 4743.09(E). See also existing R.C. 4723.94 and 4731.2910.
15 R.C. 5164.95(B); R.C. 121.95, not in the bill.
16 R.C. 5164.95(C)(1).
Independent social workers, independent marriage and family therapists, and professional clinical counselors;
Independent chemical dependency counselors;
Supervised practitioners and supervised trainees;
Audiologists and speech-language pathologists;
Audiology aides and speech-language pathology aides;
Occupational therapists and physical therapists;
Occupational therapy assistants and physical therapist assistants;
Dietitians;
A Medicaid school program;
Any other practitioner designated by the Medicaid Director.

The bill also specifies the types of providers that are eligible to submit a claim to the Department for payment under the Medicaid program for providing telehealth services:

- Any of the above-identified practitioners, except for a supervised practitioner or supervised trainee, an audiology aide or speech-language pathology aide, and an occupational therapy assistant or physical therapist assistant;
- A professional medical group;
- A federally qualified health center or rural health clinic;
- An ambulatory health care clinic;
- An outpatient hospital;
- A Medicaid school program;
- Any other provider type that the Medicaid Director considers eligible to submit a claim.

As a condition of providing telehealth services under the Medicaid program, the bill requires a practitioner to comply with all state and federal law requirements concerning the protection of patient information. Practitioners must also ensure that any username or password information and electronic communications transmitted between a practitioner and a patient are securely transmitted and stored. Every practitioner site must have access to the medical records of a patient at the time that telehealth services are provided.\(^{17}\)

\(^{17}\) R.C. 5164.95(C)(2).
\(^{18}\) R.C. 5164.95(D).
Medicaid-covered services

The bill provides that the Medicaid program will make payment for only the following services when they are delivered as telehealth services and are considered to be medically necessary: 19

- Evaluation and management of a new patient or established patient described with medical decision making not to exceed moderate complexity;
- Inpatient or office consultation for a new or established patient when providing the same quality and timeliness of care is not possible other than by telehealth;
- Mental health or substance use disorder services described as psychiatric diagnostic evaluation or psychotherapy;
- Remote evaluation of recorded video or images submitted by an established patient;
- Virtual check-in by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient;
- Online digital evaluation and management services for an established patient;
- Remote patient monitoring;
- Audiology, speech-language pathology, physical therapy, and occupational therapy services;
- Medical nutrition services;
- Lactation counseling provided by a dietitian;
- Psychological and neuropsychological testing;
- Smoking and tobacco use cessation counseling;
- Developmental test administration;
- Services provided under the Specialized Recovery Services Program;
- Any other services designated by the Medicaid Director.

Certified community mental health, addiction service providers

Under existing law, the Ohio Department of Mental Health and Addiction Services (OhioMHAS) certifies community mental health service providers and community addiction service providers. 20 The bill specifies that these providers may provide the following services as telehealth services. 21

19 R.C. 5164.95(E).
20 R.C. 5119.36, not in the bill.
21 R.C. 5119.368(B).
• General services;
• Community psychiatric supportive treatment services;
• Therapeutic behavioral services and psychosocial rehabilitative services;
• Peer recovery services;
• Substance use disorder case management services;
• Crisis intervention services;
• Assertive community treatment services;
• Intensive home-based treatment services.

Requirements for providing telehealth services

The bill establishes several requirements that must be satisfied when community mental health service providers and community addiction service providers provide telehealth services. First, each provider must establish a written policy and procedures to ensure that staff who provide telehealth services are fully trained in using the equipment necessary to provide telehealth services. Appropriate staff must be on hand in the event of a malfunction with the equipment used to provide telehealth services. The bill requires providers to establish a contingency plan in the event that technical problems arise during the provision of telehealth services to a client.22

Before providing telehealth services to a client, the bill requires a provider to describe to the client the following potential risks associated with receiving treatment through telehealth: (1) the clinical aspects of receiving treatment through telehealth services, (2) security considerations when receiving treatment through telehealth services, and (3) confidentiality for individual and group counseling. Providers must document that a client has been provided with information regarding these risks and has agreed to assume those risks.23

In addition to the above information, the bill requires that each provider maintain information regarding the local suicide prevention hotline, or the national suicide prevention hotline, as well as the contact information for the local police and fire departments. The bill requires each provider to provide clients with information on how to access assistance in a crisis, including a crisis caused by an equipment malfunction or failure.24

Under the bill, providers have the responsibility to ensure that equipment used to provide telehealth services meets the following standards: (1) confidential communication between provider and client, (2) interactive communication between provider and client, and (3) picture and audio sufficient to enable real-time communication between provider and

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22 R.C. 5119.368(C), (F), and (I).
23 R.C. 5119.368(D).
24 R.C. 5119.368(G).
client.\textsuperscript{25} The bill specifies that it is a provider’s responsibility to ensure that any entity the provider contracts with that is involved in the transmission of information through telehealth does so in a manner that maintains the confidentiality of client information.\textsuperscript{26} Telehealth services that are provided by interactive videoconferencing must (1) begin with the verification of the client through the use of a username and password or personal identification number, and (2) be provided in accordance with state and federal law. The bill requires each provider to ensure that any username or password information and electronic communications transmitted between a provider and a client are securely transmitted and stored.\textsuperscript{27}

### Rulemaking

The bill allows OhioMHAS to adopt rules as necessary to carry out the bill’s requirements. These rules are exempted from the continuing requirement that an agency remove two rules for each new rule it implements.\textsuperscript{28}

### Video-conference visitation in long-term care facilities

The bill specifies that during any declared disaster, epidemic, pandemic, public health emergency, or public safety emergency, every long-term care facility must provide each resident and their family with a video-conference visitation option, if the Governor, the Director of Health, another governmental official or entity, or the long-term care facility itself determines that allowing in-person visits at the facility would create a risk to the health of the facility’s residents. This requirement applies to all of the following types of long-term care facilities: (1) a nursing home, residential care facility, home for the aging, nursing facility, or skilled nursing facility, (2) a residential facility licensed by OhioMHAS, (3) a residential facility licensed by the Ohio Department of Developmental Disabilities, and (4) a facility operated by a hospice care program.\textsuperscript{29}

### Assistance at health care appointments

The bill also specifies that during any declared disaster, epidemic, pandemic, public health emergency, or public safety emergency, any individual with a developmental disability or other permanent disability who is in need of surgery or another health care procedure, a medical or other health care test, or any clinical care visit must have the opportunity to have at least one parent or legal guardian present during the procedure, test, surgery, or other care visit if the parent or legal guardian’s presence is necessary to help alleviate a negative reaction by the individual. The bill designates Disability Rights Ohio, which is the nonprofit corporation

\textsuperscript{25} R.C. 5119.368(H).
\textsuperscript{26} R.C. 5119.368(E).
\textsuperscript{27} R.C. 5119.368(J).
\textsuperscript{28} R.C. 5119.368(K); R.C. 121.95, not in the bill.
\textsuperscript{29} R.C. 3721.60.
serving as Ohio’s protection and advocacy system, as the entity that may enforce this provision.\(^{30}\)

**Effective date**

As an emergency measure, the bill will have an immediate effective date and will not be subject to the referendum.\(^{31}\)

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**COMMENT**

The bill applies its provisions to health benefit plans in effect on the bill’s effective date. This might raise questions under the Contracts Clauses of the U.S. and Ohio Constitutions, which prohibit the General Assembly from enacting laws that impair existing contractual obligations. These prohibitions are not absolute, however. They do not absolutely prevent a state from abridging contractual obligations when exercising its police power and passing laws for the protection of public health, safety, and welfare.

Rather, they prohibit a “substantial” impairment of existing contractual obligations unless the state can *justify the impairment on the basis of an overriding public interest and the impairing measure is appropriately tailored to serve that interest.*\(^{32}\)

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**HISTORY**

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\(^{31}\) Section 4.

MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Position Statement on Signing Death Certificates

DATE: May 28, 2020

Attached is an updated position statement on signing death certificates. The statute and rule cites have been reviewed for accuracy and information from the CDC regarding death certificates related to COVID-19 has been added to the position statement.

Action Requested: Approve Updated Position Statement for filing on the Board’s website.
Regarding the Signing of Death Certificates by the Attending Physician

June 10, 2020

This statement should not be construed as new policy; rather it is an attempt to clarify existing law. Such clarification is intended for the benefit of practitioners and the public as a way to promote better understanding of the laws governing the practice of medicine and regulating the signing of death certificates.

The State Medical Board of Ohio has received numerous inquiries concerning the signing of death certificates by attending physicians. This document clarifies the meaning of “attending physician” for purposes of determining who must sign a death certificate for a person who died under natural circumstances.¹

Pursuant to Section 3705.16(C), Ohio Revised Code (see http://codes.ohio.gov/orc/3705.16v1 ), when an individual dies under natural causes the attending physician is to sign the death certificate within forty-eight hours after the death. The language of Section 3705.16(C), Ohio Revised Code, is as follows:

The funeral director or other person in charge of the final disposition of the remains shall present the death or fetal death certificate to the attending physician of the decedent, the coroner, or the medical examiner, as appropriate for certification of the cause of death. … A physician other than the coroner in the county in which a death or fetal death occurs, or a deputy coroner, medical examiner, or deputy medical examiner serving in an equivalent capacity, may certify only those deaths that occur under natural circumstances.

(Emphasis added to facilitate understanding)

Both “physician” and “attending physician” are defined in Section 3705.01, Ohio Revised Code (see http://codes.ohio.gov/orc/3705.01v1 ) as follows:

(D) “Physician” means a person licensed pursuant to Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(E) “Attending physician” means the physician in charge of the patient’s care for the illness or condition that resulted in death.

By signing a death certificate, the physician is giving a medical opinion as to the cause of death, which is the final act of caring for the patient.² While the attending physician is the physician who was in charge of the patient’s care for the illness or condition that resulted in death, there is no requirement that the attending physician be present at the death. The
attending physician is expected to use medical training, knowledge of medicine, available medical history, symptoms, diagnostic tests, and/or autopsy results to render an opinion on the cause of death.³ “Physicians’ Handbook on Medical Certification of Death,” U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, 2003 Revision, is available at https://www.cdc.gov/nchs/data/misc/hb_cod.pdf

FREQUENTLY ASKED QUESTIONS

1. **May a physician in a graduate medical education program sign a death certificate?**

   a. No, if the physician holds a training certificate.

   b. Yes, if the physician is a fully licensed Ohio physician.

   The physician who holds a training certificate is only authorized to render care under the supervision of an attending physician as part of a training program.⁴ In contrast, the attending physician is a fully licensed physician. Although the training certificate holder renders medical care directly to a patient, the attending physician is responsible for the patient and in charge of the patient’s care. In name and practice, the physician supervising the training certificate holder is the attending physician. Accordingly, upon the death of the patient, the training certificate holder is not the physician in charge of the patient’s care for the illness or condition that resulted in death and is not the appropriate physician to sign the death certificate.

2. **Who is the attending physician for a patient in a long-term care facility?**

   The attending physician for a patient in a long-term care facility may vary according to arrangements. The physician who provided medical care to the patient before admission to the facility may continue as the patient’s physician of record. In contrast, the patient’s care may have been transferred to the facility’s medical director. Whatever the wishes of the patient or guardian and physician, the records maintained by the facility should clearly indicate the name and contact information of the patient’s attending physician.

   A physician who has been serving as the attending physician for a patient in a long-term care facility who wishes to terminate the physician/patient relationship must comply with Rule 4731-27-01(A), Ohio Administrative Code. The requirements include written notice sent by certified mail to the patient or guardian stating that the relationship is terminated, although emergency treatment and access to services will be provided for up to 30 days. The facility should also be notified of the termination of the physician/patient relationship so that accurate information will be on file.

3. **What happens in the event the attending physician has not recently seen the decedent?**

   By signing a death certificate, the physician is giving a medical opinion as to the cause of death, which is the final act of caring for the patient. An attending physician who has not seen the patient for a period of time should apply medical training, knowledge of medicine,
available medical history, symptoms, diagnostic tests and/or autopsy results to render a medical opinion on the cause of death; qualify the etiology by use of words such as “probable” or “presumed” or, as a last resort, state the cause of death as “unknown,” “undetermined,” or “unspecified.” Information on completing the cause of death portion of the death certificate for Covid19 may be obtained from the Centers for Disease Control and Prevention at:

https://www.cdc.gov/nchs/covid19/coding-and-reporting.htm

Endnotes:

1 The county coroner must be called when any person dies as a result of criminal or other violent means, by casualty, by suicide, or in any suspicious or unusual manner, when any person, including a child under two years of age, dies suddenly when in apparent good health, or when any mentally retarded person or developmentally disabled person dies regardless of the circumstances. See Section 313.12, Ohio Revised Code.


4 Section 4731.291(C), ORC, provides: The holder of a valid training certificate shall be entitled to perform such acts as may be prescribed by or incidental to the holder’s internship, residency, or clinical fellowship program, but the holder shall not be entitled otherwise to engage in the practice of medicine and surgery or osteopathic medicine and surgery in this state. The holder shall limit activities under the certificate to the programs of the hospitals or facilities for which the training certificate is issued. The holder shall train only under the supervision of the physicians responsible for supervision as part of the internship, residency, or clinical fellowship program. A training certificate may be revoked by the board upon proof, satisfactory to the board, that the holder thereof has engaged in practice in this state outside the scope of the internship, residency, or clinical fellowship program for which the training certificate has been issued, or upon proof, satisfactory to the board, that the holder thereof has engaged in unethical conduct or that there are grounds for action against the holder under section 4731.22 of the Revised Code.


Approved June 10, 2020
MEMORANDUM

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

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Weight Loss Controlled Substances FAQs

DATE: May 28, 2020

In February 2020, the manufacturer of Belviq announced that it would voluntarily withdraw Belviq from the market and discontinue sales. Information regarding this withdrawal is attached for your review. This change will not affect the Medical Board’s rule language regarding controlled substances for chronic weight management, but question #11 of the Frequently Asked Questions needs to be updated, as follows:

11. Rule 4731-11-04(C)(3) provides that except for specified situations, a physician may not initiate treatment for weight loss with a controlled substance if the patient has received controlled substances for weight loss within the last 6 months. Does this require a six-month pause before switching a patient from Qsymia® or Belviq® to a short-term weight loss drug?

No. Although Qsymia® and Belviq® are controlled substances, they are FDA-approved for chronic weight management instead of weight loss. A patient who has been on Qsymia® or Belviq® another chronic weight management drug may be switched to a short-term weight loss drug without a six-month break.

Action Requested: Approve updates to the FAQs.
FAQ’s regarding short-term weight loss anorexiants

Rule 4731-11-04, Ohio Administrative Code

1. What are short-term anorexiants?

Short-term anorexiants are those medications in Schedule III or IV that are intended to be used for weight-loss purposes and have FDA-approved labeling indicating that they can be used “for a few weeks.”

2. Can I prescribe or dispense short-term anorexiants for longer than 12 weeks in a row?

No. The FDA-approved labeling for most schedule III and IV anorexiants mentions prescribing for “a few weeks”. Ohio Administrative Code (OAC) Rule 4731-11-04(C)(2)(A) clarifies that labeling requirement to mean twelve weeks.

3. Can those 12-weeks use of schedule III and IV short-term anorexiants be interrupted for any reason?

Yes, IF:
- your patient’s illness or injury justifies a temporary cessation of treatment;
- you are unavailable; or
- your patient is unavailable, and your patient notifies you about that unavailability.

4. Can I prescribe schedule III and IV short-term anorexiants off label that I intend be used for weight loss?

No. OAC Rule 4731-11-04(C)(2) requires that schedule III and IV short-term anorexiants used for weight loss can only be employed consistent with FDA labeling.

5. Can I prescribe or dispense a short-term anorexiant during the first patient visit?

It depends. OAC Rule 4731-11-04(B)(1) requires that you do the following prior to beginning treatment with schedule III and IV short-term anorexiants:
- review your own records of any prior treatment of that patient for weight loss;
- review records of any prior treatment by another treating physician or weight-loss program, if available;
- determine that the patient has made a substantial good-faith effort to lose weight without utilizing short-term anorexiants;
- determine that those prior good-faith efforts included caloric restriction, nutritional counseling, behavior modification, and exercise;
- determine that those prior good-faith efforts were ineffective;
- obtain a thorough history;
- perform a thorough physical examination;
- determine that the patient has a body mass index (BMI) of at least 30 or a BMI of at least 27 with comorbid factors;
- determine that there are no signs in the patient of drug or alcohol abuse;
- determine whether there are any contraindications for the use of schedule III or IV short-term anorexiants in the patient;
- determine whether there are any adverse side effects for the use of schedule III or IV short-term anorexiants in the patient; and
- determine that the patient has not used a schedule III or IV short-term anorexiant within the prior six months.

OAC Rule 4731-11-02(D) requires that you document all of the above in the patient record. If you have completed all of the above, then, if appropriate, you may begin prescribing or dispensing schedule III or IV short-term anorexiants.

6. What if my patient has not made a prior substantial good-faith effort to lose weight by caloric restriction, nutritional counseling, behavior modification, and exercise without utilizing schedule III or IV short-term anorexiants? Can I start prescribing or dispensing schedule III or IV short-term anorexiants at the first visit?

No. Your patient must have made a substantial good-faith effort to lose weight by caloric restriction, nutritional counseling, behavior modification, and exercise and that effort must have proved ineffective, before you can prescribe or dispense a schedule III or IV short-term anorexiant.

7. Can I allow my physician assistant to see the patient instead of me after the first visit?

No. OAC Rule 4731-11-04(C)(1) requires that you personally see the patient at least every 30 days.

8. Do I have to document the patient's weight in the chart on every visit related to weight loss?

Yes.

9. Does my patient have to lose weight over every 30-day period that I prescribe or dispense schedule III or IV short-term anorexiants?

No. If your patient fails to lose weight after the first 30-day period, you may, if medically indicated, continue to treat that patient for an additional 30 days by prescribing a different schedule III or IV short-term anorexiant. If the patient loses weight after the switch to a different anorexiant, you may continue to prescribe or dispense that anorexiant month by month IF the patient continues to lose weight every month.

10. Are there any reasons that require me to stop utilizing schedule III or IV short-term anorexiants for treating a patient for weight loss?

Yes. You must stop utilizing schedule III or IV short-term anorexiants to treat a patient IF:
- your patient fails to lose weight at any visit except as described in FAQ number 8 above;
- your patient has a history of, or shows a propensity for, alcohol or drug abuse;
- your patient has made any false or misleading statement to you relating to the patient's use of drugs or alcohol;
- your patient has consumed or disposed of any controlled substance other than in strict compliance with your directions;
- your patient has repeatedly failed to comply with your treatment recommendations;
or
- if you know, or should know, that your patient is pregnant.

11. **Rule 4731-11-04(C)(3) provides that except for specified situations, a physician may not initiate treatment for weight loss with a controlled substance if the patient has received controlled substances for weight loss within the last 6 months. Does this require a six-month pause before switching a patient from Qsymia® or Belviq® to a short-term weight loss drug?**

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*Updated June 10, 2020*
*Updated December 12, 2018*
*Approved March 11, 2015*
Eisai to Voluntarily Withdraw BELVIQ®/BELVIQ XR® in the U.S.

Feb 13, 2020

WOODCLIFF LAKE, N.J., Feb. 13, 2020 /PRNewswire/ -- Eisai Inc. announced that it will voluntarily withdraw from the market and discontinue sales of BELVIQ® (lorcaserin HCl) CIV and BELVIQ XR (lorcaserin HCl) CIV in the U.S. This action is being taken after a request from the U.S. Food and Drug Administration (FDA), based on the Agency's recently completed analysis of data from the CAMELLIA-TIMI 61 trial.

At the time of marketing approval from BELVIQ, the FDA required Eisai to perform a long-term trial evaluating the cardiovascular effects associated with the use of the drug. The CAMELLIA-TIMI 61 trial for lorcaserin was a randomized, double-blind, placebo-controlled clinical trial to study approximately 12,000 men and women over five years with established cardiovascular disease or at high risk for cardiovascular disease. This study was conducted at over 400 sites in eight countries including the U.S. and is the largest cardiovascular outcome trial conducted to date for a weight loss medication. In this trial, lorcaserin facilitated sustained weight loss without a higher rate of major cardiovascular events than that with placebo.

Following its review of the data, FDA concluded that the potential risks of lorcaserin outweigh its benefits. More specifically FDA noted there was a numerical imbalance in the number of patients with malignancies. FDA’s analysis of the study found that during the course of the trial, 462 (7.7 percent) patients treated with lorcaserin were diagnosed with cancers compared to the placebo group, in which 423 (7.1 percent) patients were diagnosed with cancers.
Eisai’s interpretation of the data from the CAMELLIA-TIMI 61 trial differs from that of the FDA. The Company's assessment is that BELVIQ and BELVIQ XR continue to have a positive benefit-risk profile in the patient population for which they are indicated. However, based on the change in FDA’s risk-benefit assessment and as requested by the Agency, Eisai has agreed to voluntarily withdraw the products from the U.S. market. Eisai respects the FDA’s decision and is working closely with the Agency on the withdrawal process.

The [FDA’s February 13, 2020 Drug Safety Communication](https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatients-and-caregivers/ivanoreckonization) advises patients to stop taking BELVIQ and BELVIQ XR and talk to their health care professional about alternative weight-loss medications and weight management programs. The FDA’s Drug Safety Communication includes additional important information for patients and health care providers. Additionally, patients and health care providers with questions can contact Eisai Medical Information at: esi_medinfo@eisai.com or 1-888-274-2378.

As part of our human health care mission and with the goal of bringing new options to patients who are obese or overweight with weight-related medical conditions, Eisai made BELVIQ and BELVIQ XR available in the U.S. BELVIQ was approved in June 2012 by the FDA as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related co-morbid condition, and was launched in the United States in June 2013. Prior to and following market approval of BELVIQ, the product has been evaluated in more than 30 clinical trials involving over 22,000 patients over the last 15 years. Based on the extensive lorcaner clinical data, the Company believes that BELVIQ and BELVIQ XR continue to have a positive benefit-risk profile in the patient population for which they are indicated.

Eisai is having discussions with its global distribution partners regarding this issue.

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SOURCE Eisai Inc.